

RESPONSIBLE USE OF HIGH-RISK MEDICAL DEVICES: THE EXAMPLE OF 3D PRINTED MEDICAL DEVICES



RESPONSIBLE USE OF HIGH-RISK MEDICAL DEVICES: THE EXAMPLE OF 3D PRINTED MEDICAL DEVICES

IRM VINCK, AN VIJVERMAN, ERIK VOLLEBREGT, NILS BROECKX, KARLIEN WOUTERS, MARIEL PIËT, NATALIJA BACIC, JOAN VLAYEN, NANCY THIRY, MATTIAS NEYT



COLOPHON

Title:	Responsible use of high-risk medical devices: the example of 3D printed medical devices
Authors:	Irm Vinck (KCE), An Vijverman (Dewallens & partners), Erik Vollebregt (Axon lawyers), Nils Broeckx (Dewallens & partners), Karlien Wouters (Dewallens & partners), Mariel Piët (Axon lawyers), Natalija Basic (Court of Justice of the European Union), Joan Vlayen (KCE), Nancy Thiry (KCE), Mattias Neyt (KCE)
Project coordinator:	Nathalie Swartenbroeckx (KCE)
Reviewers:	Irina Cleemput (KCE), Chris De Laet (KCE)
External experts:	Ward Callens (Materialise), Augustin Coppee (Kabinet Volksgezondheid en Sociale Zaken – Cabinet Santé Publique et Affaires Sociales), Bernard Debbaut (Christelijke Mutualiteit (CM)), Marc Dooms (UZ Leuven), Vincent Duchenne (Europese Commissie DG RTD), Erik Everaert (FAGG – AFMPS), Gerrit Faelens (FAGG – AFMPS), Bart Falter (UZ Leuven), Hans Hellinckx(BeMedTech), Alexandre Jauniaux (FAGG – AFMPS), Luc Joren (AZ Herentals), Christophe Lahorte (FAGG – AFMPS), Frédéric Lecomte (RIZIV – INAMI), Marleen Louagie (RIZIV – INAMI), Katrien Martens (FAGG – AFMPS), Bart Mersseman (Notified Body), Ethel Mertens (FAGG – AFMPS), Greet Musch (FAGG – AFMPS), Stefaan Nijs (Chirurg-traumatoloog), Valerie Noblesse (RIZIV – INAMI), Valérie Nys (FAGG – AFMPS), Pierre Padilla (Idea consult), Wim Penninckx (FAGG – AFMPS), Constantinus Politis (UZ Leuven), Ward Rommel (Kom op tegen kanker), Christophe Sasserath (Centre de Chirurgie Maxillo-Faciale), Jan Schrooten (Regmed platform), Christel Slechten (FAGG – AFMPS), Bram Smits (Materialise), Philip Tack (Ugent), Richard Van den Broeck (FAGG – AFMPS), Olivier Van Obberghen (Quinz), Carla Van Steenberghe (Materialise), Wim Vandenberghe (BeMedTech), Annick Verbiest (UZ Leuven), Pieter Vergaert (Visible Patient), Bruno Verlee (Ingenieur - specialist ISO certificatie), Kevin Weatherwax (Michigan State University), Dominique Wouters (UCL)
External validators:	Robert Geertsma (Rijksinstituut voor Volksgezondheid en Milieu (RIVM)), Mieke Goossens (MiGo Consulting), Stefan Sauerland (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG))
Other reported interests:	Membership of a stakeholder group on which the results of this report could have an impact: Ward Rommel (Kom op tegen kanker), Jan Schrooten (Flanders Bio), Pieter Vergaert (Industrie: firma Visible Patient), Bernard Debbaut (Christelijke Mutualiteiten), Bram Smits (Materialise N.V. – BeMedTech V.Z.W.), Dominique Wouters (Commission for reimbursement of implants and invasive medical devices INAMI – RIZIV, Frederic Lecomte (INAMI – RIZIV), Augustin Coppee (Policy framework) Owner of subscribed capital, options, shares or other financial instruments: Ward Callens (Materialise N.V.), Jan Schrooten (Antheron B.V.B.A.), Bram Smits (Optis Materialise N.V.) Holder of intellectual property (patent, product developer, copyrights, trademarks, etc.): Jan Schrooten (IP of Antheron B.V.B.A), Pieter Vergaert (Industry: firm Visible Patient)



Participation in scientific or experimental research as an initiator, principal investigator or researcher: Philip Tack (IWT Project 'Roadmap' about medical 3D Printing (part Health economy: PHD trajet), Jan Schrooten (Projects KU Leuven – generative medicine / VLAIO feasibility assessment Antheron BV.B.A.), Stefaan Nijs (3D modelling in shoulder althea prof. (UZ Leuven – KU Leuven))

A grant, fees or funds for a member of staff or another form of compensation for the execution of research described above: Jan Schrooten (VLAIO feasibility assessment, Interreg VL-NL)

Consultancy or employment for a company, an association or an organisation that may gain or lose financially due to the results of this report: Ward Callens (Materialise N.V.), Jan Schrooten (Antheron B.V.B.A.), Pieter Vergaert (Industry: firm Visible Patient), Bram Smits (Materialise N.V.)

Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Ward Callens (Speaker for MEDPHARMPLAST – Conference Strasbourg 2016), Jan Schrooten (Regmed platform subventions)

Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Wim Vandenberghe (Adviseur BeMedTech), Jan Schrooten (Manager Antheron B.V.B.A.), Augustin Coppee (Policy framework), Luc Joren (Hospital)

Layout:

Ine Verhulst

Disclaimer:

- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
- **Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.**
- **Finally, this report has been approved by the Executive Board.**
- **Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.**

Publication date:

16 January 2018

Domain:

Health Technology Assessment (HTA)

MeSH:

Printing, Three-Dimensional, Device Approval ; Equipment and Supplies ; European Union ; Government regulation

NLM Classification:

W82 (Biomedical technology)



Language: English
Format: Adobe® PDF™ (A4)
Legal depot: D/2018/10.273/03
ISSN: 2466-6459
Copyright: KCE reports are published under a “*by/nc/nd*” Creative Commons Licence
<http://kce.fgov.be/content/about-copyrights-for-kce-publications>.



How to refer to this document?

Vinck I, Vijverman A, Vollebregt E, Broeckx N, Wouters K, Piët M, Bacic N, Vlayen J, Thiry N, Neyt M. Responsible use of high-risk medical devices: the example of 3D printed medical devices. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2018. KCE Reports . D/2018/10.273/03.

This document is available on the website of the Belgian Health Care Knowledge Centre.



■ TABLE OF CONTENTS

LIST OF FIGURES	4
LIST OF TABLES	4
LIST OF ABBREVIATIONS.....	6
■ SCIENTIFIC REPORT	9
1 BACKGROUND	9
1.1 SCOPE AND RESEARCH QUESTIONS	11
2 SOME TECHNICAL ASPECTS	12
2.1 TECHNIQUES OF 3D PRINTING	12
2.2 COMPONENT ELEMENTS	12
2.3 PROCESS OF 3D PRINTING (MEDICAL) DEVICES	13
3 SYSTEMATIC REVIEW OF THE MEDICAL LITERATURE.....	16
3.1 RESEARCH QUESTION	16
3.2 METHODOLOGY	16
3.2.1 Literature search and study selection	16
3.2.2 Quality appraisal and data extraction	17
3.2.3 Statistical analysis	17
3.2.4 GRADE.....	17
3.3 RESULTS	18
3.3.1 Overall yield of the search	18
3.3.2 Custom-made implants	21
3.3.3 Surgical guides	21
3.3.4 Model for surgery planning	26
3.3.5 Model for implant shaping	26
4 SYSTEMATIC REVIEW OF THE ECONOMIC LITERATURE	27
4.1 METHODS	27



4.1.1	Inclusion and exclusion criteria	27
4.1.2	Search strategy	27
4.1.3	Selection procedure	28
4.1.4	Data extraction	28
4.2	OVERVIEW OF THE ECONOMIC LITERATURE.....	29
4.2.1	Technical characteristics of the economic evaluations	29
4.2.2	Medical and clinical characteristics of the economic evaluations	30
4.2.3	Cost items.....	32
4.2.4	Outcome measures	32
4.2.5	Results of the economic evaluations.....	33
4.3	DISCUSSION.....	36
5	LEGAL PART	38
5.1	RESEARCH QUESTIONS.....	38
5.2	METHODOLOGY	39
5.3	MAIN LEGAL TEXTS AND DEFINITIONS	40
5.4	LEGAL QUALIFICATION (AND CLASSIFICATION) AND REQUIREMENTS FOR THE PLACING ON THE MARKET OF 3D PRINTING OF / 3D PRINTED MEDICAL DEVICES UNDER EU RULES	43
5.4.1	Current regime: Medical Devices Directive & IVD Directive	45
5.4.2	Future regime: Medical Devices Regulation & IVD Regulation.....	57
5.5	LEGAL QUALIFICATION OF 3D PRINTING/3D PRINTED MEDICAL DEVICES IN BELGIUM	64
5.5.1	Legal qualification.....	64
5.5.2	Applicable requirements for the placing on the market.....	65
5.5.3	Conclusion.....	68
5.6	LIABILITY AND INSURANCE ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES	69



5.6.1	Liability and insurance issues associated with 3D printed medical devices in the EU	70
5.6.2	Liability and insurance issues associated with 3D printed medical devices in Belgium	75
5.6.3	Conclusion.....	85
5.7	DATA PROTECTION ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES	86
5.7.1	EU.....	86
5.7.2	Belgium.....	95
5.7.3	Conclusion.....	98
5.8	PATIENTS' RIGHTS ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES	98
5.8.1	EU.....	99
5.8.2	Belgium.....	101
5.8.3	Conclusion.....	103
5.9	TRACEABILITY ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES.....	104
5.9.1	EU.....	104
5.9.2	Belgium.....	107
5.9.3	Conclusion.....	111
5.10	REIMBURSEMENT ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES.....	112
5.10.1	EU.....	112
5.10.2	Belgium.....	113
5.10.3	Conclusion.....	136
5.11	INTELLECTUAL PROPERTY RIGHTS ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES	139
5.11.1	EU.....	142
5.11.2	Belgium.....	153
5.11.3	Conclusion.....	154
■	REFERENCES	156



LIST OF FIGURES

Figure 1 – Types of 3D printed devices	10
Figure 2 – patient-specific 3D printed model, prosthesis, implant and surgical instrument.....	11
Figure 3 – 3D printing manufacturing process chart (USA)	14
Figure 4 – 3D printing medical device process chart.....	14
Figure 5 – process and intervening parties for the 3D design/printing of a model	15
Figure 6 – Pooled estimate of mechanical axis misalignment using the RCT results from Thienpont et al. ¹⁶	23
Figure 7 – Pooled estimate of operative time using the RCT results from Thienpont et al. ¹⁶	24
Figure 8 – Conformity assessment procedures for 3D printers	46
Figure 9 - Conformity assessment procedures for medical devices	53
Figure 10 – Invasive medical devices versus non-invasive medical devices	114
Figure 11 – Procedure for submission to (=reimbursement), amendment of- or removal from the list – request from the firm (*)	118
Figure 12 – Deadlines for the procedure for submission to- (=reimbursement), amendment of - or removal from the list	119
Figure 13 – Deadlines for the procedure for submission to- (=reimbursement), amendment of - or removal from the nominative list	120
Figure 14 – Reimbursement options for 3D printed custom-made medical devices and linked activities.....	138
Table 1 – Overview of RCTs comparing a group using 3D technology versus a group not using 3D technology	19
Table 2 – List of selected economic evaluations	28
Table 3 – Technical characteristics of the economic evaluations.....	29
Table 4 – Medical and clinical characteristics of the economic evaluations.....	31
Table 5 – Costs and clinical outcomes covered in the economic evaluations.....	33
Table 6 – Patient safety results.....	34
Table 7 – Time and costs results	35

LIST OF TABLES



Table 8 – Visual summary of the safety, time and cost results of the economic evaluations.....	37
Table 9 – Overview of the currently reimbursed custom-made 3D printed medical devices.....	124
Table 10 – IDEAL.....	132
Table 11 – Overview IP rights	149



LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
3D	three-dimensional
ABC	activity-based costing
AIMDD	Active Implantable medical device Directive
ATMP	advanced therapy medicinal product
BCIP	Benelux Convention on Intellectual Property
BOIP	Benelux Office for intellectual property
BFM	Budget of Financial Means
CAD	computer-aided design
CBA	cost-benefit analyses
CC	Civil Code
CCA	cost-consequence analyses
CEA	cost-effectiveness analyses
CI	confidence interval
CMA	cost-minimization analyses
CPD	College physicians-directors
CRD	Centre for Review and Dissemination
CUA	cost-utility analyses
CPC	Community Patent Convention
CT	computed tomography
CTIIMH – CRIDMI	Commissie Tegemoetkoming Implantaten en Invasieve Medische Hulpmiddelen – Commission de Remboursements des Implants et des Dispositifs Médicaux Invasifs
DI	device identifier
DICOM	digital imaging and communication
DLMS	Direct Laser Metal Sintering



DRM	digital rights management
ECJ	European Court of Justice
EED	Economic Evaluation Database
ELC	Economic Law Code
EPC	European Patent Convention
EUDAMED	European Databank on Medical Devices
EUIPO	European Union Intellectual Property Office
EUnetHTA	European Network for Health Technology Assessment
EUTM	European Union Trade Mark
DD	Directive on the legal protection of designs
DMCA	Digital Millennium Copyright Act
FAMHP	Federal Agency for Medicines and Health Products (FAGG-AFMPS)
FDA	Food and Drug Administration
GDPR	General Data Protection Regulation
HSR	Health Services Research
HTA	Health Technology Assessment
IC	Insurance Committee
IDEAL	Idea Development Exploration Assessment Long-term Safety
INAHTA	International Network of Agencies for Health Technology Assessment
IPR	intellectual property rights
IVDD	In Vitro Diagnostic medical device Directive
IVDR	In Vitro Diagnostic medical device Regulation
LY	life-year
MDD	Medical Device Directive
MDR	Medical Device Regulation



MRI	magnetic resonance image
NHS EED	National Health Service Economic Evaluation Database
NIHDI	National Institute for Health and Disabilities Insurance (RIZIV-INAMI)
OJ	Official Journal
PDPD	Personal Data Protection Directive
PI	product identifier
PIP	Poly Implant Prothèse
PSI	Patient Specific Implant
QALY	quality-adjusted life year
RCA	Restricted clinical application
RCTs	randomized controlled trials
RD	Royal Decree
REACH	Registration, evaluation, authorisation and restriction of chemicals
RR	risk ratio
SLS	Selective Laser Sintering
SSF	Special Solidarity Fund
SVHC	Substance of very high concern
TAVI	Transcatheter Aortic Valve implantations
TFEU	Treaty on the Functioning of the European Union
TMJ	Temporo-mandipular joints
TMP	Technical protective measure
TRIPS	Trade Related Aspects of Intellectual Property Rights
UDI	Unique Device Identification
WIPO	World Intellectual Property Organisation
WOMAC	Wesrn Ontario and McMaster Universities Osteoarthritis Index

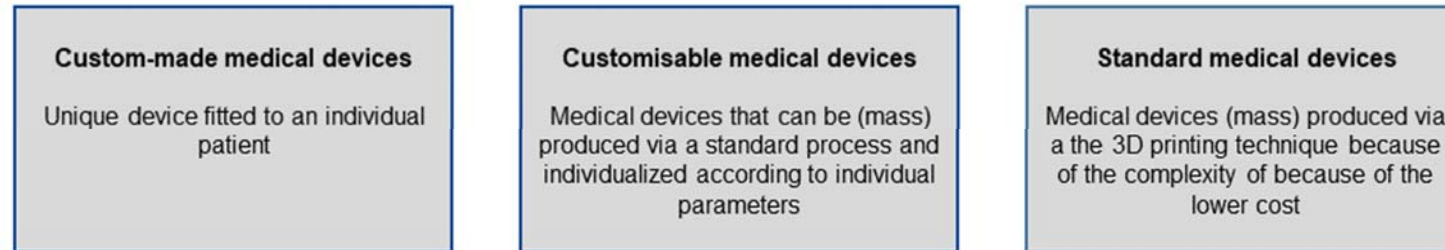
■ SCIENTIFIC REPORT

1 BACKGROUND

Three-dimensional (3D) printing is a process that creates a three-dimensional object by building successive layers of raw material, rather than removing it by cutting, drilling or machining – which is why the process is also called additive manufacturing. Each new layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design (CAD) drawing, a magnetic resonance image (MRI), computed tomography (CT) and ultrasound with the use of a digital imaging and communication (DICOM).¹ It enables manufacturers to create devices matched to a patient's anatomy or devices with very complex internal structures. These capabilities have sparked huge interest in 3D printing of medical devices and other 3D printed applications in medicine. The medical and dental sectors together correspond to around 13.1% usage of Additive Manufacturing, and as such are after the industrial and aerospace sector the third largest 3D printing market.² Several types of 3D printed devices can be distinguished according to the degree of 'customisation' (see Figure 1). The 3D printing technology enables mass custom-madeization, in that multiple individualized items can be produced simultaneously or in sequences via a standard production mode. (hereinafter called as "customisable" 3D printed medical devices). The technique also allows the construction of a unique custom-made device or model fitted to an individual patient (hereinafter called as "custom-made" 3D printed medical devices). Furthermore, the 3D printing technology can also be used to construct identical "standard" parts that are too complex or too expensive to be built by other production techniques (hereinafter called as "standard" 3D printed medical devices).

¹ <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/default.htm>

² Wohlers Report 2015: 3D Printing and Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, 2015.

**Figure 1 – Types of 3D printed devices**

The 3D printing (technology) in the medical field can serve several specific purposes.¹ It can be used to directly print a final patient-custom implant (e.g. fixation plates, cranial implant, jaw implant...- see Figure 2) or to print patient-specific molds to manufacture prosthetics (Prosthetic mold). They can also be used as printed anatomic models (see Figure 2) in order to understand the pathology and the patient's anatomical representation, from a physical model allowing manipulation. These anatomic models are then used to shape implants prior to surgery (Implant shaping) or to better plan the surgical operation of complex cases thanks to preoperative simulations/preparations on the models (Surgery planning). 3D models can also be used for training or education purposes for patients and their families as well as medical students. It should be noted that interactive (non- printed) 3D models as well can have a functional added value in enabling pre-operative analysis or planning, e.g. by simulating surgery. In this report, however, we focus on 3D printed devices and the activities and products linked to the process. Finally 3D printing techniques can serve as surgical patient-specific guides during an operation, also referred to as patient-specific instrumentation (PSI) or patient-matched instrumentation (see Figure 2). Note that the frontier between those categories is sometimes blurred and can overlap, e.g. simulations on 3D anatomical models are often translated into surgical guides.

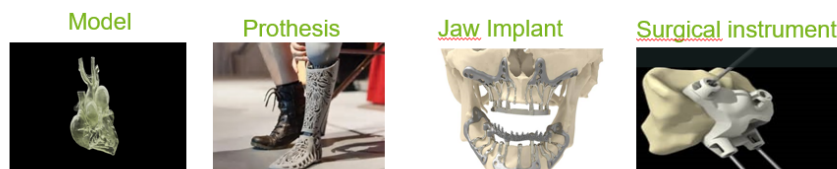
Belgium is one of the prominent players in the field of 3D printed applications in medicine. "In 2011, surgeons at the University Hospital in Ghent, Belgium, successfully performed one of the most complex facial transplants to date with extensive use of 3D printing to plan and perform the procedure. Anatomical models and patient specific guides were 3D printed for use before and during the procedure.³ *In February 2012, with the help of a 3D printer, doctors and engineers at Hasselt University successfully performed the world's first patient-specific prosthetic jaw transplant for an 83-year-old woman suffering from a chronic bone disease.*"⁴ Today, Leuven University Hospital, routinely simulate orthognathic surgical cases in 3D-software, design and print the surgical templates on high-end 3D printers in the hospital. This occurs in over 150 patients per year. A full-time engineering team is allocated to the department of oral and maxillofacial surgery and is part of the multidisciplinary treatment team. This concept further allows to design complex surgical templates for large tumour resections in the face in oncology patients and allows to construct individually designed 3D-reconstruction plates which then are 3D-printed at facilities outside the University Hospital.

³ http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2013/wipo_pub_121_2013_02.pdf

⁴ <http://www.zol.be/sites/default/files/publicaties/zolarium/pdf/zolarium-2015-55.pdf>



Figure 2 – patient-specific 3D printed model, prosthesis, implant and surgical instrument



Sources: for the images of model, jaw implant, surgical instrument: see www.materialise.com; for the prosthesis: <https://www.forbes.com/sites/tjmccue/2014/08/31/3d-printed-prosthetics/#3ebb1f9b33b4>.

1.1 Scope and research questions

As the 3D technology for devices matures, regulators, physicians, payers, manufacturers and other actors involved in the 3D printing process will need to address the risks and challenges that this technology inevitably brings. This report aims to provide the actors involved with a framework for a managed practice and use of 3D printing/3D printed medical devices in Belgium. We focus on high-risk medical devices (see Text box 1) since they have the highest potential risks for the patient and they are often the most expensive for the payer. The presented framework can be generically used for other high-risk innovative medical devices.

As the overall goal was to draft an operational framework for 3D printing/3D printed medical devices in general (and by extension to high-risk medical devices), the objective in the medical part was not to assess evidence on effectiveness and safety of 3D printing technology for a specific indication (as is typically done in a classic HTA), but to give a general overview for all indications. Accordingly, no individual reimbursement recommendations are made for the identified 3D applications. We also excluded from our analysis 3D printed products incorporating biomaterials which may be qualified as medicines, xenogeneic cell therapy preparations, 3D printed medicines and 3D bioprinting (3D fabrication technology involving biological tissues, organs and cells for medical and biotechnology applications).

Therefore the following research questions are addressed:

1. What is the effectiveness and safety for the patient of 3D printing technology for medical indications?

Originally, the research question was focused on the use of 3D printed (custom-made) implants. However, after more in depth consultation of the stakeholders, the scope was enlarged to 3D surgical guides and models for planning or shaping as these were reported to be the most clinically relevant and most frequently used applications (see chapter 3). No pre-clinical information related to the safety of the materials used in the 3D printing process was evaluated.

2. What is the available evidence on cost-effectiveness of 3D printing technology for medical indications?

In chapter 4, the available evidence on cost-effectiveness of 3D printing technology for medical indications is addressed.

3. What are the legal issues related to 3D printing/3D printed medical devices?

In chapter 5, several legal issues related to the 3D printing/3D printed medical devices are addressed:

- Requirements to enter the market (5.4 and 5.5)
- Liability (see 5.6)
- Data protection (see 0)
- Patients' rights (see 5.8)
- Traceability (see 5.9)
- Reimbursement (see 5.10)
- Intellectual Property Rights (see 5.11)



For each legal issue the relevant aspects related to (the 3D printing of) 3D printed medical devices were identified and the applicable EU, Belgian legislation, jurisprudence and doctrine related to each of these legal issues was analysed. The respective legal issues were also studied in a selection of other countries (the Netherlands, UK, France, USA – see appendix 3).

Ethical aspects, such as informed consent, patients' financial contributions were inclusive in the respective parts of the report. However, there is no separate section on overall ethical aspects.

Text box 1 – High-risk medical devices

Medical devices are segmented into classes according to the risk associated. To determine classification, a set of criteria can be combined in various ways in order to determine classification, e.g. duration of contact with the body, degree of invasiveness and local vs. systemic effect. The criteria and rules for classification of medical devices are set out in annex 9 of the European Directive 93/42/EEC. Class IIb (medium/high-risk) and Class III (high-risk) include high-risk medical devices.

It concerns amongst others implantable devices and long-term surgically invasive devices such as hip-, breast-, knee implants and implantable devices and surgically invasive devices that come in contact with the heart, the central nervous system or the central circulatory system or intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

2 SOME TECHNICAL ASPECTS

2.1 Techniques of 3D printing

There are various **methods** of 3D printing. The following are examples of commonly used methods but many others exist or are being developed.

- Selective Laser Sintering (SLS), an additive manufacturing technique that uses a high power laser to fuse small particles of plastic, metal, ceramic, or glass powders into a mass that has a desired 3-dimensional shape or
- Direct Laser Metal Sintering (DLMS) that uses a metal powder, a laser traces the outline of each part being printed, fusing (DLMS) or melting (SLS) the powder to the layer below it and the process is repeated until the print job is complete.

2.2 Component elements

Typically 3D printing will involve the following **component elements** each of which may have its own regulatory implications⁵:

- Printer: this may be a generic multipurpose device or be intended for a narrowly defined purpose.
- The commonly used materials ("ink" equivalents) are metals, plastic, ceramic and glass.
- Software to drive the printer. This may be generic or specific to a particular field.
- Software to design the object to be printed, e.g. Computer Aided Design (CAD).
- Product specification. This is likely to be a set of data that is used by the software to print the desired object.

⁵ Working document MDEG-NET WG (New & Emerging Technology in Medical Devices) - SIG: Horizon Scanning



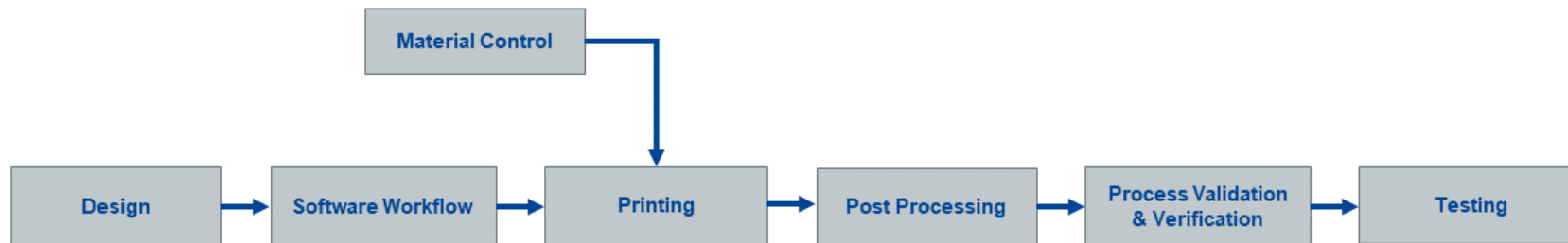
2.3 Process of 3D printing (medical) devices

There are **multiple steps** to printing a 3D device. The number of steps for each device is dependent on many factors, such as the complexity of the device or whether (parts of) the 3D printing process is outsourced. The following sequence of steps is one example of the process in the USA:

- **Device Design:** A design is created and validated using digital models with pre-specified sizes or digital models matched to a patient's anatomy.
- **Software Workflow:** The digital device design is converted to a buildable file that is sent to the printer. This file will often divide the design into layers, include additional support material to aid printing, and tell the printer where to build the device on the printer platform to prepare it for printing. The 3D printer often also requires some preparation to build different designs by changing settings for the material, type of design, and intended use.
- **Material Controls:** Like any manufacturing process, 3D printing needs high quality materials that meet consistent specifications to build consistent high quality devices. To ensure this, procedures, requirements, and agreements called material controls, which must be checked for every batch of material, are established between the suppliers, purchasers, and end-users of the material.
- **Printing:** The object is printed using the design specifications included in the file.
- **Post-Processing:** After printing is complete, one or more post-processing steps may be performed on the device or component. These may include cleaning to remove residual debris, controlled cooling (also called annealing), and/or additional steps such as drilling, cutting, polishing, and sterilization.
- **Process Validation and Verification:** Some device or component characteristics can be checked individually after they are produced to make sure they will function properly and meet specifications. This is especially true of geometric features which can be checked quickly and nondestructively. When other functional features, such as mechanical strength, cannot be checked individually because the test could destroy the object or is impractical, manufacturers validate their processes prior to production. Process validation ensures that a manufacturing process will produce product that is within defined specifications, as long as specified processing parameters are monitored and controlled.
- **Testing:** In the USA device testing methods and results are submitted to the FDA to show that the device meets regulatory requirements and is reasonably safe and effective for its intended use. Each device or type of device has its own set of tests that may be based on FDA Guidance documents, international standards, or internal process controls. This phase is not applicable in the EU.



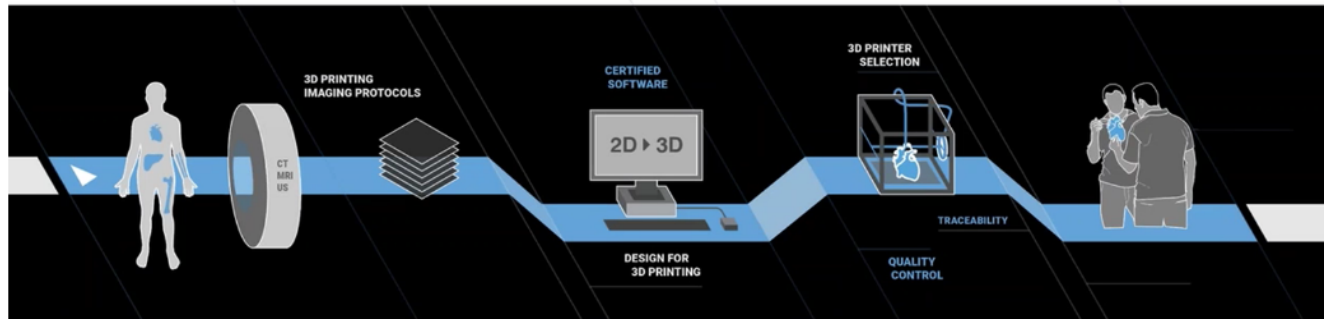
Figure 3 – 3D printing manufacturing process chart (USA)



Source: FDA⁶

The following figures show a 3D design/printing medical device process and the intervening parties.

Figure 4 – 3D printing medical device process chart

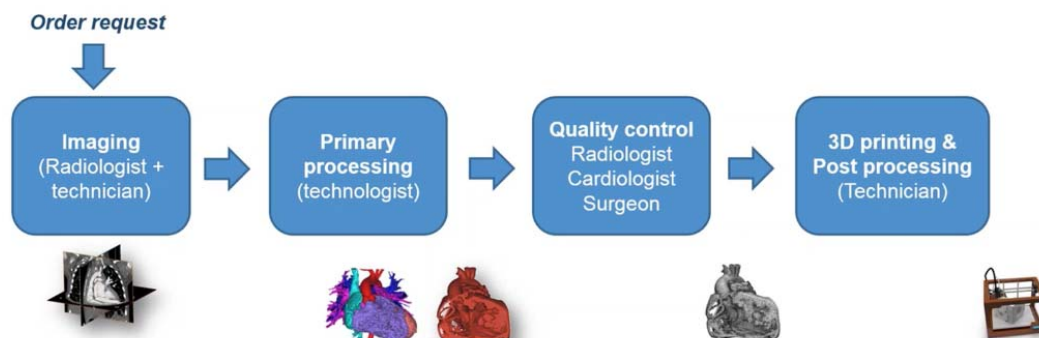


6

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500544.htm>



Figure 5 – process and intervening parties for the 3D design/printing of a model



Source: Materialise webinar: How to start implementing 3D printing in your hospital⁷

Key Points

- 3D printing enables mass customization, the construction of a unique custom-made device or a model fitted to an individual patient as well as the construction of “standard” parts that are too complex or too expensive to be built by other production techniques.
- Typically 3D printing will involve the use of a printer, material used for the printing, software to drive the printer and to design the object and product specification software. Each may have its regulatory implications.
- The 3D printing process varies according to many factors, such as the complexity of the device or, whether (parts of) the 3D printing process is outsourced.

⁷ <http://www.materialise.com/en/resources/webinar-recording/how-to-start-implementing-3d-printing-your-hospital?token=qRBOVRkmtYwasAXjphHWQoHGVIBM7P-ZyzV-lkwiukk>



3 SYSTEMATIC REVIEW OF THE MEDICAL LITERATURE

3.1 Research question

In this chapter, an overview of the medical literature is given about the use of 3D printing technology for medical indications. It aims to address the following research question: what is the effectiveness and safety of 3D printing technology for medical indications? Originally, the research question was focused on the use of 3D printed custom-made implants. An overview of the results of the original search is given in appendix 1. Mainly case series and reports were found, study designs that usually are difficult to support an evaluation of the effectiveness of an intervention.

However, after more in depth consultation of the stakeholders, the scope was enlarged to 3D surgical guides and models. For these indications, RCTs were clearly available. Therefore, it was decided to focus the search on (systematic reviews of) RCTs comparing an intervention group using 3D printing technology versus a control group not using 3D printing technology.

3.2 Methodology

This chapter was developed using a standard methodology based on a systematic review of the medical literature. Further details about the KCE methods are available at <https://kce.fgov.be/content/kce-processes>.

3.2.1 Literature search and study selection

A systematic literature review was performed by searching for (systematic reviews and meta-analyses of) randomized controlled trials (RCTs). The following databases were searched:

- The Cochrane Library (Cochrane Database of Systematic Reviews, DARE, HTA database, CENTRAL)
- Medline (including PreMedline)
- Embase

The search strategies are documented in the appendix 1.

In addition, the reference lists of included articles were checked for relevant publications that may have been missed.

To be eligible, a primary study had to:

- be a randomised trial;
- address the intervention and comparator as described above.

No inclusion criteria related to outcomes were applied because of the wide spectrum of indications in this overview. Studies with a pseudo-randomised design or comparing different types of 3D printing technology were excluded. Studies addressing 3D printing of drugs or tissue were also excluded.

Study selection was performed by one researcher in two phases. Phase one consisted of screening the titles and abstracts of the retrieved studies and excluding studies for which it was obvious that they did not fulfill the inclusion criteria. Of the remaining studies (phase two), the full text was screened. If no full-text was available, the study was not taken into account. Studies published in a language other than English, Dutch or French were not included. A date limit was not imposed.

In addition to the search above, clinical experts and the manufacturers were asked to provide any information about unpublished but upcoming (= before validation of the report) trials and/or results. One additional RCT was provided by one of the validators of the report.² The reason for missing out the RCT of Huijbregts et al. is that the search terms used in the search strategy do not match with the terms used in the abstract or those used to index the article of Huijbregts et. al. We notice that the term 'patient-specific instrument' is included in the abstract. However, in the search strategy 'patient-specific implant' was used. The key words or abstract of this article unfortunately also did not mention anything related to 3D printing.



3.2.2 Quality appraisal and data extraction

Each study was appraised for methodological quality by one researcher. The quality of systematic reviews was assessed by the use of AMSTAR (http://amstar.ca/Amstar_Checklist.php).³ For RCTs the Cochrane Collaboration's tool for assessing risk of bias was used.⁴ RCTs already included in methodologically valid systematic reviews were not quality appraised again. For example, the methodological quality of the primary studies included in the review of Thienpont et al. was assessed using a modified version of the Detsky Quality Assessment Scale. The individual scores of that particular assessment are reported in the systematic review of Thienpont et al.¹⁶

Data extraction was performed by one researcher and entered in evidence tables using standard KCE templates (see appendix 1). For each systematic review the following data were extracted: title and reference, funding sources, search date, databases being searched, number and types of included studies, details about the statistical analysis, eligibility criteria, exclusion criteria, number of participants, patient and disease characteristics, details of the intervention and comparator groups that have been addressed in the review, results for the outcomes, and limitations and other comments regarding the review. For each RCT the following data were extracted: title, reference, source of funding, country and setting, sample size, duration and follow-up, details about the statistical analysis, eligibility criteria, exclusion criteria, number of participants, patient and disease characteristics (including baseline comparability), details of the intervention and comparator (e.g. type, dose, duration, route of administration), results, and limitations and other comments regarding the study.

3.2.3 Statistical analysis

A formal meta-analysis was, because of the anticipated heterogeneity of the evidence, not foreseen. However, for the evidence about patient-specific instruments for total knee replacement, it was deemed necessary to redo a published meta-analysis (see below). For dichotomous outcomes the risk ratio (RR) was used as the measure of treatment effect and for continuous outcomes the mean difference. Meta-analyses were performed according to the guidelines described in the Cochrane Handbook⁵ and by the use of Review Manager software (RevMan 5.3). Results of studies that were sufficiently clinically homogeneous, i.e. sufficiently similar with respect to the patients, interventions, outcomes and timing of the follow-up measurements were combined by the use of a fixed-effect model. If the studies were statistically heterogeneous a random-effects model was used and – if sufficient studies available – heterogeneity was explored by subgroup analyses. Statistical heterogeneity was assessed by a combination of visual inspection of the forest plots, the Chi-square test for homogeneity (p-value set at 0.1 to increase the power of this test) and the I^2 statistic. The latter two statistics were interpreted in the light of the size of the studies included in the meta-analysis (e.g. if many large studies are included that have clinically irrelevant different effect estimates, the Chi-square test will become significant (due to high power) and I^2 will approach 100%; in that case the results of the visual inspection will dominate the judgment of heterogeneity).

3.2.4 GRADE

A formal GRADEing was not foreseen, because of the overall objectives of the report.



3.3 Results

3.3.1 Overall yield of the search

The search identified eleven systematic reviews.⁶⁻¹⁶ The review of Tack et al. was found to be the most comprehensive,¹⁵ and will be used as starting point for the overview below. Tack et al. identified 25 different RCTs that compared a group using 3D technology versus a group not using 3D technology (Table 1). In addition to the reviews identified through the search, a recent systematic review on patient-specific instruments was provided by experts.¹⁶ Five additional RCTs were cited in this review (Table 1). Finally, our search identified four more RCTs not already included in one of the identified reviews.¹⁷⁻²⁰

The evidence that was based on (in total 35) RCTs will be discussed below, structured by usage of the technology and discipline. For the following disciplines/indications, systematic reviews found no RCTs: anaesthesiology,⁸ neurosurgery,¹³ hepatic resection.¹⁴ These reviews will not be discussed further. Martelli et al. published a broad systematic review on the added value of 3D printing in surgery in general,¹¹ but found only one RCT that was already identified by Tack et al. Therefore, it will not be discussed either. Also Malik et al. published a broad systematic review on the added value of 3D printing in surgery in general,⁹ but it is unclear if and how many RCTs were included. Finally, Popescu et al. published a systematic review on the added value of patient-specific surgical orthopaedic guides, with the exception of total knee arthroplasty and cranio-maxillofacial applications.¹² Since they did not identify any RCTs, the review will not be discussed further.


Table 1 – Overview of RCTs comparing a group using 3D technology versus a group not using 3D technology

Study #	Usage	Discipline	N patients	Material of 3D printed invasive device	Included in Tack	Included in Thienpont
Shuang 2016	Custom implant	Orthopaedics - shoulder	13	?		
Noble 2012	Surgical guide	Orthopaedics - knee	29	PEEK-PSI	x	x
Boonen 2013	Surgical guide	Orthopaedics - knee	180	Acrylic based resin	x	x
Chareancholvanich 2013	Surgical guide	Orthopaedics - knee	80	Polypropylene-polyester	x	x
Hamilton 2013	Surgical guide	Orthopaedics - knee	52	PEEK-PSI	x	x
Parratte 2013	Surgical guide	Orthopaedics - knee	40	?	x	x
Pietsch 2013	Surgical guide	Orthopaedics - knee	80	?	x	x
Roh 2013	Surgical guide	Orthopaedics - knee	90	Polyamide	x	x
Vundelinkcx 2013	Surgical guide	Orthopaedics - knee	62	PEEK-PSI	x	x
Abdel 2014	Surgical guide	Orthopaedics - knee	40	?		x
Chotanaphuti 2014	Surgical guide	Orthopaedics - knee	80	?		x
Kotela 2014	Surgical guide	Orthopaedics - knee	92	Titanium and PEEK-PSI	x	x
Silva 2014	Surgical guide	Orthopaedics - knee	45	PEEK-PSI	x	x
Victor 2014	Surgical guide	Orthopaedics - knee	125	?	x	x
Woolson 2014	Surgical guide	Orthopaedics - knee	48	HA	x	x
Abane 2015	Surgical guide	Orthopaedics - knee	126	Titanium	x	x
Ferrara 2015	Surgical guide	Orthopaedics - knee	30	Titanium	x	x
Gan 2015	Surgical guide	Orthopaedics - knee	70	HA	x	
Kotela 2015	Surgical guide	Orthopaedics - knee	112	Titanium	x	x
Molcinik 2015	Surgical guide	Orthopaedics - knee	38	?		x
Pfitzner 2014	Surgical guide	Orthopaedics - knee	90	?	x	
Vide 2015	Surgical guide	Orthopaedics - knee	95	?		x
Yan 2015	Surgical guide	Orthopaedics - knee	60	?		x
Huijbregts 2016	Surgical guide	Orthopaedics - knee	133	?		
Qiu 2017	Surgical guide	Orthopaedics - knee	26	?		



Zhang 2011	Surgical guide	Orthopaedics - hip	22	Acrylic based resin	x
Small 2014	Surgical guide	Orthopaedics - hip	36	Polyetheretherketone	x
Hendel 2012	Surgical guide	Orthopaedics – shoulder	31	?	
Modabber 2012	Surgical guide	Maxillofacial surgery	10	Titanium	x
Ayoub 2014	Surgical guide	Maxillofacial surgery	20	PEEK-PSI	x
Iannotti 2015	Model for surgery planning	Orthopaedics – shoulder	46	Acrylic based resin	x
Yang 2016	Model for surgery planning	Orthopaedics – ankle	30	Polyactic acid	
de Farias 2014	Model for surgery planning	Maxillofacial surgery	37	Polymethylmethacrylate	x
Kozakiewicz 2013	Model for implant shaping	Maxillofacial surgery	57	?	x
Chrzan 2012	Model for implant shaping	Cranial surgery	39	Polyurethane resin	x

Italic = studies newly identified through our search. HA: Hydroxyapatite; PEEK-PSI: Polyetheretherketone- Patient Specific Implant.



3.3.2 Custom-made implants

Only one small RCT evaluated the added value of custom-made implants in orthopaedic surgery.¹⁹ An overview of comparative observational studies, case series and reports for this indication is provided in appendix 1. The study design and limited sample size did not allow us to formulate robust conclusions based on these studies. For completeness, a summary of the results of these observational studies is presented in appendix 1.

Shuang et al. randomized 13 patients with distal intercondylar humeral fractures to undergo surgery using either conventional plates (N=7) or 3D-printed plates (N=6).¹⁹ The study had an unclear risk of bias, because no description of the randomization method or blinding was provided.

The 3D-printing group had a significantly shorter mean operative time (70.6 +/- 12.1 min) than the conventional plates group (92.3 +/- 17.4 min; $p=0.026$). After a mean follow-up of 10.6 months, there was no significant difference between groups in the rate of patients with good or excellent elbow function, although the 3D-printing group saw a slightly higher rate of good or excellent evaluations (83.1%) compared to the conventional group (71.4%). One patient in the conventional group experienced intraoperative traction injury of the ulnar nerve. The injury resolved after 3 months of rehabilitation. No wound infections or other complications were observed.

3.3.3 Surgical guides

Surgical guides are probably the most frequently studied medical applications of 3D printing, and most experience is available for knee arthroplasty.¹⁵

3.3.3.1 Orthopaedics – knee

The systematic review of Thienpont et al. is the most comprehensive review on patient-specific instruments for total knee arthroplasty, and included 20 RCTs and 24 observational studies.¹⁶ Unfortunately, the authors combined the results of both the RCTs and the observational studies in a meta-analysis, which is against the recommendation of the Cochrane Collaboration (see Cochrane Handbook, [chapter 13.6.2.2](#)): results from different study designs should be expected to differ systematically, resulting in increased heterogeneity. For this reason, we recalculated the pooled estimates with RevMan v5.3 by excluding the results of the observational studies.

Pooling the results from 14 RCTs (N=1156) included in the review of Thienpont et al.¹⁶ showed no difference in the risk of mechanical axis misalignment between patient-specific versus standard instrumentation (relative risk = 0.96; 95%CI 0.74-1.24) (Figure 6).

The pooled results of 11 RCTs (N=920) included in the review of Thienpont et al.¹⁶ showed a significantly shorter operative time with patient-specific instruments (mean difference = -3.79 minutes; 95%CI -7.01 to -0.58) (Figure 7).

Tack et al. identified two additional RCTs.¹⁵ Gan et al. included 70 patients undergoing total knee arthroplasty.²¹ In the navigational template group, 97.1% of the patients (34/35) had a postoperative leg axis within the range of $\pm 3^\circ$ compared with 77.1% (27/35) in the conventional group ($p<0.001$). Operative time was 45 minutes in the navigational template group versus 60 minutes in the conventional group ($p<0.001$). Pfitzner et al. randomized 90 patients undergoing total knee arthroplasty to CT-based patient-specific instrumentation (N=30), MRI-based patient-specific instrumentation (N=30), and conventional instrumentation (N=30).²² Compared with conventional instrumentation MRI- and CT-based patient-specific instrumentation showed higher accuracy regarding the coronal limb axis (MRI versus conventional, 1.0° versus 4.5° , $p<0.001$; CT versus conventional, 3.0° versus 4.5° , $p=0.02$), femoral rotation (MRI versus conventional, 1.0° versus 4.0° , $p<0.001$; CT versus conventional, 1.0° versus 4.0° , $p<0.001$), and tibial slope (MRI versus conventional, 1.0° versus 3.5° , $p<0.001$; CT versus conventional, 1.0° versus 3.5° , $p<0.001$). There was a significant reduction



of the duration of surgery in both patient-specific instrumentation groups in comparison to conventional instrumentation (MRI versus conventional, 58 versus 76 minutes, $p < 0.001$; CT versus conventional, 63 versus 76 minutes, $p < 0.001$). There were no differences in the postoperative Knee Society pain and function and WOMAC scores among the groups.

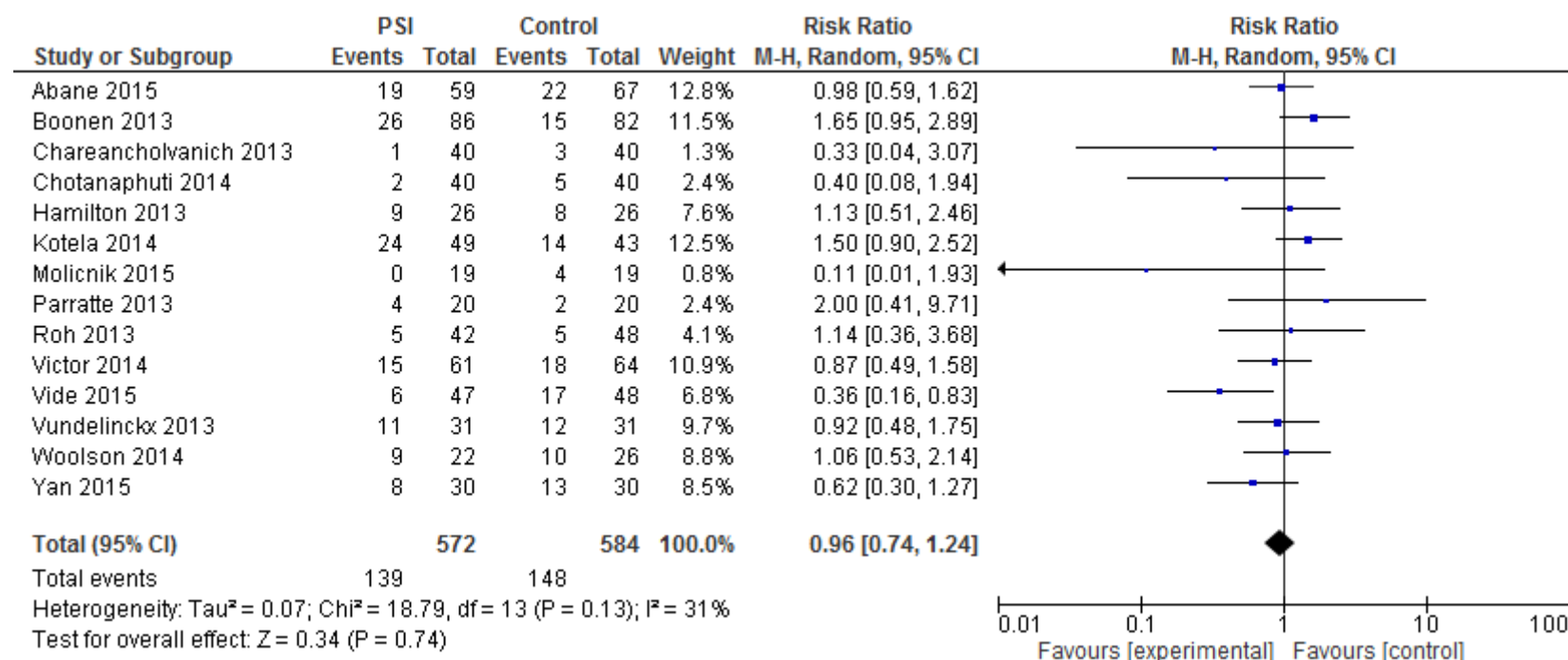
Our search identified one small additional RCT.¹⁸ Qiu et al. randomized 26 patients to total knee arthroplasty with patient-specific instrumentation (N=10) or conventional instruments (N=16). The deviations of the hip-knee-ankle (0.77 vs. 3.13), frontal femoral component (0.37 vs. 2.35), frontal tibial component (0.11 vs. 1.09) and lateral tibial component angles (0.11 vs. 0.66) were significantly less in the patient-specific instrumentation group. Operative time was not reported.

Finally, during the validation process of this report, one additional RCT was identified (see 3.2.1).²

Sixty-four total knee arthroplasties in the standard group were compared to 69 PSIs. *“There were 14 HKA-angle outliers (22%) in the standard group and nine (13%) in the PSI group ($p = 0.251$). ... The accuracy of alignment in the coronal and axial planes and the proportion of outliers was not different in the two groups. The femoral component was more flexed ($p = 0.035$) and there were significantly more tibial slope outliers (29% versus 13%) in the PSI group ($p = 0.032$). Operating time [53.2 vs. 49.8 minutes] and the median three-month Oxford knee score [OKS] were similar ($p = 0.218$ and $p = 0.472$, respectively). Physical and mental SF-12 scores were not significantly different at three months ($p = 0.418$ and $p = 0.267$, respectively) or at one year post-operatively ($p = 0.114$ and $p = 0.569$). The median one-year OKS was two points higher in the PSI group ($p = 0.049$).”* The authors concluded that the use of PSI did not significantly reduce the numbers of outliers or the mean operating time, nor did it clinically improve the accuracy of alignment or the median OKS. Their data did not support the routine use of PSI when undertaking total knee arthroplasty.²



Figure 6 – Pooled estimate of mechanical axis misalignment using the RCT results from Thienpont et al.¹⁶

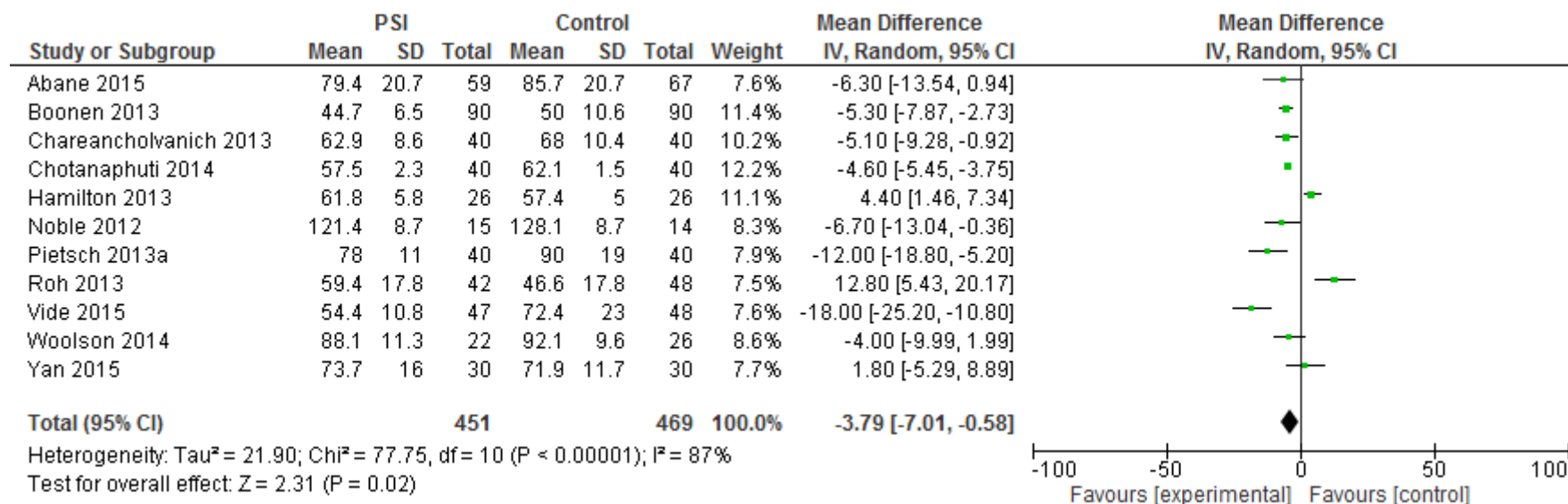




In addition to the reviews of Tack et al.¹⁵ and Thienpont et al.,¹⁶ several other systematic reviews were identified on the added value of patient-specific instruments for total knee arthroplasty. Cavaignac et al. pooled the results of 6 RCTs (all of which already were included in the pooled analysis above), and found no significant effect on mechanical axis misalignment (relative risk = 1.01; 95%CI 0.71-1.44).⁷ The authors concluded that there is 'no evidence that using patient-specific cutting blocks provides superior accuracy to using manual instrumentation during total knee arthroplasty.' Mannan et al. also included 6 RCTs,²³ but not identically the same as Cavaignac et al. A significantly decreased risk of femoral rotational axis misalignment was found in favour of patient-specific instrumentation (relative risk = 0.40; 95%CI 0.16-0.95). The authors concluded: 'This Level

1 systematic review and meta-analysis demonstrates favourable femoral rotational alignment outcomes in PSI (Patient Specific Implant) knee arthroplasty. Only limited data is available for tibial rotational outcomes. Further studies with standardised measurement tools and "gold-standard" assessment criteria are required to clarify tibial rotational outcomes in PSI total knee arthroplasty.' In another review of the same authors, 5 RCTs and 3 prospective comparative studies were included.¹⁰ Unfortunately, the results of both study types were mixed in one meta-analysis, rendering the results methodologically invalid.

Figure 7 – Pooled estimate of operative time using the RCT results from Thienpont et al.¹⁶





3.3.3.2 Orthopaedics – hip

Tack et al.¹⁵ identified two RCTs that used 3D printed surgical guides for hip arthroplasty. Small et al. randomized 36 patients undergoing total hip arthroplasty to patient-specific instrumentation (N=18) or standard instrumentation (N=18).²⁴ The mean difference from planned versus actual anteversion was $-6.9^\circ \pm 8.9^\circ$ for standard instrumentation and $-0.2^\circ \pm 6.9^\circ$ for patient-specific instrumentation ($p=0.018$). The mean difference in abduction from planned versus actual was $1.3^\circ \pm 9.1^\circ$ and $-2.0^\circ \pm 7.3^\circ$ for standard instrumentation and patient-specific instrumentation, respectively ($p=0.25$). There was one complication in the standard instrumentation group of a postoperative anterior dislocation, and none in the intervention group.

Zhang et al. randomized 22 patients with single developmental dysplasia of the hip to conventional total hip arthroplasty (N=11) or navigation template implantation (N=11).²⁵ The mean operative time was slightly lower in the intervention group (119.6 versus 125.3 minutes; p -value not reported). The deviation in cup abduction angle was significantly less in the intervention group than in the control group (1.6° versus 5.8° ; $p<0.05$). The deviation in cup anteversion angle was significantly less in the intervention group than in the control group (1.9° versus 3.9° ; $p<0.05$).

3.3.3.3 Orthopaedics – shoulder

Our search identified one small RCT that evaluated the use of patient-specific instruments for glenoid component placement.¹⁷ Hendel et al. randomized 31 patients undergoing total shoulder replacement to patient-specific instrumentation (N=15) or standard instruments (N=16). Overall, the average deviation in version was 6.9° in the standard surgical group and 4.3° in the glenoid positioning system group ($p=0.11$). The average deviation in inclination was 11.6° in the standard surgical group and 2.9° in the glenoid positioning system group ($p<0.0001$). One patient (5.9%) in the standard surgical group experienced a transient partial axillary nerve injury. No patient in the glenoid positioning system group had an adverse event.

3.3.3.4 Maxillofacial surgery

Tack et al.¹⁵ identified two RCTs that used 3D printed surgical guides for maxillofacial surgery. Ayoub et al. randomized 20 patients undergoing mandibular reconstruction to computer-assisted (N=10) or conventional reconstruction (N=10) with vascularized iliac crest bone graft.²⁶ Computer-assisted surgery shortened the time of transplant ischemia (96.1 versus 122.9 minutes; $p<0.005$) and defect reconstruction (16.4 versus 38.5 minutes; $p<0.001$) compared to conventional surgery. The time to saw and shape the transplant at the donor site was shorter using conventional surgery (62.1 versus 37.8 minutes; $p<0.005$). Therefore, the overall time for surgery didn't change (498.5 versus 525.2 minutes; $p=0.527$). In the computer-assisted group, the amount of bone harvested equalled the defect size, whereas the transplant size in the conventional group exceeded the defect site by 16.8 ± 5.6 mm ($p<0.001$) on average. The intercondylar distance before compared to after surgery was less affected in the computer-assisted than in the conventional group ($p<0.001$).

Modabber et al. randomized 10 patients undergoing secondary maxillary or mandibular reconstruction with free vascularized fibular flaps to computer-assisted surgery (N=5) or conventional surgery (N=5).²⁷ Shaping procedure (18 versus 39 minutes, $p=0.014$) and ischaemic time (105 versus 131 minutes, $p=0.014$) were significantly shorter when compared to conventional surgery. Using surgical guides, there was no change between the defect size of the fibula and the necessary transplant size. In conventional surgery, a mean change of 1.92 cm occurred ($p=0.001$). The graft success rate was 80% in conventional surgery and 100% in computer-assisted surgical procedures.



3.3.4 Model for surgery planning

Tack et al.¹⁵ identified two RCTs that used 3D-printed anatomical models for surgery planning,^{28, 29} our search identified a third trial.²⁰

3.3.4.1 Orthopaedics – shoulder

Iannotti et al. randomized 46 patients with end-stage primary glenohumeral osteoarthritis to total shoulder arthroplasty with the use of 3D intelligent reusable instrument (N=25) or 3D imaging (N=21).²⁹ Both groups were also compared with a non-randomized historical control group of 17 patients who had surgical planning using only two-dimensional CT imaging without implant templating or computer measurements of glenoid bone loss. There was no significant difference in implant position when comparing the 3D imaging group and the 3D intelligent reusable instrument group (anteroposterior position: mean difference = -0.58, p=0.27; superoinferior position: mean difference = -0.63, p=0.29). There was also no difference in the accuracy of implant placement (inclination: mean difference = -0.098, p=0.67; version: mean difference = -0.27, p=0.99).

3.3.4.2 Orthopaedics – ankle

Yang et al. randomized 30 patients with a trimalleolar fracture to 3D printing assisted design surgery (N=15) or conventional surgery (N=15).²⁰ Mean operative time was significantly shorter in the intervention group (71 versus 98 minutes, p<0.05), as was the intraoperative blood loss (65 versus 90 ml, p<0.05).

3.3.4.3 Maxillofacial surgery

de Farias et al. randomized 37 patients, planned for microsurgical reconstruction after segmental mandibulectomy for a mandibular tumour, to prototyping (N=17) or no prototyping (N=20) during the preoperative period.²⁸ The prototype group had a shorter operative time (43.7 minutes vs 127.7 minutes; p=0.001). There was also a tendency to reduce the size of the bone flap taken for reconstruction (2.1 versus 8.7 cm).

3.3.5 Model for implant shaping

Tack et al.¹⁵ identified two RCTs that used 3D-printed anatomical models for implant shaping in maxillofacial³⁰ and cranial surgery.³¹

3.3.5.1 Maxillofacial surgery

Kozakiewicz et al. randomized 57 patients with orbital wall fracture to patient-specific treatment by titanium mesh shaped on a 3D printed model of a mirrored intact orbit (N=37) or an individually manufactured polyethylene implant (N=20).³⁰ No differences in binocular single vision loss was found between both groups at 1 and 6 months post-surgery.

3.3.5.2 Cranial surgery

Chrzan et al. randomized 39 patients with focal skull bone loss after craniectomy to reverse engineering/rapid prototyping-based cranioplasty (N=19) or a manually adjusted prosthesis (N=20).³¹ Operative time was shorter in the intervention group (120.3 versus 136.5 minutes; p=0.000004).

Key points

- **Most randomised evidence is available for 3D printed patient-specific surgical guides for orthopaedic surgery, and total knee arthroplasty in particular. However, pooled results show no effect on mechanical axis malalignment and only limited decrease in operative time.**
- **For most other indications (custom-made implants, surgical guides for orthopaedic surgery other than total knee arthroplasty, surgical guides for maxillofacial surgery, models for surgery planning or implant shaping) the identified trials were small and/or did not find significant effects.**
- **Based on the current evidence from RCTs, no conclusions can be drawn about the effect of 3D applications on (long-term) patient-relevant outcomes (such as rehospitalisation and quality of life).**
- **From the available RCTs no robust conclusions related to (long-term) safety of 3D applications for the patients can be drawn.**



4 SYSTEMATIC REVIEW OF THE ECONOMIC LITERATURE

4.1 Methods

4.1.1 Inclusion and exclusion criteria

The following criteria were developed:

- Inclusion and exclusion criteria describing the Population, Intervention and Comparator of interest were defined as in the methods chapter for the clinical effectiveness and safety assessment of 3D-printing techniques. These criteria can be found in appendix 1.
- Design:
 - o Full economic evaluations were considered, i.e. studies comparing at least two alternative treatments in terms of both costs and health outcomes. Cost-minimization analyses (CMA), cost-utility analyses (CUA, with results expressed as incremental cost per quality-adjusted life year (QALY) gained), cost-effectiveness analyses (CEA, with results expressed as cost per life-year (LY) gained), cost-benefit analyses (CBA, with a monetary valuation of health outcomes), and cost-consequence analyses (CCA⁸) were eligible.
 - o 3D-printing techniques being a recent topic presumably yielding few published full economic evaluations, the design criteria was extended to also cover partial economic evaluations: cost comparisons (not considering health outcomes) were thus eligible.
 - o Both primary and secondary studies (i.e. reviews of economic evaluations) were relevant. Due to the expected paucity of published evidence, abstracts were also considered eligible, mainly with the view to keep track of the upcoming information.

- o Cost-outcome (not considering an alternative treatment) and simple cost descriptions were not considered relevant.
- o Letters, news and editorials were removed.

4.1.2 Search strategy

Both electronic and manual searches were performed.

- Electronic search: the following databases were searched in January 2017: Medline(Ovid), Medline(Ovid) in-process and other non-indexed citations, Embase, EconLit(Ovid), CRD (Centre for Review and Dissemination) HTA (Health Technology Assessment) and CRD NHS EED (National Health Service Economic Evaluation Database). A combination of MeSH/EMTREE and text word terms related to 3D printing and 3D models were combined with a broad range of terms to identify (full) economic evaluations (see appendix 2). The websites of the HTA institutes listed on the International Network of Agencies for Health Technology Assessment (INAHTA) and the websites of non-INAHTA members (e.g. NICE) were also consulted.
- Manual search: the reference lists of relevant review papers and economic evaluations were scrutinized for additional relevant articles.

⁸ CCA examines costs and consequences, without the necessity of focusing on a single consequence and without combining disparate consequences into a single, commensurable measure. See European Network for Health Technology Assessment (EUnetHTA) Methods for health economic evaluations - A guideline based on current practices in Europe



4.1.3 Selection procedure

The selection was performed in a two-step procedure: initial assessment of the title, abstract and keywords; followed by full-text assessment if the title, abstract or keywords suggested relevant information, or if no abstract was available. The flow chart of the selection process can be found in appendix 2.

The search strategy yielded 210 unique, potentially relevant citations. After title, abstract and keywords review, 177 articles were excluded, the majority of which were not economic evaluations or did not deal with 3D printing/modelling. Of the 33 full-text articles reviewed, 25 were excluded; either because the economic results reported were limited to the unit costs of specific machines and software used, or because studies focused on

clinical and practical aspects without reporting any economic results (most of those studies claimed 3D-printing techniques to be cost-effective without supporting this with numbers). The recent systematic literature review by Tack was not selected as this was a narrative review, not reporting any number/figure, and in which the perception of the authors about cost(-effectiveness) was reported, even if not backed with evidence.¹⁵ A total of 8 citations were retained (see Table 2).

4.1.4 Data extraction

Data from the 8 economic evaluations were extracted to provide the basis for summary tables and to allow a critical assessment.

Table 2 – List of selected economic evaluations

Citation	Reference number
Baj A, Bolzoni AR, Giannì AB. Virtual planning and patient-specific implants in mandibular reconstruction surgery: A micro-costing analysis. <i>Value in Health</i> . 2016; 19(7):A723.	32
Resnick CM, Inverso G, Wrzosek M, Padwa BL, Kaban LB, Peacock ZS. Is There a Difference in Cost Between Standard and Virtual Surgical Planning for Orthognathic Surgery? <i>Journal of Oral and Maxillofacial Surgery</i> . 2016; 74(9):1827-1833.	33
Rogers-Vizena CR, Flath Sporn S, Daniels KM, Padwa BL, Weinstock P. Cost-Benefit Analysis of Three-Dimensional Craniofacial Models for Midfacial Distraction: A Pilot Study. <i>Cleft Palate Craniofacial Journal</i> . 2016; 3(3).	34
Tack P, Annemans L. Preliminary cost-effectiveness assessment of 3D printed anatomic models for congenital heart diseases. <i>Value in Health</i> . 2016; 19(7):A692.	1
Romero L, Jiménez M, del Mar Espinosa M, Domínguez M. New design for rapid prototyping of digital master casts for multiple dental implant restorations. <i>PLoS ONE</i> . 2015; 10(12): e0145253.	35
Yang M, Li C, Li Y, Zhao Y, Wei X, Zhang G et al. Application of 3D rapid prototyping technology in posterior corrective surgery for Lenke 1 adolescent idiopathic scoliosis patients. <i>Medicine (Baltimore)</i> . 2015; 94(8):e582.	36
Lethaus B, Bloebaum M, Koper D, Poort-Ter Laak M, Kessler P. Interval cranioplasty with patient-specific implants and autogenous bone grafts--success and cost analysis. <i>J Craniomaxillofac Surg</i> . 2014;42(8):1948-51.	37
Prisman E, Haerle SK, Irish JC, Daly M, Miles B, Chan H. Value of preoperative mandibular plating in reconstruction of the mandible. <i>Head Neck</i> . 2014; 36(6):828-33.	38



4.2 Overview of the economic literature

4.2.1 Technical characteristics of the economic evaluations

Table 3 gives an overview of the technical characteristics of the 8 economic evaluations.

Table 3 – Technical characteristics of the economic evaluations

Author	Country	Funding source [§]	Publication type	Analytic technique	Design	Time horizon (cost)
<i>Full economic evaluations</i>						
Tack et al., 2016¹	Belgium	Unknown	Abstract	Cost-effectiveness	Markov model	1 year
Rogers-Vizena et al., 2016³⁴	USA	No industry support	Article	Cost-consequence analysis	Time-driven ABC on retrospective cases	Operative time
Yang et al., 2015³⁶	China	No industry support	Article	Cost-consequence analysis	Micro-costing on retrospective cases	Hospital stay
Lethaus et al., 2014³⁷	The Netherlands	Unknown	Article	Cost-consequence analysis	Micro-costing on retrospective cases	Hospital stay
<i>Partial economic evaluations</i>						
Baj et al., 2016³²	Italy	Unknown	Abstract	Cost-comparison	Micro-costing on retrospective cases	Hospital stay
Resnick et al., 2016³³	USA	No industry support	Article	Cost-comparison	Time-driven ABC on retrospective cases	Pre-operative time
Romero et al., 2015³⁵	Spain	No industry support	Article	Cost-comparison	Prospective cases	Pre-operative time
Prisman et al., 2014³⁸	Canada	No industry support	Article	Cost-comparison	Time-driven ABC on prospective cases	Pre-operative time

ABC: activity-based costing. § Funding source was classified using three categories. 1) Industry support: any explicit acknowledgment of support from private industry. 2) Unknown: no information about support provided. 3) No industry support: explicit acknowledgment of support that did not include private industry (generally from either public sources or private foundations). An explicit statement of “funding source: none” was also included in this last category.



All papers dated after 2014, illustrating that 3D-printing became more important recently. Four studies were performed in European countries, including one study from Belgium.^{1, 32, 35, 37} Three studies originated from North America (2 in the USA and 1 in Canada),^{33, 34, 38} and a final study originated from China.³⁶

Only one study was a cost-effectiveness study, performed in Belgium and so far published as an abstract.¹ Three studies were cost-consequence analyses that compared the cost of 3D-printing strategies with conventional procedures while also reporting a comparison of clinical outcomes such as complication rates and blood loss.^{34, 36, 37} Four studies were cost comparison analyses not considering any clinical outcome in their assessment.^{32, 33, 35, 38}

One study used a Markov model to carry out their cost-effectiveness analysis.¹ Five economic evaluations adopted a micro-costing approach, where resource (or time) consumption at the patient-level was identified based on a retrospective review of cases, which was multiplied by unit (or time) costs.^{32-34, 36, 37} Prisman et al. performed a similar micro-costing analysis but applied it on prospectively enrolled patients.³⁸ In Romero et al. time and operating costs were collected prospectively but the methods used and the sources of information were not described.³⁵

In all studies the time horizons were short, ranging from the pre-operative time required for surgery planning^{33, 35, 38} up to 1 year.¹

4.2.2 Medical and clinical characteristics of the economic evaluations

The medical fields investigated by the studies mostly concerned maxillofacial surgery (4 studies).^{32-34, 38} Other domains were dental,³⁵ cardiovascular,¹ spinal³⁶ and cranial³⁷ surgery (Table 4).

Three studies used the 3D-printing technique to produce patient-specific implants. In Lethaus et al. 3D-printed implants were used for the reconstruction of large cranial bone defects and the procedure was compared with autogenous skull bone graft.³⁷ In Resnick et al. 3D surgical splints were printed and compared to manual splint fabrication (based on casts) in bimaxillary orthognathic surgery.³³ In Baj et al. 3D-printed customized implants were compared to traditional osseous free flaps in mandibular reconstruction surgery.³² In the majority (7 out of 8) of the identified economic evaluations however, 3D-printed techniques were used for surgery planning; where staff members reviewed a 3D-printed anatomical model prior to surgery to understand the anatomy and conceptualise an operation. There were also three studies reporting on the use of 3D printing for implant shaping. In Roger-Vizena et al. and Prisman et al. reconstruction plates were precontoured to precisely fit 3D-printed craniofacial and mandible models in osteotomies and mandibulectomies, and were compared with traditional intraoperative techniques.^{34, 38} In Romero et al. dental prostheses were fabricated based on 3D-printed dental casts.³⁵ Most studies used 3D printing techniques for multiple purposes.

As can be expected from such a recent technique, the sample sizes on which the studies relied to derive their results were limited to less than 20 patients per arm in most studies. In two studies, samples sizes were larger and varied from 43 to 76 patients per arm.^{33, 36}



Table 4 – Medical and clinical characteristics of the economic evaluations

Author	Medical field	Pathology	Purpose of 3D printing	Intervention	Comparator	Patients numbers
<i>Full economic evaluations</i>						
Tack et al., 2016¹	Cardiovascular surgery	Congenital heart disease	Model for surgery planning	Repair of Atrial Septum Defect and Truncus Arteriosus	Standard procedure	Not relevant [§]
Rogers-Vizena et al., 2016³⁴	Maxillofacial surgery	Le Fort III midfacial distraction	Model for surgery planning Implant shaping	Osteotomy with preoperative contouring of surgical plates based on 3D-printed craniofacial model	Standard osteotomy with intraoperative contouring of surgical plates	I: 9 C: 20
Yang et al., 2015³⁶	Spinal surgery	Lenke 1 adolescent idiopathic scoliosis	Model for surgery planning	Corrective surgery based on preoperative 3D spine models	Standard corrective surgery (no 3D model)	I: 50 C: 76
Lethaus et al., 2014³⁷	Cranial surgery	Large skull bone defects ($\geq 100 \text{ cm}^2$)	Custom implant	Skull reconstruction with 3D-printed implant	Autogenous skull bone graft	I: 17 C: 16
<i>Partial economic evaluations</i>						
Baj et al., 2016³²	Maxillofacial surgery	NS	Model for surgery planning Custom implant	Osseous free flaps mandibular reconstruction with use of 3D model and 3D-printed implant	Standard osseous free flaps mandibular reconstruction	I: 13 C: 21
Resnick et al., 2016³³	Maxillofacial surgery	Patients with Le Fort I or bilateral sagittal split osteotomy	Model for surgery planning Custom implant	3D bimaxillary orthognatic surgery planning and 3D-printed splints	Standard bimaxillary surgery planning and manual splints fabrication	43*
Romero et al., 2015³⁵	Dental	Edentulous patients (partially or totally)	Model for surgery planning Implant shaping	Treatment planning and prostheses fabrication based on 3D-printed dental cast	Conventional treatment planning and prostheses fabrication	NS
Prisman et al., 2014³⁸	Maxillofacial surgery	Patients with mandibulectomy (partial or total)	Model for surgery planning Implant shaping	Preoperative adaptation of the surgical plates based on 3D-printed mandible	Standard intraoperative adaptation of surgical plates	10*

NS: not stated, I: intervention, C: comparator. * The same patients underwent both the intervention and the comparator; § Not relevant as the study design is a Markov simulation model.



4.2.3 Cost items

Table 5 gives an overview of the type of resources valued in the studies and the cost input.

The costing perspective was explicitly reported in two studies: a health care payer perspective was adopted in Tack et al.¹ while a provider (i.e. hospital) perspective was used in Baj et al.³² In Lethaus et al. hospital and treatment costs were obtained from the financial administration of the study hospital, thereby suggesting a provider perspective.³⁷ In Romero et al. and Yang et al. it was not possible to infer the potential perspective adopted because the nature (and sources) of the resources valued were poorly documented.^{35, 36} The three North-American studies used a time-driven activity-based costing methodology in which the costs of all activities and services are usually considered, including direct (e.g. drugs, staff and surgeon time) and indirect overhead costs (i.e. resources used to support the organisation overall, without providing direct care: management, security, administration, building, light, heating...),^{33, 34, 38} Overhead costs were however not covered in Prisman et al.³⁸

The cost of a 3D-printed implant produced in-house varied from €13 to \$1000-2000.^{34, 35, 38} In Lethaus et al. the cost of the 3D implant (€10 000) was derived from the bills received from an outsourced company.³⁷ In Resnick et al. the 3D-printed implants (splints) were purchased from third-party vendors and the cost obtained from national estimates (\$1931).³³

4.2.4 Outcome measures

Table 5 gives an overview of the clinical outcome measures used in the cost-effectiveness¹ and in the three cost-consequence analyses.^{34, 36, 37} Per definition, cost-comparison analyses only focus on costs and do not report any clinical outcome.^{32, 33, 35, 38}

The four studies reported on the incidence of complications post-surgery. Complications were retrospectively collected from patients records within 45 days, 24 months and 32-43 months of their surgery in Roger-Vizena et al.,³⁴ Yang et al.³⁶ and Lethaus et al.,³⁷ respectively. Roger-Vizena et al. and Yang et al. further collected the volume of blood lost during the operation. In Tack et al. complication rates were inferred from a literature review and from expert opinion.¹


Table 5 – Costs and clinical outcomes covered in the economic evaluations

Author	Costing perspective	Resources valued	Resources unit costs	Cost of 3D printed implant	Clinical outcomes
<i>Full economic evaluations</i>					
Tack et al., 2016 ¹	HCP	NS (abstract)	NS (abstract)	€1500	(QALY) [†] Complications
Rogers-Vizena et al., 2016 ³⁴	NS	Staff time: plastic surgeon, oral surgeon, anesthesiologist Direct and indirect operating room costs	Cost rate per minute: - \$33.09	\$1000 to \$2000	Blood loss Complications
Yang et al., 2015 ³⁶	NS	Hospital costs	NS	NS	Blood loss Complications Transfusion volume
Lethaus et al., 2014 ³⁷	(Provider)	Hospital and treatment costs	NS	€10 000	Complications
<i>Partial economic evaluations</i>					
Baj et al., 2016 ³²	Provider	Hospital stay, diagnoses, staff time, operation time, surgical hardware	NS (abstract)	NS	Not relevant*
Resnick et al., 2016 ³³	NS	Staff time: salary, fringe benefits Overhead costs attributable to staff	Cost rates per minute: - \$0.38 (receptionist) - \$0.52 (surgery assistant) - \$7.61 (maxillofacial surgeon)	\$1931	Not relevant*
Romero et al., 2015 ³⁵	NS	Operating costs	NS	€13	Not relevant*
Prisman et al., 2014 ³⁸	NS	Operating time: anaesthesia supplies, nurses, operating room attendants, clerks	Cost rate per minute: - \$10.05	\$110	Not relevant*

HCP: health care payer, NS: not stated, QALY: quality-adjusted life-year.

[†] Quality of life implications could finally not be calculated due to lack of relevant literature; * Not relevant as the analytic technique of the studies is cost-comparison.

4.2.5 Results of the economic evaluations

4.2.5.1 Impact on patient safety

Lethaus et al. reported significantly lower complication rates with a 3D-printed implant, up to 43 months post-operation (Table 6).³⁷ By contrast, Roger-Vizena et al. and Yang et al. did not observe a significant difference in the postoperative complications between the 3D-printing and the standard technology.^{34, 36} From their literature review, Tack et al. did not find any

quantitative evidence of the clinical advantages of 3D models for surgical planning of congenital heart surgery. Only suggested advantages referred to a decrease in incidence of complications that they valued at 3% based on expert opinion.¹

Results about the blood lost during the operation were also contrasted; with Yang et al. reporting significantly less blood loss during the surgery with the 3D technique while no differences were observed in Roger-Vizena et al.^{34, 36}



Table 6 – Patient safety results

Author	Follow-up period	3D procedure	Standard procedure	Difference	Source
<i>Postoperative complications</i>					
Tack et al., 2016 ¹	1 year	NS (abstract)	NS (abstract)	Relative reduction: 3%	Expert opinion
Rogers-Vizena et al., 2016 ³⁴	45 days	0 / 9 (0%)	6 / 20 (30%) [†]	NS (p>0.05 [‡])	Retrospective review
Yang et al., 2015 ³⁶	2 years	4 / 50 (8%) [§]	11 / 76 (14.47%) [§]	p=0.34	Retrospective review
Lethaus et al., 2014 ³⁷	32-43 months	1 / 17 (5.9%)	7 / 16 (43.8%)	p<0.05	Retrospective review
<i>Blood loss in operation (millimetres)</i>					
Rogers-Vizena et al., 2016 ³⁴	-	1013	1016	No difference	Retrospective review
Yang et al., 2015 ³⁶	-	846.68 (SD 26.11)*	1029.65 (SD 72.18)*	p<0.001	Retrospective review

NS: not stated; SD: standard deviation. Cells coloured in grey indicate a result in favour of the 3D printed procedure. † Cerebrospinal fluid leak, premature consolidation of the midfacial unit, fracture of the distractor footplate, malposition of the distractor footplate. ‡ Own computations. § Wound infection, screw loosening. * No information provided on the type of complication.

4.2.5.2 Impact on time and costs

The impact of using 3D-printing techniques on the (pre-) operative time was contrasted between the studies. Four of them reported significantly reduced (pre-) operation time with the use of a 3D-printed technique,^{32, 33, 35, 36} while three studies reported no significant difference between the 3D and the standard procedures.^{34, 37, 38}

In two studies there appeared to be a benefit using the 3D-printed technology with respect to the length of hospital stay.^{32, 37} In Yang et al. however no significant difference was observed on this item.³⁶

On the cost side, 3 studies indicated that 3D-printing techniques resulted in net cost-savings compared to traditional techniques.^{32, 33, 35} Savings were also reported in Roger-Vizena et al. but they failed to include the cost of the 3D-printed model in their computations, estimated at \$1000-2000 for an onsite production.³⁴ When included, their results were no longer cost-saving but rather cost-neutral or cost-increasing. Three-dimension-printing techniques resulted in an increase in health care costs in three other studies.³⁶⁻³⁸ Among them, Lethaus et al. justify this by the high cost of manufacturing their customized skull implant (outsourced at €10 000), that counterweighted the savings obtained from reduced treatment costs with 3D-printed implant.³⁷ In Tack et al. 3D-printed models resulted in an increase or in a decrease in health care costs, depending on the congenital heart disease considered.¹



Table 7 – Time and costs results

Author	Time horizon	Time			Cost		
		3D procedure	Standard procedure	Difference	3D procedure	Standard procedure	Difference
Tack et al., 2016 ¹	1 year	-	-	-	-	-	-€1420 to €1435 [‡]
Rogers-Vizena et al., 2016 ³⁴	Operation time	6.1 h (SD 1.2)	6.7 h (SD 0.9)	-31.3 min (p=0.2)	-	-	-\$1036 *
Yang et al., 2015 ³⁶	Operation time	184.32 m (SD 4.65)	212.32 m (SD 8.17)	p<0.001	€21 450 [§] † (SD 1360)	€20 843 [§] † (SD 1564)	€607 [§] † (p=0.03)
	Hospital stay	11.92 days (SD 1.10)	12.24 days (SD 1.13)	p=0.12			
Lethaus et al., 2014 ³⁷	Operation time	120 m (59-208)	141 m (65-257)	p=0.338	€15 226 [†]	€8016 [†]	€7210 [†]
	Hospital stay	6.4 days (3-27)	13.6 days (5-38)	p<0.05			
Baj et al., 2016 ³²	Operation time	9.33 h	10.96 h	p<0.05	€20 342 [†]	€26 163 [†]	-€5821 [†] (p<0.01)
	Hospital stay	11.23 days	24 days	p<0.0001			
Resnick et al., 2016 ³³	Pre-operative time	194 m (SD 14.1)	540.9 m (SD 99.5)	p<0.001	\$2766	\$3519	-\$753 (p<0.001)
Romero et al., 2015 ³⁵	Pre-operative time	60 m	90 m	-30 min	€75	€120	-€45
Prisman et al., 2014 ³⁸	Pre-operative time	14.45 m (SD 4.05)	13.88 m (SD 4.82)	p=0.83	\$147.5	\$139.5	\$8

SD: standard deviation; m: minutes; h: hours. Cells coloured in grey indicate a result in favour of the 3D printed procedure.

‡ -€1420 for truncus artherosus repair and €1436 for atrial septum defect repair. * The cost of the 3D model (\$1000-2000) is not included. § Original costs were converted to Euro with 1 Chinese Ren Min Bi = 0.1366 Euro (Rate February 2017). † The time horizon for the cost computations is the hospital stay.



4.3 Discussion

This systematic review of the economic literature on 3D-printing techniques highlighted the paucity of available costing information. Many publications assert that 3D-printing applications are cost-effective or even cost-saving, but those claims usually arise from subjective perceived benefits and are rarely backed with quantitative assessment. Only 8 economic studies were identified. The quality of the studies was variable and for some of them very poor, with barely no description of the methods, sources and input used. The sample sizes from which data were collected were limited (most often less than 20 patients per arm), which questions the reliability of the data generated and the studies' results. Likewise, the time horizons explored were extremely short (limited to the (pre-)operative time or to the hospital stay for the majority of the studies), such that longer-term clinical and economic consequences were ignored. Results were most often obtained from retrospective case reviews, thereby encompassing potential publication biases.

The results of the studies considerably varied (see visual summary in Table 8). Three studies in maxillofacial and dental surgery concluded that 3D-models for surgery planning and 3D implants reduced the (pre-)operative time (and length of stay in Baj et al.³²) and, as a consequence, were less expensive than traditional techniques.^{32, 33, 35} By contrast, two other studies also in maxillofacial surgery reported no significant gain in complication rate or operative time with a 3D-printed technique, and no cost difference or even an increase in costs between the 3D and standard procedures.^{34, 38} In two other studies in spinal and cranial surgery, costs were reported to increase with 3D-printing techniques, with either no significant difference in (pre-) operation time³⁷ and hospital length of stay,³⁶ or despite a significantly reduced operation time³⁶ or hospital length of stay.³⁷ Finally in the abstract by Tack et al., 3D-printed models could either decrease the health care costs or increase them which, combined with an assumed (expert opinion) reduction in the incidence of complications, led the authors to conclude that 3D-printing models are a cost-effective and perhaps a dominant strategy.¹

It has been argued that 3D-printing technologies would generate the highest benefits in labor-intensive processes and where the experience of a highly specialized surgeon is essential. 3D-printing technologies would then eliminate the time-consuming steps and save time to the surgeon that could be better used elsewhere.³⁹ Evidence from 4 economic evaluations in maxillofacial surgery, per definition a labor-intensive surgical field, is however mitigated and does not allow to conclude that all perceived benefits are real.

Two studies estimated that their 3D implant (skull bone in Lethaus et al.³⁷ and surgical splint in Resnick et al.³³) would not be produced in house but outsourced to external companies that would bear the full cost of the initial investment in 3D-printing technology. High start-up costs can indeed be an obstacle to the implementation of 3D-printing strategies due to the investment required for 3D printers and related materials and software. Three studies explicitly mentioned that their 3D model/implant would be printed in house.^{34, 35, 38} None of them however seem to have considered the initial investment required.

It is likely that the cost of the 3D-printing technology will decrease over time, as the technology improves (e.g. the software) and the material costs might decline. The technology would then become increasingly affordable and available. But this still needs to be confirmed by quantitative, prospective studies with larger sample sizes and longer follow-up times.

In conclusion, based on the results of this review, the frequently reported claim that 3D-printed applications will reduce surgical time and cost and improve patient safety cannot be backed so far.


Table 8 – Visual summary of the safety, time and cost results of the economic evaluations

Author	Medical field	Purpose 3D-printing	Time horizon	Complication rate	(pre) operation time	Hospital length of stay	Cost
Tack et al., 2016[†]	Cardiovascular surgery	Surgery planning	1 year	Reduced [†]	-	-	Reduced or increased [‡]
Rogers-Vizena et al., 2016[§]	Maxillofacial surgery	Surgery planning Implant shaping	Operative time	Equal [§]	Equal [§]	-	Equal or increased *
Yang et al., 2015³⁶	Spinal surgery	Surgery planning	Hospital stay	Equal	Reduced	Equal	Increased
Lethaus et al., 2014³⁷	Cranial surgery	Custom implant	Hospital stay	Reduced	Equal	Reduced	Increased
Baj et al., 2016³²	Maxillofacial surgery	Surgery planning Custom implant	Hospital stay	-	Reduced	Reduced	Reduced
Resnick et al., 2016³³	Maxillofacial surgery	Surgery planning Custom implant	Pre-operative time	-	Reduced	-	Reduced
Romero et al., 2015³⁵	Dental	Surgery planning Implant shaping	Pre-operative time	-	Reduced	-	Reduced
Prisman et al., 2014³⁸	Maxillofacial surgery	Surgery planning Implant shaping	Pre-operative time	-	Equal	-	Equal

Note: Colored cells illustrate the results of the comparison 3D-printing versus standard technology. Green: in favor of 3D-printing technology. Red: in favor of standard technology. Orange: no difference between the technologies. [†] Based on expert opinion. [‡] Depending on the pathology considered. [§] The observed difference was found non-significant by the authors, this may also result from a lack of study power. * When accounting for the cost of the 3D model (\$1000-2000).



Key points

- **Eight economic studies were identified. The sample sizes from which data were collected were limited (most often less than 20 patients per treatment arm), which questions the reliability of the data generated and the studies' results. Results were most often obtained from retrospective case reviews, thereby encompassing potential publication biases.**
- **The results of the economic studies considerably varied. Based on these results, the frequently reported claim that 3D-printed applications will reduce surgical time and cost and improve patient safety cannot be backed so far.**

5 LEGAL PART

5.1 Research questions

In this chapter, the following legal issues related to 3D printing/ 3D printed medical devices are analysed on the EU level and for Belgium.

- Legal qualification and classification of the different categories of 3D printed medical devices, incl. legal qualification of the 3D printer, the software and the input material (see 0).
- Requirements for marketing and entry on the market, taking into account the different categories of 3D printed medical devices
- Liability and insurance law issues
- Data protection
- Patient's rights
- Traceability
- Reimbursement
- Intellectual Property Rights

In appendix 3, the respective legal issues were also studied in a selection of countries (UK, France, The Netherlands and the USA). The international comparison was performed in order to explore whether countries have (in the respective case, within the limits of the European legal framework) different or particular policies with regard to the legal issues related to 3D printing/3D printed medical devices.



5.2 Methodology

For each legal issue the relevant aspects related to the 3D printing of/3D printed medical devices were identified and the applicable EU and national (Belgian, the Netherlands, UK, France, USA) legislation, jurisprudence and doctrine related to each of these legal issues was analysed. However in the jurisprudence and in the doctrine no specific information concerning (the 3D printing of) 3D printed medical devices was found. As a consequence, the main legal source for this study was the legislation. This legislation was analysed and subsequently applied to the 3D printing domain (as neither in this legislation specific provisions concerning 3D printing could be found).

The European legislation and the national legal databases thus formed the most important legal sources for writing the legal part of this study report. The most relevant legislation which was used for this study, can be found above in the section concerning the “main legal texts and definitions” (see section 5.3).

But of course also other information sources, beside the legislation, were consulted for writing the legal part of this report.

The following information sources were consulted in the conduct of this study:

- European and national legal databases (such as *www.jura.be*);
- Communications, Guidelines and reports of the European Commission, Parliament and Council
- Parliamentary work of the European and national legislation
- Position papers from professional and sectorial associations
- Articles published in scientific or legal publications
- Legal experts and lawyers from across Europe were consulted:
 - o the expert team includes 2 lawyers and an HTA-specialist from the Netherlands, a lawyer from the UK and a lawyer from France. These experts are all member of a group of lawyers, united in the “Alliance of European Life Sciences boutique Law Firms”. This group is an alliance of independent European Life sciences boutique firms from around Europe, active in all areas of life sciences and medical technology. The Alliance was founded in 2011 and consists presently of five law firms, uniting a unique team of lawyers with many years of experience as external and in-house counsel in a large variety of areas the life sciences industry.
 - o contacts with and membership of key organisations, associations and committees in the selected countries and on a European level
 - o contacts with Professor Kevin Weatherwax of the University of Michigan (USA).
- Official websites and documentation from national health products and reimbursement authorities in various European countries
- Representatives from the Belgian health product and reimbursement authorities (Federal Agency for Medicines and Health Products (FAMHP - fagg-afmps) and National Institute for Health and Disabilities Insurance (NIHDI))
- Contacts with manufacturers’ association BeMedTech
- Contacts with individual manufacturers



5.3 Main legal texts and definitions

In order to facilitate the reading of the legal part, the main legal text and definitions used throughout the text are listed underneath.

Medical Device Directive (or “MDD”):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, *OJ.L* of 12 July 1993, iss. 196, 1.

Related directives:

- In Vitro Diagnostic medical device Directive (or “IVDD”)
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, *OJ.L* of 7 December 1998, iss. 331, 1.
- Active Implantable medical device Directive (or “AIMDD”)
Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, *OJ.L* of 20 July 1990, iss. 189, 17.

Medical Device Regulation (or “MDR”)

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, *OJ. L* of 5 May 2017, iss. 117, 1.

Related regulation:

- In Vitro Diagnostic medical device Regulation (or “IVDR”)
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, *OJ. L* of 5 May 2017, iss. 117, 176.

Royal Decree on medical devices (or “RD Medical Devices”)

Royal Decree of 18 March 1999 on medical devices, *B. Off. J.* 1 June 2005.

Related royal decrees:

- Royal Decree on in-vitro diagnostic medical devices (or “RD In-vitro Devices”)
Royal Decree of 14 November 2001 on in-vitro diagnostic medical devices, *B. Off. J.* 12 December 2001
- Royal Decree on active implantable medical devices (or “RD Active Implantable Devices”)
Royal Decree of 15 July 1997 on active implantable medical devices, *B. Off. J.* 1 August 1997

Medical Device (or “standard medical device”)

Under the MDD and the RD Medical Devices, a medical device is:

“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- o *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- o *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- o *investigation, replacement or modification of the anatomy or of a physiological process control of conception.*
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”



Under the MDR, a medical device is:

“any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;*
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point”*

Custom-made device:

Under the MDD and the RD Medical Devices, a custom-made device is:

“any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices”

Under the MDR, a custom-made device is:

“any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices”

Accessory:

Under the MDD and the RD Medical Devices, an accessory is:

“an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device”

Under the MDR, an accessory is:

“an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)”

**Hospital produced devices:**

This term will be used to refer to devices that fall under the exemption regime of article 5, sec. 5 MDR:

“With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

- (a) the devices are not transferred to another legal entity,*
- (b) manufacture and use of the devices occur under appropriate quality management systems,*
- (c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,*
- (d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;*
- (e) the health institution draws up a declaration which it shall make publicly available, including:*
 - (i) the name and address of the manufacturing health institution;*
 - (ii) the details necessary to identify the devices;*
 - (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,*
- (f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to*

ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

- (g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and*
- (h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions*

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions

This paragraph shall not apply to devices that are manufactured on an industrial scale.”

A health institution is “an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health”.



5.4 Legal qualification (and classification) and requirements for the placing on the market of 3D printing of / 3D printed medical devices under EU rules

The development of new and innovative 3D printing technologies and the emergence of new techniques enabling faster design and manufacturing times for increasingly complex products necessitates that the regulatory landscape governing 3D printing technology is revisited from a medical devices regulation policy perspective.

3D printing is a fabrication mode that allows the fabrication of **standard** devices, devices that can be **adapted to the features of the patient (customisable)** and medical devices that are **unique** for one patient (**custom-made**). Currently, 3D printed devices that can be adapted to the features of the patient are considered as manufacturing of custom-made devices (see further below).⁹

The regime of custom-made devices has originally been set up with a low regulatory burden, intended to regulate devices such as orthopaedic footwear. Basically, the result of production is a truly unique device made by an expert (dental technician, orthopaedic shoemaker, etc.) that is made only once for the specific patient indicated in the prescription. This is reflected in MEDDEV 2.1/1:

“Custom-made devices (such as dental appliances, prosthesis, hearing-aid inserts) are in most cases one-off devices and the Directive subjects their manufacture to the procedure of article 11(6) in conjunction with Annex VIII.”

Because custom-made devices are essentially one-off devices in accordance with a specific prescription for a specific individual, the EU legislator did not subject them to the normal quality system requirements or conformity assessment requirements (as follows from Annex VIII that exempts custom medical devices from the normal conformity assessment and allows for justification of divergence from the essential requirements in Annex I as well). This way the MDD exempts custom-made devices from conformity assessment¹⁰ and subsequent CE marking¹¹ and provides that they should instead be subject to the Annex VIII statement requirements.¹² However,

“Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices.”¹³

The regime of custom-made devices under the MDD is neutral as to the risk profile of the device that is custom-made – the same requirements apply regardless of the risk profile of the device. All custom-made devices are subject to ex-post controls by the competent authorities. On the other hand, for ‘normal’ devices the requirements increase with the increase of the risk profile of the device. Devices in higher risk classes are subjected to independent third party control of the conformity assessment and the requirements for underlying clinical data increase. For the highest risk classes of devices (e.g. implantable devices) an independent design dossier review is required. All these requirements are intended to ensure that devices that are produced for populations of patients rather than for individuals by exemption are safe and effective.

⁹ <https://medicaldeviceslegal.com/2014/03/05/3d-printing-of-custom-medical-devices-under-future-eu-law/>

¹⁰ Article 11 MDD.

¹¹ Article 17 MDD.

¹² Article 11(6) MDD.

¹³ 12-01-10_COEN_5.1.3, GUIDANCE NOTE FOR MANUFACTURERS OF CUSTOM-MADE MEDICAL DEVICES, p. 2 and article 1(2)(d) MDD.



With the advent of 3D printing it has become possible to produce highly individually customised devices in a way that can potentially be scaled without limitation. In that regard 3D printing is similar to “*normal*” production techniques. Given the scalability of 3D printing to controlled standardised production processes, the question is **whether the repeatability and standardisation of 3D printing of devices does not merit seeing 3D printing of medical devices as “normal” production of devices with a high degree of customisation in the production process, rather than the production of custom-made devices**. 3D printed devices are printed pursuant to software models with built in tolerances that ensure repeatability and a degree of standardisation of the 3D printed devices.

In addition, the question is **whether it is appropriate that an increasing amount of devices (also in higher risk classes, such as orthopaedic implants) is mass-produced under an exemption regime in the MDD, without ex-ante oversight¹⁴ as is required for the exact same devices that are produced with “normal” production processes**.

These two questions, given the increasing application of 3D printing as production technique for devices, constitute an important matter from a policy perspective under the MDR.

The AIMDD contains the same definition of a custom-made device as the MDD.¹⁵

The IVDD does not contain a definition of custom-made device like the MDD and the AIMDD do as such a regime was not contemplated for IVDs.

While 3D printing of IVDs does not seem to have started at this point at any significant scale (3D printing of medical devices seems mostly limited currently to dental, orthopaedic and wearable devices because of the homogeneity of the materials used for printing) there is no particular reason why 3D printing of IVDs would not become technically possible and

commercially viable at some point.¹⁶ Yet, 3D printing in IVD would never be custom-made.

In this chapter we will provide some background information about the current and future EU regimes regarding the legal qualifications of 3D printing and 3D printed devices as this is decisive for the applicable safety and quality requirements. The current legal framework consists of Directive 93/42/EEC regarding Medical Devices (MDD), Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD) and Directive 90/385/EEC regarding active implantable medical devices (AIMDD).

The new regime is provided by the Medical Devices Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR), which were published on 05/05/2017 and entered into force on 25/05/2017. The dates of full application are 26/05/2020 for the MDR and 26/05/2022 for the IVDR. The MDD and the MDR will be the main focus of this report, while references will be made to the IVDD and IVDR where appropriate. The MDR and IVDR will replace the three existing medical devices directives and will have direct effect in Member States once adopted by the European Parliament and by the Council. However, Member states can further specify parts of the regulations in national law when the regulations foresee in this option. Also, there remain numerous Implementing and Delegated Acts for both Regulations.

This chapter will discuss the current legal framework and the effects of the changes in the new legal framework on the qualification on 3D printing and 3D printed medical devices in the EU.

¹⁴ Manufacturers of custom-made devices need to provide a statement that all essential technical requirements have been complied with, and, in Belgium they need to notify these devices to the national competent authority. Yet, these formalities are a posteriori actions and do not include any a priori assessment of the device.

¹⁵ Article 1(2)(d) AIMDD.

¹⁶ See for example: 3D printed MRSA bacterie assay in R. Han, G. Haghighashtiani, and M. McAlpine, “3D Printing a Susceptibility Assay for Multidrug-Resistant Bacteria”, *Chem.* 1, 342-350. September 8, 2016.



5.4.1 *Current regime: Medical Devices Directive & IVD Directive*

5.4.1.1 *Legal qualification*

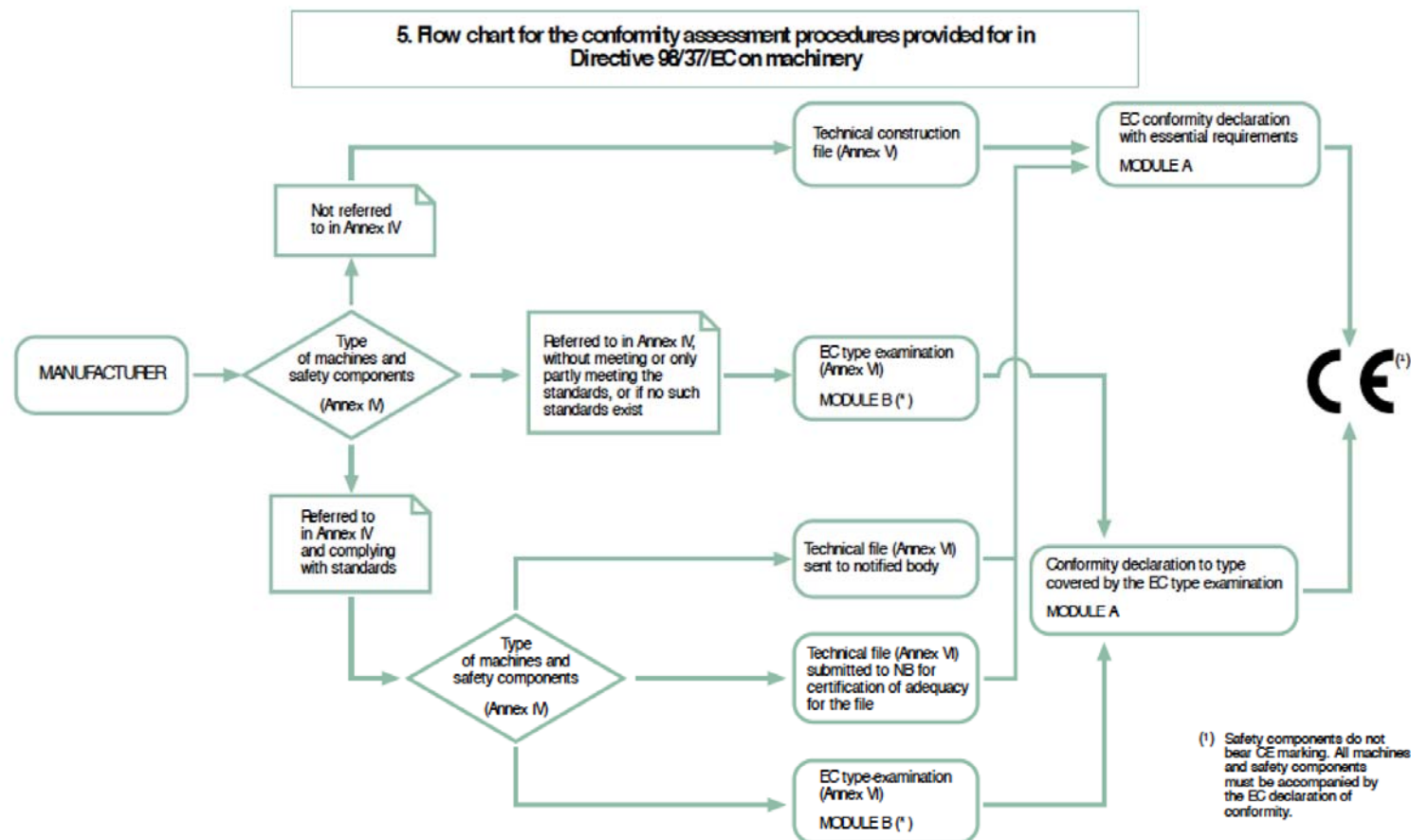
The following subsection will outline the legal qualification of the subjects relevant to 3D printing and 3D printed medical devices. The relevant subjects include the qualification of the **3D printer** itself, the **software used to design the 3D model** that is printed by the 3D printer, preoperative/surgical planning software, the **input material** used to produce the final products and **the end products** (3D printed medical devices).

Qualification of 3D printer

The 3D printer itself is considered advanced manufacturing technology, and as such it is qualified as a **production tool rather than as a medical device**. 3D printers are therefore regulated under the EU Machinery Directive 2006/42/EC.¹⁷ This Directive sets essential and conformity requirements guaranteeing standard levels of safety. The conformity assessment procedures available are shown in the chart below.

¹⁷ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on Machinery, and amending Directive 95/16/EC

Figure 8 – Conformity assessment procedures for 3D printers



(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



Qualification of design software

Software can be used in many different ways with regard to 3D printing. Its regulatory status will therefore depend on the intended purpose of the software. There are two relevant aspects to the qualification of software:

1. what is the intended purpose of the software; and
2. has the software been placed on the market or put into use for the end-user.

1. The intended purpose of the manufacturer

Pursuant to article 1 (2) (g) MDD and 1 (2) (f) AIMDD:

“intended purpose” means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;”

If the intended use is that of a medical device, an AIMD or an IVD, the software must be CE marked under the MDD, AIMDD or IVDD respectively. But if its use is, for example, solely one of validation, amendment of (initial) design, creation of input data or the purpose of creating a 3D model, etc., then the software is not considered a medical device, an AIMD or an IVD because the software is not itself intended for therapeutic or diagnostic purposes. Instead, the software is used in the process for producing a device that is intended for diagnostic or therapeutic purposes. A relevant example is production software for e.g. surgical guides or 3D printed crowns. For comprehensive guidelines concerning the qualification and classification of standalone software please refer to the MEDDEV 2.1/6 Guidance document.

Production software exists solely to enable the production of the product that the 3D printer is producing. In order for software to fall within the scope of the definition of a medical device, the software must be intended for therapeutic or diagnostic purposes with the principle intended action being in or on the human body. As such, production software is thus not a medical device.

Neither is it an accessory. A product that is used for production of another product cannot be an accessory to that other product. In order for a product to be an accessory it must be a device in its own right, and be placed on the market for the purpose of enabling the intended use of a medical device. A production tool neither is a device nor is it placed on the market. An accessory must moreover be “*specifically intended by the manufacturer of the accessory to be used together with a device*”¹⁸ (emphasis added). Software used to produce a device is not intended to be used “*together*” with a device, meaning, it is not used to enable the use of the device for its intended purpose. It is not possible to use devices together for the intended purpose of the accessorized device, if the alleged accessory is used to manufacture the device it allegedly accessorizes. Enabling the creation of a device is not enabling a device to be used in accordance with its intended purpose. None of the examples of accessories in the applicable MEDDEV points to production means constituting accessories.¹⁹ If this argument were to be upheld, medical devices production technology far and wide would constitute accessories to the medical devices it is used to produce.

The difficulty with the design software is that manufacturers often blend in functionality that is regulated under the MDD, e.g. integrated (in software) surgical planning functionality that may make the software a medical device. However, where software is purely intended to acquire an image and process it into a 3D printed file, the software is no different from other process production software used for e.g. milling or metal cutting or 3D printing of non-medical devices. It often appears that production software has further going intended functionality as production software for 3D printing is so multifunctional. A solution would be for software providers to separate functionality more clearly in modules.

If the software is not a medical device (= general purpose software) then no specific medical device related standards apply but rather just standards related to good software development and security. In practice companies would logically choose to apply the EN IEC 62304 for software design for clinical purposes and possibly the new IEC 82304 standard for healthcare

¹⁸ MEDDEV 2.1/1, p. 7

¹⁹ See the examples on p. 7 of MEDDEV 2.1/1, p. 7



software. Further, there is no European guidance imposing specific quality standards to be respected by production for medical devices production.

2. “Placing on the market” and “putting into service”

The regulatory obligations under the MDD are triggered by both “*placing on the market*” and “*putting into service*”²⁰, because these are both considered “*making available*”, which triggers the regulatory obligations under the MDD.²¹ The MDD discusses both of these concepts.²²

Pursuant to article 1 (2) (h) MDD/AIMDD and article 1 (2) (i) MDD and 1 (2) (g) AIMDD respectively:

“placing on the market” means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished’, and,

“putting into service” means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose”; and,

“putting into service’ means making available to the profession for implantation”.

The concept of making available “*results in the scope of Union harmonisation legislation being extended beyond the moment of making available of a product.*”²³ The overarching concept of making available introduced in Regulation 765/2008 precedes the putting into service and triggers regulatory obligations for software when “[a] product is made

*available on the market when supplied for [...] use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.”*²⁴ The timing of the regulatory trigger is identical to that of placing on the market.²⁵

Under the MDD, the provision of service by use of a software device that is not itself placed on the market is not considered “*placing on the market*” of that software device. **For the software to be put into service it must be made available to the end user.**²⁶ While use by a surgeon as end-user would be considered “*placing on the market*”, when a manufacturer merely collects design input for a custom-made device using software for that purpose, it does not amount to putting that software into service as a medical device. The fact that the software is used to create a medical device does not mean that the software itself is a medical device or accessory.

The custom-made devices regime under the MDD also assumes such end user input in Annex VIII by stating that the Annex VIII statement of the manufacturer must contain:

*“the specific characteristics of the product as indicated by the prescription”*²⁷

The custom-made devices regime under the AIMDD also assumes such end user input as stated in Annex 6 where the manufacturer must provide a statement which must contain, in the case of a custom-made device:

*“the specific characteristics of the product revealed by the prescription,”*²⁸

²⁰ Meaning the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose” (article 1 (2) (i) MDD) and 1 (2) (g) and (h) AIMDD.

²¹ Article 2 MDD: “Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.”

²² See article 2 MDD.

²³ Blue Guide 2014, p. 19

²⁴ Blue Guide 2014, p. 17

²⁵ Blue Guide 2014, p. 17

²⁶ Blue Guide, § 2.5 on p. 19

²⁷ Annex VIII, § 2.1, 5th indent

²⁸ Annex 6, § 2.1, 5th indent



The custom-made devices guidance actually states that surgeon input on the design is an essential characteristic of a custom-made device:

“a custom-made medical device is a device that is manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner who gives, under his responsibility, specific characteristics as to its design, and that it is intended for the sole use of a particular patient.”²⁹

Therefore, the mere fine-tuning of a software model of the device to be 3D printed pursuant to the initial written prescription, which, in the custom-made devices guidance is defined as “a predefined specification”³⁰, does not constitute a design that would qualify as a medical device in itself. More generally, the healthcare practitioner input on the design is an essential element of what makes a custom-made device. This fact is not changed by adding another feedback iteration (software) to amend the initial prescription.

As such, if software, like **design software**, never leaves the stage of production, as is required for placing on the market³¹, nor is it ever made available for distribution or use by end users³², nor is it ever put into service for use by an end user outside the stage of production³³, then the software is not “placed on the market” or “put into service” within the meaning of the MDD and AIMDD. Moreover, the production software does not have its own medical intended purpose. It is therefore classified as unregulated general purpose production software. However, the manufacturer of medical devices

may choose to apply relevant standards to the software as a matter of quality management pursuant to its quality management system.

We have noticed in the market that some notified bodies have started to request CE marking as standalone software medical device of “final product design software” and “customer requirements fine-tuning collaboration software”. This however seems like an unhelpful and wrong approach as this would regulate production tools as medical devices that will be placed on the market.

Software used for preoperative/surgical planning can be qualified as a standalone medical device because its intended use is that of an active medical device.³⁴ As surgical planning software performs “an action on data”, that is not limited to “storage, archival, communication, ‘simple search’ or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it can be considered a medical device in its own right.³⁵ Some of this software may also alter “the representation of data for a medical purpose”, and is therefore considered a medical device.³⁶

Also, “Software which is intended to create or modify medical information might be qualified as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals when reviewing medical information, (e.g. when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy) the software could be a medical device.”³⁷

²⁹ 12-01-10_COEN_5.1.3, GUIDANCE NOTE FOR MANUFACTURERS OF CUSTOM-MADE MEDICAL DEVICES, p. 3

³⁰ 12-01-10_COEN_5.1.3, GUIDANCE NOTE FOR MANUFACTURERS OF CUSTOM-MADE MEDICAL DEVICES, p. 2

³¹ See Commission Interpretative document of the Commission's services on placing on the market of medical devices

³² Blue Guide, § 2.2

³³ Blue Guide, § 2.2

³⁴ Article 1.4 MDD; Article 1 92) (a) AIMDD.

³⁵ Ref. Ares(2016)3473012 - 15/07/2016, MEDDEV 2.1/6 July 2016, Medical Devices: Guidance document Qualification and Classification of stand alone software, p. 11.

³⁶ Ref. Ares(2016)3473012 - 15/07/2016, MEDDEV 2.1/6 July 2016, Medical Devices: Guidance document Qualification and Classification of stand alone software, p. 11.

³⁷ Ref. Ares(2016)3473012 - 15/07/2016, MEDDEV 2.1/6 July 2016, Medical Devices: Guidance document Qualification and Classification of stand alone software, p. 12.



In these cases, software can be considered a medical device rather than production software such as the software used to design the 3D printed medical devices.

Key points

- **Design software cannot be classified as a medical device if it does not have its own medical intended purpose and is not placed on the market.**
- **Software used for preoperative/surgical planning can be qualified as a stand alone medical device because its intended use is that of an active medical device.**

Qualification of input material

With regard to the input material it is the intended purpose of the material that determines its qualification. If the intended purpose of the input material is to manufacture a medical device, then the input material itself may also be considered a medical device and will require a CE marking. This happened for example in the medical gasses market where generic (industrial) gasses (*i.e.* oxygen) are either medicinal products or commodity gasses depending solely on the intended use. The EU Guidance Note For Manufacturers Of Custom-made Medical Devices sets out specifically in this regard:

“Intermediate products specifically intended for manufacture of custom-made devices may also be considered as medical devices. This applies essentially to dental alloys, dental ceramics, modular components for

prosthesis, if the intended purpose of such products is specifically related to medical devices”³⁸

Qualifying input material as a medical device however goes against the logic of general medical device law under the MDD and seems to be used by some member states to ensure that the quality of input material is sufficiently ensured, given the light regulatory burden on custom-made devices.³⁹ Under general medical devices law input material is not considered a finished and regulated medical device, if only because input material is evidently not placed on the market with a medical intended purpose but with the purpose of being used in manufacturing of a medical device. Quality controls on input material take place in the process of assessment of the medical device's compliance with the Essential Requirements in Annex I of the MDD that apply to the device concerned.

Some other important legal aspects that should be considered with regard to input materials are:

- Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH);⁴⁰
- Directive 2004/23/EC EU Tissues & Cells Directive (live cells and tissues);⁴¹ and,
- Regulation 722/2012/EC Special regime for medical devices manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue (e.g. proteins).⁴²

³⁸ Guidance Note For Manufacturers Of Custom-made Medical Devices, 12-01-10_COEN_5.1.3, p. 4

³⁹ See for example HPRA Guide for Custom-Made Dental Device Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994, p. 11.

⁴⁰ Regulation 1907/2006/EC of 18 December 2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) and,

Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

⁴¹ Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.

⁴² Regulation 722/2012/EEC of 8 August 2012 concerning particular requirements with respect to active implantable medical devices and medical devices manufactures utilising tissues of animal origin.



Qualification of 3D printed medical device (= output)

The first step in qualifying a 3D printed medical device is determining if the product is (i) a medical device (or an in-vitro diagnostic device), (ii) an accessory, (iii) a component of a device, or (iv) a different type of product. Next it must be determined if the medical device is considered a standard medical device or if it is a custom-made medical device.

Pursuant to article 1 (2) (a) MDD/AIMDD a **medical device** is defined as follows:

“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- o diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- o diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- o investigation, replacement or modification of the anatomy or of a physiological process;*
- o control of conception.*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

Pursuant to article 1 (2) (c) MDD an **in-vitro diagnostic medical device** is defined as follows:

“any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- o concerning a physiological or pathological state; or*
- o concerning a congenital abnormality; or*

- o to determine the safety and compatibility with potential recipients; or*
- o to monitor therapeutic measures.*

Specimen receptacles are considered to be in vitro diagnostic medical devices. “Specimen receptacles” are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;”

Pursuant to article 1 (2) (c) AIMDD an active implantable medical device is defined as follows:

“active implantable medical device’ means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure”;

Pursuant to article 1 (2) (b) MDD an **accessory** is:

“an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device”

3D printed products can be either a medical device, an active implantable medical device, an in-vitro medical device, an accessory to either or a product that cannot be classified as a medical device. Guides are considered accessories. Under article 1(1) MDD, accessories to medical



devices are also considered devices⁴³, therefore 3D printed guides are also considered devices. There is no consensus on a European level whether 3D printed models should be considered as medical devices. Models rarely have a purely diagnostic or therapeutic function, but often serve as aids in the preparatory phase. In that case they are not considered as medical devices. If a manufacturer, however, considers that the use of a model is necessary for an appropriate/optimal utilisation of the medical apparatus, the model can be considered as an accessory (e.g. for an optimal use of a radiation apparatus, it might be recommended to test it on a 3D printed model of the patient's head).

For the 3D printed products that are qualified as medical device, active implantable medical device, in-vitro medical device, or an accessory to either, the main issue lies with the qualification of the medical device as a standard device or a custom-made device.

Pursuant to article 1 (2) (d) MDD/AIMDD a custom-made device is:

“Any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;”

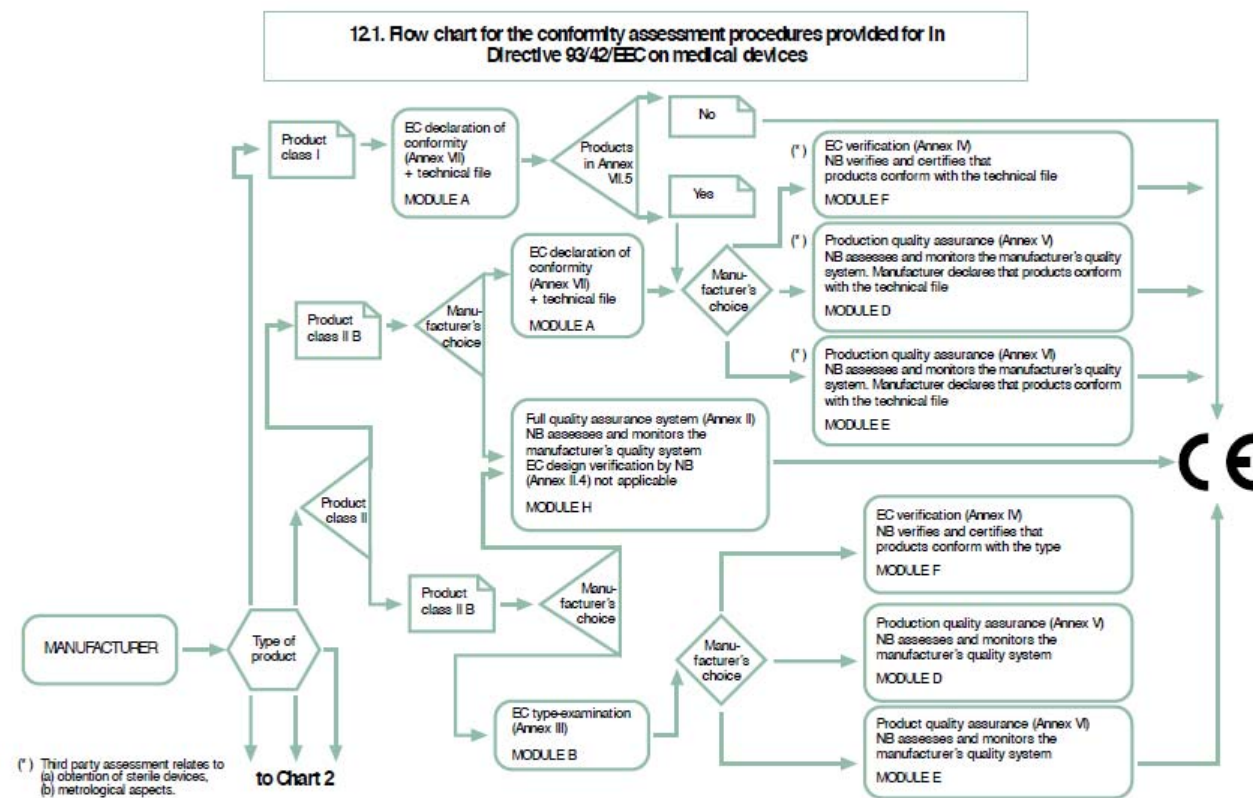
As mentioned above, several types of 3D printed devices can be distinguished according to the degree of 'customisation' (see Figure 1). **Standard 3D printed devices** are identical (parts of) devices that are produced via the 3D technique because of the cost (e.g. because less material is “wasted”) or because the technique is appropriate for the complexity of the design. These standard 3D printed devices do not differ from other standard devices produced via traditional fabrication techniques. Therefore the CE marking and conformity assessment requirements related to the risk class of the device are applicable (see Figure 9).⁴⁴

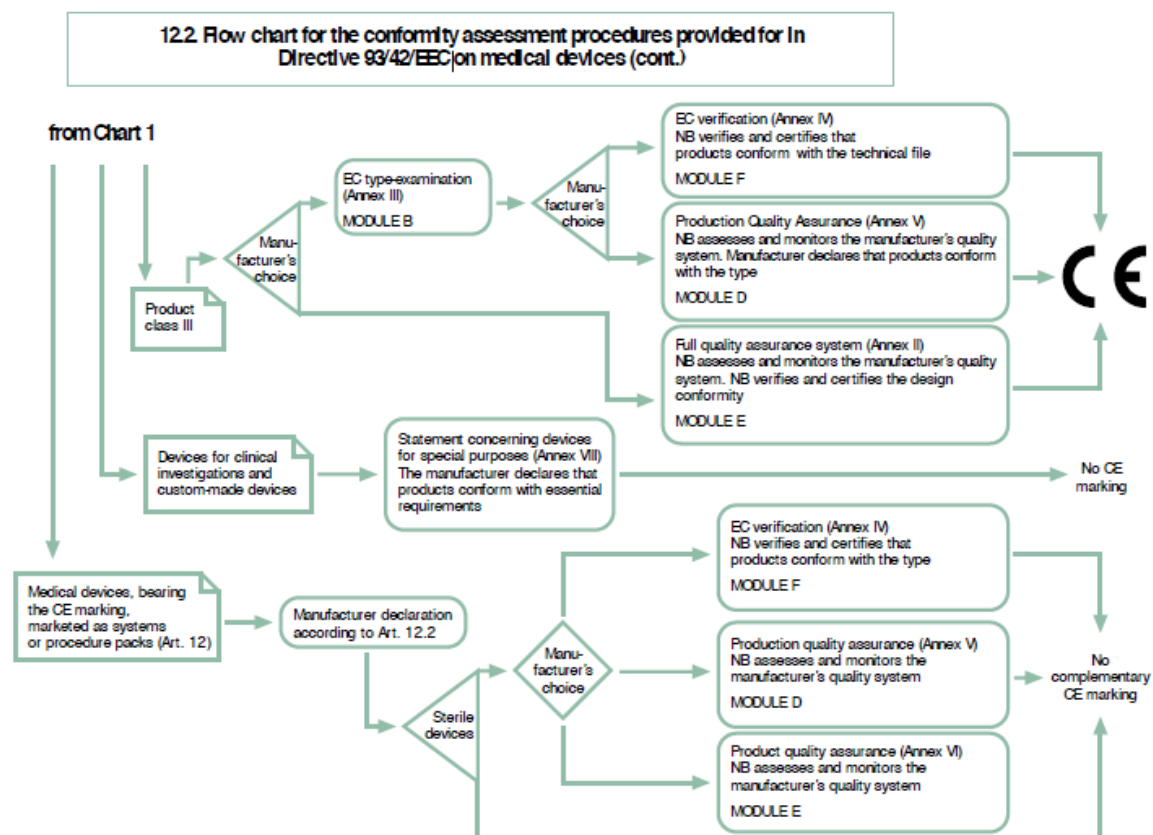
⁴³ As stated in MEDDEV 2.1/1 on p. 6: “The question whether a product is a “device” or a “accessory” has no practical consequence. Following article 1(1) of Directive 93/42/EEC, “accessories shall be treated as medical devices in their own right”.

⁴⁴ http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en; see also Hulstaert F, Neyt M, Vinck I, Stordeur S, Huić M, Sauerland S, Kuijpers MR, Abrishami P, Vondeling H, Van Brabandt H. De klinische evaluatie vóór markttoegang van innovatieve hoogrisico medische hulpmiddelen. Health Services Research (HSR). Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE). 2011. KCE Report 158A.



Figure 9 – Conformity assessment procedures for medical devices







Under the MDD, customisable 3D printed medical devices, – accessories to these medical devices and unique one-off prints are considered as custom-made devices.⁴⁵ Manufacturers that produce customisable 3D printed devices – as they *ex ante* decide on the classification of the products – generally decide to classify their product as a custom-made device. This is accepted by national competent authorities as there is no *ex-post* reaction as to the possible wrong qualification of the devices. Moreover notified bodies that are requested to perform a conformity assessment for customisable 3D printed devices mostly state that it concerns custom-made devices for which they are not competent.⁴⁶

Initially the regime set up for custom-made devices was intended to provide low levels of regulation⁴⁷ as the custom-made devices the regulators had in mind were more along the lines of (handmade) orthopaedic footwear. The definition of custom-made devices is divided into two main parts. The first part requires that a custom-made medical device is manufactured specifically for the sole use of one particular patient and per the specific written prescription of a “*duly qualified medical practitioner*” who specifies, under his/her responsibility specific characteristics to the design. This prescription may result in an entirely new design, or a customization of a commercially available existing design for which the application as a medical device was not outlined by the manufacturer in the instructions for use. An example would be 3D printed exoskeleton intended for heavy lifting that was repurposed as a medical device used to aid paralysis patients in standing and moving around. In all of these instances a device should be considered a custom-made device. However, devices intended to be assembled, tweaked or fine-tuned, or installed, before use, are not considered custom-made medical devices under the MDD.

The second part determines that any *mass-produced* product cannot be considered a custom-made medical device, despite the possibility of the mass produced device being adapted/alterd to fit the specific requirements of the prescriber or user.

In current practice, 3D printed customisable medical devices are considered not *mass-produced*, and as such are qualified as custom-made medical devices. Yet, as mentioned higher, the question is whether the repeatability and standardisation of 3D printing of devices does not merit seeing 3D printing of medical devices as “*normal*” production of devices with a high degree of customisation in the production process, rather than the production of custom-made devices (for a more detailed discussion on this topic see 5.4.2.1).

Accessories to medical devices can also be custom-made 3D printed devices. A typical case in point is the 3D printed surgical guide, which is used to position the implant correctly by providing drill holes in the right place and at the right angle and/or saw lines at the right angle. A guide is not a medical device in itself since it is intended to enable the implant concerned to be fitted correctly (i.e. used in accordance with the implant’s intended purpose). This places the surgical guide in the scope of the definition of accessory. Since it is 3D printed for an individual patient pursuant to the directions of a physician, it is considered custom-made for the purposes of the MDD and subject to the requirements in Annex VIII (see below).

⁴⁵ See MEDDEV 2. 1/1 April 1994 on customizing (p. 4).

⁴⁶ personal communication notified bodies.

⁴⁷ See the explanatory memorandum to the MDR, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical

devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009/* COM/2012/0542 final - 2012/0266 (COD).



5.4.1.2 *Applicable requirements for the placing on the market of the 3D printed medical device*

Manufacturer of 3D printed medical devices

The manufacturer of 3D printed medical devices is “the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.”⁴⁸ This means that the person that actually prints the device is not necessarily the manufacturer. The manufacturer is the person that makes the device available to the end user and may do so via third parties. For example, in a scenario of an online service that allows patients to print out their own device locally, the manufacturer would be the party offering the service to that patient.

Quality system requirements for 3D printed medical devices

As 3D printed customisable medical devices and unique 3D prints are considered custom-made devices under the MDD, they do not bear the CE marking⁴⁹ and there are no particular quality system requirements⁵⁰ or conformity assessment requirements⁵¹, instead they are subject to the Annex VIII statement requirements⁵². This means that the only safeguards are the manufacturer’s diligence, the prescription by a qualified person that defines the custom-made device, and the ex-post controls exercised by competent authorities.

5.4.1.3 *Legal requirements*

3D printed medical devices, like all medical devices, must meet the essential requirements as set out under Annex I of the MDD or IVDD or justify the different points of general requirements which cannot be fulfilled. These essential requirements are also applicable to custom-made medical devices.⁵³

Manufacturers of custom-made medical devices must, pursuant to article 11 (6) MDD, follow the procedures as referred to in Annex VIII resulting in the drawing up of the so-called Annex VIII statement before placing the device on the market pursuant to Annex VIII of the MDD.

Key points

- **The 3D printer is qualified as a *production tool* rather than a medical device, and is regulated by the EU Machinery Directive 2006/42/EC, which sets out relevant conformity requirements and conformity assessment procedures.**
- **Design software is qualified according to**
 - 1) **Intended purpose (Art.1(2)(g) MDD):** If it is used as a medical device for therapeutic or diagnostic purposes with the principal intended action being in or on the human body, then the software must be CE marked under the MDD like any other medical device. If instead the intended use is solely for the production of a medical device (e.g. production software), then it is not a medical device, nor an accessory if it enables only the creation, but not use, of the final end product.
 - 2) **Whether it has been marketed or put into use for the end-user:** Making available the software results in MDD regulation applicability. If the software is confined to the production stage and is not ‘put into service’ in the sense of use by the end-user (e.g. surgeon), then it has not been made available and is not regulated.
- **While general medical devices law does not consider input material a finished/regulated medical device to the extent that it is not placed on the market with a medical intended purpose, it may require CE marking as a *medical device* if it is intended to manufacture a medical device.**

⁴⁸ Article 1 (2) (f) MDD

⁴⁹ Article 4 (2) MDD

⁵⁰ Some general requirements for manufacturers like a system for incident reporting and post marketing surveillance applies to them as well.

⁵¹ Article 11 MDD

⁵² Article 11 (6) MDD

⁵³ Article 3 MDD.



- The final, 3D printed product can be qualified as a “normal” product to which the MDD/IVDD does not apply (e.g. models without a diagnostic or therapeutic purpose) or as a medical device under Art.(1)(2)(a) MDD, an in-vitro diagnostic medical device under Art.(1)(2)(c) MDD or an accessory (e.g. 3D printed surgical guide) under Art.1(2)(b). Medical devices or accessories are qualified as a custom-made device under Art.(1)(2)(d) MDD where the device is manufactured specifically for the sole use of one particular patient and per the specific written prescription of a ‘duly qualified medical practitioner’.
- Standard 3D printed devices do not differ from other standard devices produced via traditional fabrication techniques and are submitted to the CE marking and conformity assessment requirements related to the risk class of the device.
- In current practice, customisable and unique 3D printed medical devices are regarded as custom-made devices under the MDD. They enjoy a low regulatory burden. They require neither CE marking nor quality system or conformity assessment requirements. They are subject to Annex VIII statement requirements, with the only safeguards being the manufacturer’s diligence, the prescription by a qualified person, and the ex-post controls exercised by competent authorities
- Custom-made devices must still meet the essential requirements under Annex I of the MDD. According to Art.(11)(6) MDD, their manufacturers must follow the procedures as referred to in Annex VIII before placing the device on the market under Annex VIII MDD which includes demonstrating compliance with Annex I or demonstrating why and how this is not possible.

5.4.2 Future regime: Medical Devices Regulation & IVD Regulation

In this section we will discuss the same qualifications and requirement as in the previous section, however we will now reconsider these elements under the future MDR/IVDR regime. The relevant differences and effects of these changes will be discussed to provide a clear overview of both regimes.

It must be stressed that when 3D printing would be used in IVD it would never be specific for one patient. If in the following sections the IVDR is referred to, it does not concern custom-made or customisable products.

5.4.2.1 Legal qualification and classification

Qualification of 3D printer

See section 5.4.1.1. There are no relevant differences between the two regimes with regard to the qualification of the 3D printer.

Qualification of design software

See section 5.4.1.1. There are no relevant differences between the two regimes with regard to the qualification of the design software.

Qualification of printing

- Printing as a service (outsourcing)

A new qualification relevant to the 3D printing market is defined in the MDR as “*distance sales*”, or in this case specifically, “*printing at a distance*”, and, therefore, printing as a service. Pursuant to article 6 MDR, a device offered by means of information society services (3D printed device printed at a location of choice) to a natural or legal person in the EU shall comply with the MDR. In these cases, the resulting device is subject to regulation as a device under the MDR.



- Printing in health institutions (hospital produced device)

When the 3D printing of devices takes place in health institutions, the requirements of the MDR, save the relevant general safety and performance requirements of Annex I, will not apply to these devices, if certain conditions are met. Pursuant to article 5 (5) MDR, hospital produced devices are “*manufactured and used only within health institutions established in the Union*”. The conditions that must be met are (i) that the medical device is not transferred to another legal entity (it stays “*in-house*”), (ii) there are appropriate quality management systems in place, (iii) the documentation contains a justification as to why the in-house 3D printing is the only/best way to meet the needs of the target patient(s)/no equivalent device is available on the market, (iv) a publicly available safety and performance declaration by the manufacturer, (v) production control, (vi) post market surveillance, and (vii) vigilance.

Article 2 (36) MDR defines health institution as “*an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health*”. Recital 30 MDR suggests that this concept is applied broadly, as it is intended as “including hospitals as well as institutions, such as laboratories and public health institutes that support the healthcare system and/or address patient needs, but which do not treat or care for patients directly”. This would seem to cover any healthcare provider, even private practitioners. However, it is important to realise that the provisions of article 5 (5) MDR do not apply to devices that are manufactured on an industrial scale. The interpretation and application in practice of this new concept “industrial scale” is still uncertain. At the time of writing the report, the EU is working on a common interpretation. Although so far, there are no interpretation rules yet, it is already clear -based on the text of the MDR- that industrial scale means that: the hospital produced devices cannot be transferred to another legal entity, but also that the volume and process of production is not routine-based/standard (this is in the same way formulated in the hospital exemption for Advanced Therapy Medicinal Products or

ATMPs⁵⁴). It could also be decided on a national level when a production process is (not) routine-based/standard and which volume is allowed to fall under the hospital exemption. In recital 25aaa of the MDR it has been clarified that “*Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, not on an industrial scale, target patient group specific needs which cannot be met at the appropriate level of performance by an equivalent device available on the market*”. This is a clear indication that in-house manufacturing is not on an industrial scale.

If the manufacturing activity of a health institution is not within the scope of the hospital produced devices exemption, the health institution will be considered a “*normal*” manufacturer for the purposes of the MDR and will have to meet all requirements of the MDR that other manufacturers must meet.

An important restriction to hospital production of devices is the requirement in article 5 (5) (a) that “the devices are not transferred to another legal entity”. This will make it difficult, if not impossible, for hospitals to share or pool resources for printing for several health institutions, e.g. by investing in a joint 3D printing lab, unless one of them operates as legal manufacturer of the devices.

It may also be that specific Member States restrict 3D printing of certain specific devices as in-house manufactured devices, for example because of the risks involved. Article 5 (5) MDR provided for controls in this respect: Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory and Member States retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

⁵⁴ Preamble 6 of the Regulation No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004: “Advanced therapy medicinal products which are prepared on a **non-routine basis** according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of

a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Regulation whilst at the same time ensuring that relevant Community rules related to quality and safety are not undermined”.



Qualification of input material

See section 5.4.1.1. Much like under to the MDD, the intended purpose of the input material determines its qualification. However we must note that the EU Guidance Note For Manufacturers Of Custom-made Medical Devices is no longer applicable as the notice clearly defines its scope as limited to custom-made devices as defined in the MDD and the AIMDD.⁵⁵ It is unsure yet if and what existing MEDDEV and other guidance documents currently existing under the MDD, AIMDD and IVDD will be re-adopted under the MDR and IVDR. We understand from the Belgian competent authority that new guidance for custom-made devices will be developed.

- Nano-materials

Due to the uncertainty around the risks and benefits of nanomaterials, the MDR now includes a uniform definition for nanomaterials based on the Commission Recommendation 2011/696/EU⁵⁶, as well as new classification rules for devices using nanomaterials.

Pursuant to article 2 (1) (15) MDR a “nanomaterial” is:

“a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials”

Under rule 19 of the classification rules under the MDR

“all devices incorporating or consisting of nanomaterials are classified as:

- *in class III if they present a high or medium potential for internal exposure;*
- *in class IIb if they present a low potential for internal exposure; and*

- *in class IIa if they present a negligible potential for internal exposure.”*

As many 3D printed devices will inherently contain nanomaterials after printing because input materials incorporate or consist of nanomaterials (e.g. carbon nanotubes), considering their risk/potential for internal exposure will determine which class of medical device the 3D printed device will fall under. This will have a significant impact on the requirements these devices will need to adhere to, because devices that may fall in a low risk class based on their intended use could fall in a high-risk class based on the potential for exposure because “*If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device’s intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.*” (Annex VIII, rule 2.5 MDR)

- Hazardous substances requirements

The MDR contains a new regime for the use of certain hazardous substances in medical devices.

Paragraph 7.4 of Annex I contains a new regime of design requirements for devices containing hazardous substances, requiring that devices, or those parts thereof or those materials used therein:

- o that are invasive and come into direct contact with the human body; or
- o that (re)administer medicines, body liquids or other substances, including gases, to/from the body; or
- o that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

shall only contain the following substances in a concentration above 0.1% weight by weight (w/w) when justified pursuant to the criteria set out in section 7.4.2 of Annex I:

⁵⁵ Guidance Note For Manufacturers Of Custom-made Medical Devices, 12-01-10_COEN_5.1.3, p. 1

⁵⁶ Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).



- o substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008; or
- o substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 (REACH) (SVHCs⁵⁷ subject to authorization) or in accordance with the (forthcoming) criteria established in the delegated act adopted under the Biocidal Products Regulation.

Section 7.4.2 provides that the justification for the presence of such substances shall be based upon:

- o an analysis and estimation of potential patient or user exposure to the substance;
- o an analysis of possible alternative substances, materials or designs, including, when available information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and an analysis of the availability of such alternatives;
- o argumentation why possible substance and/ or material substitutes or design changes, if available, are inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials;

- o where applicable and available, the latest relevant Scientific Committee guidelines in accordance with sections 7.4.3 (phthalates guidance) and 7.4.4 (other CMR or endocrine disrupting substances guidance) of Annex I.

Annex I section 7.4.5 contains labelling requirements for these devices.

These provisions are currently mainly relevant to 3D printed devices printed from some kind of plastics that are invasive and come into direct contact with the human body as these are 3D printed the most at the moment, such as surgical guides.

Qualification of 3D printed medical device (= output)

Much like under the MDD, the first step to qualifying a 3D printed medical device is to determine whether it is a medical device/IVD or not. Next we must determine whether it is a standard medical device, a custom-made medical device, an accessory, a component, or otherwise. Transitioning from the MDD to the MDR there are some relevant changes regarding the definition of a custom-made device. Under the new definition of the MDR, a custom-made device is

“any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;” (underlined elements are new or changed compared to MDD)



Existing guidance has clarified that custom-made devices cannot be mass-produced.⁵⁸ This was reiterated, and further clarified, in the new regulation proposal in one of the Parliament amendments to the MDR containing the above-mentioned definition of custom-made device. But, there are notable differences when compared to the MDD, namely, the scope of the prescribers and the addition of the exclusion of “**devices which are mass-produced by means of industrial manufacturing processes**” from custom-made devices.

In the EU regulatory logic, mass produced but adjustable medical devices are customizable “*standard*” medical devices. The big question is whether this definition excludes individualized 3D printed devices or not. The answer to this will depend entirely on whether or not 3D printing is considered an “*industrial manufacturing processes in accordance with [...] written prescriptions*”. **There are solid arguments to support the claim that individualized 3D printed medical devices are customizable standard medical devices.** The available EU guidance on custom-made products says that mass-production according to individual specifications can still constitute a non-custom-made medical device. In the field of other regulated life sciences products, such as ATMPs, authorities have been very quick to find, with almost no exception, that the cells or tissues of the ATMPs have been produced using an industrial manufacturing process, even in the smallest batches. This was likely done because the perceived risk profile invariably prompts them into a precautionary regulatory approach, qualifying the products as standard ATMPs and thus in scope of the heaviest regulatory regime to remain on the safe side. It is quite possible that 3D printing is a customization of a standard virtual device defined in a software model rather than custom production in the sense of a production process that is not entirely pre-determined, as would be the case with a true traditional custom-made device.

It can be argued that an industrial manufacturing process is characterized by a standardized production method, which is intended to ensure that each device is produced in the exact same way and with a controlled outcome, using the same materials and the same manufacturing template, though still taking into account customization features that are implemented in the production process. This description seems to fit that of the manufacturing of individualized devices by means of 3D printing quite accurately. Moreover, this description is an exact fit with regard to the 3D printing of non-individualized devices. We would argue that the 3D printing of customised devices is the mass-production of devices that are customized in the production process, rather than producing “*uniquely conceived and built devices one at a time*”. In short, the devices are customizable, not custom-made. As a result, they would constitute normal medical devices for the purposes of the MDR. However, it still remains possible that very small batches or one-off 3D printed devices are still considered custom-made devices, for example in cases where a new software model for the 3D print has to be developed for a specific patient. However, where such a new software model is used to print customized devices for groups of patients, it would seem that this would constitute mass-production again, taking the device outside the scope of the concept of custom-made device again.

One exception that has already been mentioned are “*hospital produced*” devices. The hospital produced devices regime will allow hospitals, under certain conditions, to print their own medical devices when no equivalent alternative is available on the market. This regime mirrors that of the IVDR home brew regime set out in article 54 (5) of the IVD regulation. This regime focuses on quality system requirements for the production of home brew IVD devices and makes sure that lab developed tests have at least been developed in an accredited laboratory, with the other requirements (e.g. ex-post notification to member state) being remarkably similar. **This approach will help ensure that at least the production environment is controlled, which would be important for higher risk 3D printed devices.**

⁵⁸ Guidance Notes for Manufacturers of Custom-Made Medical Devices, <http://ec.europa.eu/docsroom/documents/10273/attachments/1/translations/en/renditions/pdf>



The MDR/IVDR provides for a number of national control measures by Member States in article 5 (5) MDR/IVDR: they may require that health institutions submit to the competent authority any further relevant information about in-house manufactured devices which have been manufactured and used on their territory and they retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions. Article 5 (6) MDR/IVDR provides that when Member States diverge too much in their application of national controls regarding the general safety and performance requirements for the devices concerned (set out in Annex I MDR), the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

Characteristic for 3D printing is that it concentrates manufacturing in one place, and limits reliance on suppliers (except for the raw materials input for the printer). On the other hand, because anybody that can obtain the software models for devices and can print them anywhere where one can install a 3D printer and associated machines (to polish, clean, etc. the product), quality systems become increasingly important. More so if we would come to the conclusion that individualized 3D printed devices are custom-made and, therefore, do not constitute devices fully subject to MDR. The MDR increased regulatory requirements for custom-made devices considerably with application of most of the article 10 requirements such as risk management system, clinical evaluation and quality management system requirements. The same regulatory reasoning would apply to accessories (like e.g. surgical guides) under the MDR as well. If they are mass-produced along with the implants they are intended to be used with, the guides would also constitute “normal” devices (accessories) under the MDR. Manufacturers of custom made devices shall follow the procedure set out in Annex XIII of the MDR. In addition manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment as specified in Chapter I of Annex IX or part A of Annex XI, both being the assessment of the quality management system by a notified body.

5.4.2.2 Applicable requirements for the placing on the market of the 3D printed medical device

Quality system requirements for 3D printed medical devices

The current custom-made devices regime assumes that the prescription specifics, the expertise of the custom-made device manufacturer and compliance with the essential requirements set out in annex I are sufficient safeguards for the safety and performance of the device. This may be true for many of the traditional custom-made devices, but will arguably not be sufficient for higher risk devices that are customized.

Consequently, depending on the qualification afforded to 3D printed devices, namely custom-made or standard, differences in the quality management system will apply. But, if the 3D printed devices are qualified as standard medical devices, they must adhere to the general conformity assessment procedures, as well as the conformity assessment procedures specific to that type of device, as set out in the MDR. These procedures are more stringent and result in considerably better quality control for 3D printed medical devices.

Legal requirements

Much like the abovementioned applicable quality system requirements, the legal requirements will depend entirely on the qualification of the 3D printed medical device as either a custom-made medical device or a standard medical device.



5.4.2.3 Conclusions

In conclusion, the regulatory view on 3D printing of medical devices will change considerably under the MDR. Health institutions will not be able to rely on the hospital produced devices exemption if their production reaches an industrial scale or requires transfer from one legal entity to another nor if they produce a product for which an equivalent alternative is available on the market. Also, devices that are mass-produced by means of industrial manufacturing processes are not custom-made devices anymore. There are no clear standards yet on what constitutes mass-production, production on an industrial scale or production by means of industrial manufacturing processes. The interpretation of these concepts will need to be developed at Member State level under oversight of the competent authorities and may be harmonized by judgments of the European Court of Justice or Commission guidance. Also, Member States can exercise control over 3D printing in hospitals under the hospital exemption by requiring information and performing inspections as contemplated in article 5 (5) MDR/IVDR, and they may choose not to allow in-house manufacturing of specific devices. This gives Member States ample control over quality of medical devices 3D printed in the hospitals, provided that Member States make the resources available for effective oversight.

Key points

- **Custom-made devices will maintain lower regulatory burden under new MDR although requirements for manufacturers (art 10) are applicable to all manufacturers incl. those manufacturing custom made devices.**
- **There are no anticipated differences in the new Regulation concerning the qualification of the 3D printer and the design software.**
- **“Sales at a distance”, which can include printing ‘as a service’ (outsourcing) is introduced as a new regulatory concept.**
- **Printing in health institutions (hospital produced device) is also introduced as a new regulatory concept. With the exception of Annex I, the MDR will not apply to devices that have been 3D printed in health institutions if the conditions in Art.5(5) MDR are met and if the devices are not manufactured on an ‘industrial scale’. The interpretation and application in practice of this new concept “industrial scale” is still uncertain.**
- **Presence of nanomaterials in the 3D printed device and the risk/potential for internal exposure will determine the class of medical device that the 3D printed device falls under, influencing the requirements that such a device will have to adhere to even if the risk based on intended use is low (Annex VIII, rule 2.5 MDR and Art. 2(1)(15) MDR Rule 19 of Classification rules)**
- **A new regime is introduced for the use of certain hazardous substances in medical devices. Under Annex I Para. 7.4, certain devices, such as those that are invasive or come into direct contact with the human body, can only contain certain substances mentioned in the provision, such as substances carcinogenic to human reproduction, in a concentration above 0.1% weight by weight when justified according to Annex I Section 7.4.2.**



- Customisable 3D printed medical devices printed via a standard production mode will probably be classified as standard devices under the MDR.
- If 3D printed devices are considered *standard* medical devices (with perhaps a degree of customization in the production process), then they must adhere to normal conformity assessment procedures and are regulated as general medical devices for the purpose of the MDR.

5.5 Legal qualification of 3D printing/3D printed medical devices in Belgium

In this section we will examine the Belgian regime on the legal qualification of 3D printing and 3D printed medical devices. The current regime mainly consists of RD Medical Devices and RD In-vitro Medical Devices. In the future, the MDR and IVDR will largely replace this regime as these new regulations will have direct effect in Belgium.

5.5.1 Legal qualification

5.5.1.1 Qualification of 3D printer

Under Belgian law, the qualification of the 3D printer is the **same as under the EU regime**, where it is qualified as a “*machine*” rather than an medical device. This qualification is based on the EU Machinery Directive 2006/42/EC (see section 5.4.1.1), which has been implemented in Belgium through the Royal Decree of 12 August 2008 regarding the placing on the market of machines.⁵⁹ The essential and conformity requirements of this Royal Decree are in accordance with the European directive.

⁵⁹ B. Off. J. 1 October 2008.

⁶⁰ Art. 1, §2, 7°, 8° and 9° RD Medical Devices.

⁶¹ In section 2.1.1.2, reference is made to other relevant EU regulatory instruments including Directive 2004/23/EC. This directive has been

5.5.1.2 Qualification of design software

Under Belgian law, the qualification of the design software is the **same as under the EU regime** (see section 5.4.1.1). The MDD has been implemented in Belgium through the RD Medical Devices, which copies the MDD definitions of “*intended purpose*”, “*placing on the market*” and “*putting into service*”.⁶⁰ Therefore, also under current Belgian law the design software must be considered production software rather than a medical device. This Royal Decree copies the definitions of the European MDD relating to software. This will not change under the future MDR (see section 5.4.2.1), which will apply directly in Belgium.

5.5.1.3 Qualification of printing

See section 5.4.2.1 on the provisions concerning “*printing at a distance*” and “*hospital produced devices*” under the future MDR. The MDR will directly apply to Belgium.

5.5.1.4 Qualification of input material

Under current Belgian law, the qualification of the input material will be **the same as under the EU regime** (see section 5.4.1.1). The reasoning set out in section 5.4.1.1. also applies in Belgium,⁶¹ which means that also under current Belgian law the input material does not appear to qualify as a medical device. This will remain so under the future regime of the MDR (see section 5.4.2.1), which will directly apply in Belgium. In case of doubt, Belgium could always request the European Commission to make a binding qualification decision on this matter.⁶²

Although input material does not seem to qualify as a medical device, it does qualify as a “*product*” pursuant to article I.10, 1° of the Belgian Economic Law Code (“ELC”):

“all physical goods, whether it is new, second hand or restored in good condition, that have been delivered or made available, against a fee or

implemented in Belgium through the Act of 19 December 2008 on the procurement and the use of human bodily material for medical applications on human beings or for scientific research, B. Off. J. 30 December 2008.

⁶² Art. 13 MDD; art. 45 MDR.



free of charge, to a user⁶³, as well as all physical goods that are put in use by an employer or that are manufactured by an employer to be made available to an employee for the execution of his work".

This means that producers of the input material must provide the users of that input material with sufficient information regarding the inherent risks of the input material.⁶⁴ It also means that the Belgian government can establish by royal decree specific quality and safety requirements for the input material.⁶⁵

5.5.1.5 Qualification of 3D printed medical device (= output)

Under current Belgian law, the qualification of 3D printed medical devices is the **same as under the current EU regime** (see section 5.4.1.1). The RD Medical Devices has copied the definitions of “*medical device*”, “*custom-made device*” and “*in vitro diagnostic device*” of the MDD. Therefore, also under current Belgian law a 3D printed medical device can either qualify as a standard-, custom-made- or as an in vitro diagnostic.

See section 5.4.2.1 for the future regime under the MDR and the IVDR, which will directly apply in Belgium. This means that under the future regime also in Belgium most customisable 3D printed medical devices will most likely no longer qualify as custom-made devices, but rather as standard medical devices (apart from some exceptions such as hospital produced devices and probably also devices produced in small batches).

5.5.2 Applicable requirements for the placing on the market

5.5.2.1 Current Belgian regime for the placing on the market of 3D printed medical devices

Under the current Belgian regime, the same requirements for 3D printed custom-made devices and in vitro diagnostic devices apply as under the MDD and IVDD (see section 0). These requirements have been implemented in Belgium through the RD Medical Devices and the RD In-vitro Devices in accordance with the MDD and IVDD. These means *inter alia* that 3D printed custom-made devices must meet the essential requirements in Annex I and that they must be accompanied by the Annex VIII declaration.⁶⁶

The Belgian regime however also imposes **some additional requirements** related to the marketing of medical devices, including 3D printed (standard or custom-made) medical devices:

- first of all, there are some specific restrictions on the **distribution** of medical devices to healthcare professionals and patients. These restrictions are not based on any EU legislation, but are purely a Belgian addition to the legal framework. These national restrictions are however currently under revision and are expected to be changed before the end of 2017.⁶⁷ The goal is a free market for medical devices where healthcare professionals can receive medical devices without the intervention of a pharmacist. Until then, the current national restrictions remain applicable and must therefore certainly be taken into consideration for now.

The current distribution restrictions only apply to certain types of medical devices, namely (3D printed) sterile medical devices and (3D printed) implants. Distributors of these medical devices can only sell or distribute them to other distributors or to (officina or hospital) pharmacists.⁶⁸ Furthermore, these medical devices can only be

⁶³ Pursuant to article I.10,12° ELC, a user is “*the consumer, the employer or the employee*”.

⁶⁴ Art. IX.8 ELC.

⁶⁵ Art. IX.4. ELC.

⁶⁶ Art. 3 and 5, §1, 7° RD Medical Devices.

⁶⁷ Personal communication FAMHP.

⁶⁸ This restrictions do not apply to dental implants and intra-ocular implants, nor to non-implantable devices which are to be used for examinations or interventions in private cabinets. Distributors of such device scan deliver them



received, stored and delivered to patients by (officina or hospital) pharmacists, or in case of 3D printed dental implants and prosthesis by dentists.⁶⁹

These distribution requirements do not apply to dental devices⁷⁰ or to (non-sterile and non-implantable)⁷¹ optical,⁷² orthopaedic and auditive (3D printed) medical devices.⁷³

It is not entirely clear whether these distribution restrictions apply to 3D printed surgical guides. It would be the case, if such guides could be classified as sterile medical material in which case the guides should be delivered sterile to the hospital. This is however seldom the case; most hospitals sterilise them themselves. The restrictions would not apply if the guides can be qualified as equipment with a measuring function (displaying results of the measurement in legal units (cm,...)). By default, they can be classified as invasive medical devices for which the restriction does not apply⁷⁴. It is however expected that this qualification issue will no longer exist after the revision of these distribution rules;

- there are also some restrictions on the **advertising** of medical devices. Advertising is defined quite broadly. In general, every communication that is directly or indirectly intended for the promotion of the medical device can be considered advertising.⁷⁵ The law however explicitly states that the following content will not be considered advertising: instructions for use and labelling information, letters and purely informative information sent in response to a specific request for information on a specific medical device, specific information (and accompanying documentation) on medical devices without containing data on the medical device itself, and information on human health and diseases without reference to a specific medical device.⁷⁶

With regard to 3D printed medical devices, the following (generally) prohibited forms of advertising are important to mention:

- o advertising is not allowed for medical devices (and their accessories) that do not bear the CE marking.⁷⁷ The question rises whether this prohibition applies to all medical devices or only to devices that legally require a CE-marking to begin with.

Strictly speaking, the prohibition applies to all medical devices, regardless of whether a CE-marking is required or not. The text of the law does not make any distinction on this point. As already mentioned, custom-made devices do not (need to) bear the CE-marking. This means that advertising for 3D printed custom-made devices is not allowed, apart from some exceptions with regard to demonstrations and exhibitions.⁷⁸

directly to authorized physicians/dentists under certain conditions (art. 10*bis*, §7 RD Medical Devices *iuncto* art. 1 and annex Ministerial Decree of 18 May 2005 concerning the implementation of article 10*bis*, §7 of the RD of 18 March 1999 on medical devices, *B. Off. J.* 1 June 2005).

⁶⁹ Art. 10*bis*, §3 and §6 and Annex XIII, art. 1.1. to 1.5. and 1.7. RD Medical Devices. See also: art. 52 Law of 15 December 2013 regarding medical devices, *B. Off. J.* 20 December 2013.

⁷⁰ Annex XIII, 1.6 RD Medical Devices. For dental implants, see: art. 1 and annex MD of 18 May 2005.

⁷¹ The distribution restrictions apply to all implantable medical devices and all sterile medical devices that come into contact with the patient (annex XIII, art. 1.1. and 1.3. RD Medical Devices).

⁷² Including intra-ocular implants. See: art. 1 and annex MD of 18 May 2005.

⁷³ Annex XIII, 1.14 RD Medical Devices.

⁷⁴ Annex XIII, art. 1.1. versus art. 1.10 and art. 1.12 RD Medical Devices.

⁷⁵ Cf. art. I.8, 11° and 13° ELC; art. 22 RD Medical Devices *iuncto* art. 9, §1, sec. 5 Law of 25 March 1964 on medicinal products, *B. Off. J.* 17 April 1964.

⁷⁶ Art. 22 RD Medical Devices *iuncto* art. 9, §1, sec. 6 Law of 25 March 1964 on medicinal products.

⁷⁷ Art. 17 RD Medical Devices and art. 14 RD In-vitro Devices.

⁷⁸ These exceptions are required for the Belgian legislation to be in conformity with the MDD (cf. art. 4, sec. 3 MDD).



The law however also provides an argument to say that the prohibition only applies to medical devices which require a CE-marking, so that advertising of 3D printed medical devices would be allowed then (even if the 3D printed device does not bear a CE-marking, because it is not obliged). When defining the exceptions to this advertising prohibition, the law no longer refers to devices “*that do not bear the CE-marking*” but rather to devices “*that are not in conformity with this decree*”.⁷⁹ This indeed suggests that the prohibition only apply to devices for which it is required to have a CE-marking to be in conformity with the Royal Decree on medical devices. It would seem that the lawmaker only wanted to prohibit advertising for medical devices that have not yet met the legal requirements for (safe) marketing. This interpretation corresponds with the intention of MDD to support the free movement of medical devices that meet the (safety) requirements of the MDD.⁸⁰

- advertising of (standard or custom-made) 3D printed implants aimed towards the general public (including patients) is strictly prohibited either way. Advertising of 3D printed implants is therefore only allowed when aimed towards health care professionals;⁸¹
 - o finally, there are restrictions on certain **other promotional activities** as well. It is not allowed to promote 3D printed medical devices by (directly or indirectly) offering premiums or advantages to healthcare professionals and health institutions in the context of supplying, prescribing, delivering or using 3D printed medical devices, except in some well defined cases such as low value premiums/advantages or invitations to scientific events.⁸² The intention of the Belgian legislator is to prevent practices that influence healthcare professionals in a way that might not lead to the best therapeutic choice for the patient, such as the offering of a sum of money or various objects (e.g. art) and invitations to

exclusively sports, social, tourist or cultural activities. This prohibition was apparently however not intended to prevent normal commercial practices.⁸³ This provides an argument to say that e.g. a moderate, one-time discount does not qualify as a forbidden advantage. A large discount is however not allowed, even if it is only a one-time discount.

5.5.2.2 Future Belgian regime for the placing on the market of 3D printed medical devices

See section 5.4.2. on the future regime under the MDR and IVDR, which will directly apply in Belgium. Assuming that under the future regime most 3D printed medical devices will no longer qualify as custom-made devices, the 3D printed medical devices will then have to comply with the normal requirements of conformity assessment procedures and CE marking. For some aspects, the MDR even allows Belgium to provide for some additional requirements (e.g. restricting the use and manufacturing of certain hospital produced devices⁸⁴ or stopping certain distant sales for public health reasons⁸⁵).

The requirement of CE marking for 3D printed medical devices will indirectly influence the applicable advertising restriction under Belgian law. Because 3D printed devices will have to bear an CE marking, advertising will no longer be automatically prohibited for these devices. But there are still some other relevant advertising restrictions, such as the prohibition on public advertising on implantable medical devices.⁸⁶

⁷⁹ Art. 17, sec. 2 RD Medical Devices.

⁸⁰ Cf. art. 4, sec. 1 and 2 MDD.

⁸¹ Art. 9, §4 Law of 25 March 1964 on medicinal products.

⁸² Art. 10, §2 Law of 25 March 1964 on medicinal products.

⁸³ Explanatory Memorandum, *Doc. Ch.* 2003-2004, n. 1272/1, 16.

⁸⁴ Art. 5, sec. 5, al. 2 MDR. A working group has already been created within the FAMHP to prepare the implementation of such restrictions for hospitals.

⁸⁵ Art. 6, sec. 4 MDR.

⁸⁶ Art. 9, §4 Law of 25 March 1964 on medicinal products.



Key points

- **The qualification of 3D printed medical devices under Belgian law is the same as under the European regime.**
- **On top of the European requirements for placing medical devices on the market, the Belgian law imposes some additional marketing requirements for delivering, for advertising and for offering premiums or advantages with regard to medical devices. In general, these additional requirements do not lead to a particularly more burdensome regime for 3D printed medical devices in comparison with other medical devices.**

5.5.3 Conclusion

Up to now there are no quality and safety requirements that are specific to **3D printed devices**. Because most of these devices are however intended to be used for therapeutic or diagnostic purposes in itself (except for 3D printed anatomical models), it is nevertheless possible to legally qualify them as medical devices (e.g. 3D printed implants) or accessories (e.g. 3D printed surgical guides) to which several quality and safety requirements apply if they are to be placed on the market. Which requirements apply exactly depends on the type of medical devices to which the 3D printed device belongs.

Under current legislation, we found that customisable 3D printed devices and unique one-off 3D prints will mostly qualify as custom-made devices because they are made for a particular patient with a specific prescription for that patient. Custom-made devices enjoy a **lower regulatory burden** than standard medical devices. Even if custom-made devices must meet the essential Annex I requirements, a prior conformity assessment by a notified body and a CE-marking are not required, regardless of the risk profile of the 3D printed devices. This raises some concern for 3D printed devices that potentially entail high-risks for the patient, such as invasive or implantable devices. The (exclusively Belgian) requirement that certain devices, namely sterile or implantable devices, can only be delivered through a (officina or hospital) pharmacist does not remove this concern (and is expected to be changed anyway). The Belgian legislation also contains certain restrictions on the 'promotion' of (3D printed and other) medical devices. Advertising on 3D printed devices is not categorically prohibited, but is nevertheless subject

to limitations. Furthermore, it is not allowed to offer premiums or advantages (e.g. discounts) to hospitals or healthcare professionals in the context of supplying, prescribing or delivering 3D printed devices, except in some well-defined cases (e.g. a one-time, low value discount). Although these 'promotion restrictions' contribute to patient safety by preventing overconsumption, they do not remove the concerns regarding the 'low' custom-made device requirements either.

It is however probable that the legal status of 3D printed devices **will change significantly in the near future (see 5.4.2)**. The MDR changes the definition of custom-made devices, which will now exclude devices that are mass-produced by means of industrial manufacturing processes. This provides an argument to say that many customisable 3D printed devices will henceforth qualify as standard medical devices, because they are produced in the exact same way, using the same materials and manufacturing template (though still taking into account customization features). This means that these 3D printed devices will have to meet stricter quality and safety requirements depending on their risk profile, which can be considered an improvement. For high-risk custom-made devices, however, the regulatory requirements remain low.

For **hospitals** that want to 3D print medical devices in-house, the new regime for health institution produced devices under the MDR deserves special attention. Under this regime, hospitals could 3D print devices without having to meet the (standard or custom-made) requirements, except the essential Annex I requirements. For this exemption regime to be applicable, the hospital must however meet several conditions. Further interpretation of some of these conditions, like the notion of production on "industrial scale" is needed. Most likely the production volume will play a role in the interpretation of this concept. As in-house manufacturing will likely require substantial volume to be cost-efficient, hospitals might not be able to benefit from the exemption regime if this substantial volume is considered as production on an industrial scale. Moreover, the fact that the exemption regime is limited to situations where the specific needs of the target patient group cannot be met by any alternative device on the market can also imply that it will probably concern low quantities. This raises the question whether it will ever be cost efficient for a hospital to invest in 3D printing equipment if they cannot produce large quantities. Moreover, the MDR allows Belgium to provide some additional national restrictions (e.g. no implants, no metallic input materials). The role of the hospital exemption for 3D printing will thus



largely depend on the European and international interpretation of ‘industrial scale’, as well as on which additional restrictions will be implemented by the Belgian legislator. If the hospital exemption would indeed apply to 3D printing, the next concern is which quality and safety management systems have to be implemented by the hospital. The MDR does not say. It will be up to the hospitals and the FAMHP to establish the appropriate standards.

Besides the 3D printed device itself, **the products used to 3D print the device** naturally also play a role in the quality and safety of the final 3D printed product. With regard to these products we can conclude the following:

- the 3D printer is not considered a medical device, but rather a machine which follows its own quality and safety requirements;
- for the 3D printing software, a distinction must be made according to the intended purpose. As soon as a software function is intended to be used for therapeutic or diagnostic purposes in itself, it would qualify as a stand alone medical device. As such, software used for preoperative/surgical planning qualifies as a medical device, like in the USA, because it performs an action on data for medical purposes which is not limited to mere storage, communication, simple search or lossless compression. 3D design software is however not intended to be used as a medical means in itself and is furthermore legally speaking not placed on the market as a medical device, which means it cannot be considered a medical device. It will be up to the manufacturers themselves to implement appropriate standards for this design software (e.g. EN IEC 62304 and IEC 82304) and up to the FAMHP, just like the FDA, to provide guidance hereto;
- the 3D input material is sometimes considered a medical device (notably in the UK) because its intended purpose is specifically related to medical devices. This however goes against the logic of medical device legislation, seeing that the input material is actually not intended to be used in itself for a medical purpose but rather for manufacturing a medical device. Even if the input material is not considered a medical

device, the quality of this material would still be taken into account in assessing the compliance of the 3D printed medical device with the essential Annex I requirements. The MDR will additionally have specific attention for nano materials and hazardous substances.

5.6 Liability and insurance issues associated with 3D printed medical devices

A jawbone is manufactured by 3D printing, the design is modified by the physician to customized specifications. The jawbone breaks a year later, leaches component material and causes an infection leading to the death of the recipient.

Who are the possible defendants of the rightful claimants of the patient? The CAD (= “*Computer Aided Design*”) designer, the jaw bone manufacturer, the filament manufacturer, the physician having implanted the 3D printed jaw bone, the hospital where the patient was operated, the 3D printer being used for the printing of the jaw bone? What insurance lines could be implicated: professional liability of the manufacturer or professional liability of the physician?⁸⁷

3D printing presents particular challenges related to liability as it blurs the traditional manufacturer based production and distribution scheme and it multiplies the number of possible products. This implies that elements that characterize tort liability may need to be re(de)efined. What can be considered a product? How approaching non-traditional medical device manufacturers and what about their responsibilities? Which parties involved in the 3D design and printing chain can be considered as a manufacturer?

The 3D printing process can induce various scenarios of liability for different parties involved: a defective original product being used to create the design; a defective original digital design; a defective digital file (bug); a defective copy/modification of the original; a defective 3D printer; defective material used in the printer; human error in using the 3D printer and/or materials; human errors in implementing the digital design, etcetera.

⁸⁷ Presentation “3D Printing. From Hype to Reality and Insurance Implications”, Robert Weireter, Senior Underwriter – Treaty Casualty, Swiss Re, CANE Fall Meeting.



Insurance contracts might help guarding against liability claims for defective devices and related claims.

5.6.1 *Liability and insurance issues associated with 3D printed medical devices in the EU*

5.6.1.1 *Product Liability Directive (85/374/EEG)*

The Product Liability Directive⁸⁸ aims to ensure the protection of consumers (in this case patients) against damages caused by defective products and to create a measure of harmonization between national regimes.

The Product Liability Directive requires Member States to enforce strict liability (liability without fault⁸⁹) on producers when their products are defective and cause personal injury.⁹⁰ However, it is important to note that as product liability cases are tried at the national level, it is left up to the Member States to provide for cause of action^{91, 92}.

Under the Product Liability Directive a “product” is:

‘all movables’⁹³

However, the considerations of the Product Liability Directive state that liability without fault is only applicable to “*movables which have been industrially produced*”.⁹⁴ While no definition is given in the Directive for “*industrially produced*”, and while this specification might not have been problematic previously, in light of the custom/customizable nature of 3D printed medical devices, the concept of “*industrially produced*” becomes pertinent. As it stands, the qualification of 3D printed medical devices as

either custom-made or as customizable could potentially have real consequences for the applicable liability regime. Whether or not this will truly be the case has yet to be determined at the European level, as there is no EU Court case law on the concept of “*industrially produced*” under the Product Liability Directive.

Yet, the MDR/IVDR refers to the Product Liability Directive for possible compensation of damage caused by a defective medical device.⁹⁵ For the remainder of this section we will assume all 3D printed medical devices fall under the Product Liability Directive as movables. As such, the following products are relevant in the 3D printing of medical devices:

- the 3D printer;
- the input material;
- the final 3D printed medical device (output).

The Product Liability Directive covers all devices manufactured or imported into the EU, and that have caused damage to an individual.⁹⁶

“The producer shall be liable for damage caused by a defect in his product”⁹⁷

Where a producer is:

“the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who,

⁸⁸ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ. L of 7 August 1985, iss. 210, 29.

⁸⁹ See the considerations of the Product Liability Directive.

⁹⁰ Article 1 Product Liability Directive.

⁹¹ ‘Cause of action’ is defined as ‘[a] set of predefined factual elements that allow for a legal remedy. The factual elements needed for a specific cause of action can come from a constitution, statute, judicial precedent, or administrative regulation’ in the Cornell University Law School Legal

Information Institute at: https://www.law.cornell.edu/wex/cause_of_action; also note that

⁹² Also note that the Product Liability Directive has no effect on national provisions regarding contractual or non-contractual liability conform article 13 Product Liability Directive.

⁹³ Article 2 Product Liability Directive.

⁹⁴ See the considerations of the Product Liability Directive.

⁹⁵ Art. 10.16 MDR/IVDR

⁹⁶ See the considerations of the Product Liability Directive.

⁹⁷ Article 1 Product Liability Directive.



*by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer*⁹⁸

In order to protect consumers (and in this case patients), the Directive requires all producers involved in the production process and all actors in the supply chain to be made liable.⁹⁹

*“Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.”*¹⁰⁰

and:

*“Whereas, in situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them”*¹⁰¹, therefore, *‘[w]here the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated,’*¹⁰² and, *‘Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.’*¹⁰³

Under this definition we can identify several different producers relevant to 3D printed medical devices:

- the producer of the 3D printer;
- the producer of the components of the 3D printer;
- the producer of the input material;
- the producer of the 3D printed medical device (output);
- the actor presenting himself as producer by putting his name, trademark, or other distinguishing feature on the product;
- the supplier of the 3D printer;
- the supplier of the input material;
- the supplier of the 3D printed medical device (output);
- the importer placing products on the EU market.

The manufacturer is ultimately responsible for the conformity of the product. 3D printing of medical devices could possibly occur “as a service” outside of the EU, however, as the Product Liability Directive has qualified any person who “imports into the Community” (placing onto the market) as a manufacturer¹⁰⁴, the responsibilities of the importer/manufacturer are the same whether the product is produced inside or outside of the EU.

In case of liability claims, the injured person has to prove damage, the defect of the product and the causal relationship between the damage and the defect.¹⁰⁵ The definition of “defective” is found in article 6 of the Product Liability Directive and is based on the principle that a product is defective if “it does not provide the safety which a person is entitled to expect”.¹⁰⁶ The definition of “damage” is found in article 9 of the Product Liability Directive. There are several instances where the producer will not be held liable, these are found in article 7 of the Product Liability Directive.

⁹⁸ Article 4 Product Liability Directive.

⁹⁹ See the considerations of the Product Liability Directive.

¹⁰⁰ Article 1 Product Liability Directive.

¹⁰¹ See the considerations of the Product Liability Directive.

¹⁰² Article 3.3 Product Liability Directive.

¹⁰³ Article 5 Product Liability Directive.

¹⁰⁴ See NIST SP 951, ‘A Guide to EU Standards and Conformity Assessment’, Order No. 43 NANB912297, May 2000, p. 23.

¹⁰⁵ Article 4 Product Liability Directive; note that the consumer is not required to prove that the producer was negligent, merely that there was a causal relationship, see article 8 Product Liability Directive.

¹⁰⁶ Article 6 Product Liability Directive.



The Product Liability Directive seems less than ideally equipped to deal with the new circumstances surrounding 3D printing. Intangible products, like the design and the CAD files and software, and other actors than the producer and manufacturer that can influence the product (the product designer, the healthcare professional applying in process specifications, the software designer) do not fall under this liability regime. Similar to the “*industrially produced*” requirement for the product to fall under the Directive, the rest of the Directive seems equally irreconcilable with the more custom(ized) nature of 3D printed medical devices rather than the mass-produced/industrial scale production.

To minimize risk for the consumer (patient), it is essential that parties limit the risks as much as possible through contractual provisions between the different actors in the chain (before reaching the customer), ensuring safety and quality measures. In time, case law will clarify the EU regime for product liability regarding 3D printed medical devices. As the consumer is able to claim full compensation from any “*producer*”¹⁰⁷, contractual provisions will serve to protect not only the customer, but also to distribute responsibility to the actors not currently identified as “*producers*” under the Product Liability Directive.

5.6.1.2 Case-law of the Court of Justice

In the case **Henning Veedfald v Århus Amtskommune** the Court of Justice applied the Directive Product Liability to a product used during the provision of a medical service.¹⁰⁸ This judgment is interesting also for judging liability issues with regard to 3D printing of medical devices.

Mr Veedfald was due to undergo a kidney transplant operation in the Skejby hospital (Denmark). After a kidney had been removed from the donor, the kidney was prepared for transplantation through flushing with a perfusion fluid designed for that purpose. This fluid proved to be defective and a kidney artery became blocked during the flushing process, making the kidney unusable for transplant. The fluid had been manufactured in the laboratories

of the dispensary of another hospital, the Århus District Hospital, and was prepared with a view to its use in the Skejby hospital. The Amtskommune is the owner and manager of both hospitals. Mr Veedfald claimed damages from the Amtskommune. The latter denied liability on the ground that it had not put the product into circulation and that the product had not been manufactured for an economic purpose, since the two hospitals concerned were funded entirely from public funds.

The Court judged that:

*“Article 7(a) of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products is to be interpreted as meaning that a defective product is **put into circulation** when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to the organ results from that preparatory treatment.*

*Article 7(c) of Directive 85/374 is to be interpreted as meaning that the exemption from liability where an activity has **no economic or business purpose** does **not** extend to the case of a defective product which has been **manufactured and used in the course of a specific medical service which is financed entirely from public funds and for which the patient is not required to pay any consideration.**”*

With regard to the 3D printing of medical devices, this could be particularly relevant in the case where hospitals will increasingly start to use “*hospital produced devices*”. In such a case, based on this case law, the hospitals will not be able to avoid liability by claiming their product was never “*put into circulation*”, thus requiring hospitals to take into consideration the extra responsibilities as “*producers*”.

- Also interesting in this regard is the **Boston Scientific Medizintechnik GmbH**¹⁰⁹ case.

G. Corporation manufactures and sells pacemakers and implantable cardioverter defibrillators. In a letter of 2005 sent, inter alia, to treating

¹⁰⁷ See the considerations of the Product Liability Directive.

¹⁰⁸ ECJ C-203/99, Henning Veedfald v Århus Amtskommune, 2001.

¹⁰⁹ ECJ C-503/13, Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse, 2015 joined with ECJ C-504/13, Boston Scientific Medizintechnik GmbH v Betriebskrankenkasse RWE, 2015.



physicians, G. indicated that a component utilised to hermetically seal the pacemakers which it marketed may experience a gradual degradation. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning. As a consequence, G. recommended physicians to consider, inter alia, replacing such pacemakers for the patients affected.

In this case the Court of Justice considered that:

*“Article 6(1) of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products must be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a **potential defect**, such a product may be classified as **defective** without there being any need to establish that that product has such a defect.*

*Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes ‘**damage caused by death or personal injuries**’ for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. It is for the national court to verify whether that condition is satisfied in the main proceedings.”*

This case applies a, so to say, “*batch-liability*”. With regard to the 3D printing of medical devices, this could be particularly relevant when considering the “*in production customizable*” medical devices, which could then potentially be regarded as the same “*batch*”, and therefore, liability for potential defects can be based on “*potential defect*” of that “*batch*” or type of design, widening the possibility to claim liability and protecting consumers.

- In the case **Centre hospitalier universitaire de Besançon v Thomas Dutreux and Caisse primaire d’assurance maladie du Jura**¹¹⁰, the Court of Justice was confronted with the following facts: Mr Dutreux,

13 years old at the time, suffered burns during surgery carried out on 3 October 2000 at Besançon CHU: the burns were caused by a defect in the temperature-control mechanism of a heated mattress on which he had been laid.

The Court of Justice considered the following concerning the scope of the Directive Product Liability:

*“The **liability of a service provider** which, in the course of providing services such as treatment given in a hospital, **uses defective equipment or products of which it is not the producer** within the meaning of Article 3 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, and thereby causes damage to the recipient of the service does **not fall within the scope of the directive**. Directive 85/374 does not therefore prevent a Member State from applying rules, such as those at issue in the main proceedings, under which such a provider is liable for damage thus caused, even in the absence of any fault on its part, provided, however, that the injured person and/or the service provider retain the right to put in issue the producer’s liability on the basis of the directive when the conditions laid down by the latter are fulfilled.”*

This judgement could imply that a physician (service provider) working in a hospital where a defective 3D printed medical device (being manufactured outside the hospital) is being used, cannot be held liable based on the Product Liability Directive for the damage caused to the patient due to that defective medical device. The physician could however be held liable e.g. for using defective 3D printed medical devices, based on the rules of national liability law.

Recently, the Court of Justice delivered its much awaited judgement in the case that was a direct result of the PIP breast implants scandal: the **Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH**¹¹¹ case. This case concerned the **liability of notified bodies**. In 2008, Mrs Schmitt had breast implants manufactured in France fitted in Germany. The

¹¹⁰ ECJ C-495/10, Centre hospitalier universitaire de Besançon v Thomas Dutreux and Caisse primaire d’assurance maladie du Jura, 2011.

¹¹¹ ECJ C-219/15, Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH, 2017.



manufacturer of those implants had appointed TÜV Rheinland as the notified body to assess its quality system. Between 1998 and 2008 that notified body made eight visits to the manufacturer's premises, all of which were announced in advance. In 2010, the competent French authority established that the manufacturer had produced breast implants using industrial silicone which did not comply with the applicable quality standards. Accordingly, Mrs Schmitt had the implants removed in 2012. Taking the view that TÜV Rheinland had not fulfilled its obligations satisfactorily, Mrs Schmitt claimed € 40.000,- by way of compensation for non-material damage from that notified body.

- The Court of Justice finally considered the following concerning the liability of the notified body TÜV Rheinland:

*“The provisions of Annex II to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, read in the light of Article 11(1) and (10) and Article 16(6) of the directive, are to be interpreted as meaning that the **notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records.** However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in Directive 93/42, as amended by Regulation No 1882/2003, the notified body must take **all the steps necessary** to ensure that it **fulfils its obligations** under Article 16(6) of the directive and Sections 3.2, 3.3, 4.1 to 4.3 and 5.1 of Annex II to the directive.*

*Directive 93/42, as amended, is to be interpreted as meaning that, in the procedure relating to the EC declaration of conformity, the **purpose of the notified body's involvement** is to **protect the end users of medical devices.** The conditions under which culpable failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by **national law**, subject to the principles of equivalence and effectiveness.”*

If a notified body is involved in the certification of a 3D printed medical device, this notified body is thus not per definition obliged to carry out unannounced inspections, to examine the 3D printed medical devices and/or to examine the manufacturer's business records. According to this judgement, this notified body is however obliged to take all the steps necessary to ensure that it fulfils its obligations as stipulated in

the Product Liability Directive. Here too, the aim is to protect the “end users” of the 3D printed medical devices.

Key points

- **The Product Liability Directive requires States to enforce strict liability on producers when their products are defective and cause personal injury. This ‘strict liability’ applies only to ‘movables [products] which have been industrially produced’, making the custom-made vs. customizable standard dilemma for qualifying 3D printed devices relevant again. The dilemma can have real consequences for the applicable liability regime. The applicability of the Product Liability regime on custom-made devices has yet to be determined at EU level (no EU court case law on concept of ‘industrially produced’ under Product Liability Directive’). Yet, as the liability requirement of the MDR (art 10 (16)) refers to the Product Liability Directive and makes no exemptions for manufacturers of custom-made devices, it can be argued that this liability regime is also applicable to the manufacturers of custom-made devices.**
- **The Product Liability Directive covers all devices manufactured or imported into the EU, and that have caused damage to an individual. The producer is liable for that damage that has been caused by defect in the product. All producers involved in the production process and all actors in the supply chain can be liable. Where several persons are liable, they are liable jointly and severally. Each supplier of the product is treated as the producer unless he informs the injured person within an reasonable period of time of the identity of the producer. The producer can be the producer or supplier of the 3D printer, components thereof or the input material, as well as the actor presenting himself as producer. If no producer can be identified, it is possible that the distributor is product liable.**
- **Liability claim requires proof by the injured person of (1) damage, (2) defect of the product, (3) causation. A product is defective (Art.6) if it does not provide the safety which a person is entitled to expect. Damage is defined in Art. 9.**



- Intangible products like design- and CAD files and software and other actors do not fall under the Product Liability Directive.
- If products belonging to the same group or forming part of the same production series have a potential defect, such a product series may be classified as defective without there being any need to establish that each individual product in that series does indeed have defect.
- Member states are not prevented from applying no fault-based rules additional to the Product Liability Directive under which a healthcare provider is liable for damage caused by a medical device used in treatment, even in the absence of any fault on his part, provided that the injured person and/or the service provider retain the right to claim product liability on the basis of the Product Liability Directive when the conditions laid down by the latter are fulfilled.
- Notified bodies involved in the certification of 3D printed medical devices are not (yet) obliged to carry out unannounced inspections, examine the 3D printed devices and/or to examine the manufacturer's business records, but must ensure that they fulfil their obligations under the Product Liability Directive. Under the MDR, notified bodies will be obliged to carry out unannounced inspections; competent authorities will not be obliged to inspect all custom-made medical device manufacturers, though member states may opt for a stricter regime.

5.6.2 *Liability and insurance issues associated with 3D printed medical devices in Belgium*

5.6.2.1 *Product Liability Law*

The Product Liability Directive was implemented into Belgian Law by the Law of 25 February 1991 concerning the liability for defective products ("*Product Liability Law*"). The definitions, scope and principles of the Product Liability Law are very similar to the definitions, scope and principles of the Product Liability Directive. As a consequence the principles mentioned above (see section 5.6.1) are also relevant for the way in which liability-issues should be handled in Belgium.

According to the Belgian Product Liability Law the **producer is liable for damage by a defect in his product**.¹¹² To apply this general product liability principle to 3D printing, the different aspects of this general principle have to be analysed first.

Product

A "*product*" in the meaning of the Product Liability Law means any tangible movable.¹¹³ Based on the above mentioned explanations (see section 5.6.1), it is clear that the 3D printer, the input material and the 3D printed medical devices (= output) all have to be considered "*products*" in the meaning of the Product Liability Law. These three elements involved in the 3D printing process are all movables. Software does however not qualify as a product in the meaning of the Product Liability Law. It is not clear whether a CAD file could also be considered a product that is placed on the market by the manufacturer. If the CAD file is only used by the manufacturer of 3D printed devices for the internal production process, the CAD file should not be considered a product. If the CAD file is bought by an end user who wants to 3D print himself, then the CAD file could be considered a product. However, at the moment, it is not clear whether the concept "product" in the Product Liability Directive also covers software and digital files. As the Product Liability Directive was published in 1985 it seems probable that with the concept "product" only tangible products were endorsed.

¹¹² Article 1 Product Liability Law.

¹¹³ Article 2 Product Liability Law.



Defective

Obviously each of these products (3D printer, input material and 3D printed medical devices) might be or become malfunctioning or defective. These products will be considered as “**defective**” if they are not providing the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation.¹¹⁴ A 3D printer could e.g. be considered “**defective**” if the printer does not print due to a technical defect. Another example of defective products are blueprints having a higher strength than advertised. Products (e.g. 3D printed devices) could also become defective as a result of putting the wrong spool of base material into the printer; an error in implementing the digital design; an error in using the 3D printer and/or materials; a hacking of the blueprints, etcetera. The safety a person is entitled to expect is based on an objective criterion, i.e. the safety the public at large is entitled to expect. It is also possible that not the public at large but the safety expectations of a more specific group are taken into account, e.g. the medical sector as in the medical sector specific safety expectations can apply.¹¹⁵ In the doctrine multiple examples can be found of products (devices) used in the medical sector that were considered defective by the Belgian courts (for instance a defective surgical knife, a defective respirator, a defective infrared heating lamp, a defective suction device, et cetera).¹¹⁶

If 3D printed devices contain a functionality allowing to adapt the device to the specifics of the patient, then this functionality should -for the purposes of the Product Liability Directive- also be considered a part of the product. As a result a product can be considered defective if the functionality does not function as could be expected. For example, if a 3D printed stent that

should expand into a blood vessel to fit exactly, expands in a defective way, this stent could be considered “defective” in the meaning of the Product Liability Law (of course only if the conditions for a “defective” product in the meaning of the Product Liability Law are fulfilled).

Producer

According to the Product Liability Law the “**producer**” is liable in case his product is considered defective. It is thus important to determine who the producer of a defective product is. According to the Product Liability Law the following persons are considered producer: the manufacturer of a finished product, the producer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer. Notwithstanding this liability of the producer, any person who imports into the EU a product for sale, hire, leasing or any form of distribution in the course of his business shall also be considered a producer and shall thus also be responsible as a producer. And where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless the supplier informs the injured person, within reasonable time, of the identity of the producer or of the person who supplied him with the product. In case of an imported product, the supplier of the product shall also be considered the producer if the product does not indicate the identity of the importer, even if the name of the producer is indicated, unless the supplier informs the victim, within reasonable time, of the identity of the importer or of the person who supplied him with the product.¹¹⁷ It is clear that the interpretation of the concept “**producer**” is very broad.¹¹⁸ The overall objective of the legislator was to protect the consumer.¹¹⁹

¹¹⁴ Article 5 Product Liability Law.

¹¹⁵ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1494, nr. 3090.

¹¹⁶ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1497, nr. 3094.

¹¹⁷ Article 4 Product Liability Law.

¹¹⁸ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1497, nr. 3096.

¹¹⁹ This follows from the preamble to the Product Liability Directive where reference is made, multiple times, to the objective to protect the consumer: “Whereas protection of the consumer requires that (...); “whereas, to protect the physical well-being and property of the consumer,(...)”.



When applied to 3D printing the group of persons that could be considered “producer” in the meaning of the Product Liability Law, is consequently also very broad/large.

Below it is analysed to what extent different actors implicated in the 3D printing process might be qualified as a producer in the meaning of the Product Liability Law or not:

- the service providers to the 3D printing company:
 - o the “digital designer” who wrote the code being used to instruct the printer what to print ≠ manufacturer of a product → no liability as producer → liability under common civil law;
 - o the developer of the blueprint ≠ manufacturer of a product → no liability as producer → liability under common civil law;
 - o the developer of the website where the software was downloaded from = manufacturer of a product (website = product) = producer;
 - o the manufacturer or supplier of the bulk printing material = manufacturer of a component part (= input material) = producer;
 - o the manufacturer of the 3D printer being used to “print” the (defective) item = manufacturer of a finished product (= 3D printer) = producer;
- the 3D printing company:
 - o the person operating the printer (this can be the “traditional” manufacturer or a doctor, pharmacist, hospital employee, etcetera) = manufacturer of a finished product (= 3D printed device) → producer;
 - o the person implementing the digital design ≠ manufacturer of a finished product → no liability as producer → liability under common civil law;
 - o the person pushing the button of the 3D printer ≠ putting the product into circulation → no liability as producer → liability under common civil law;
- the hospital:
 - as client of the 3D device manufacturer/supplier (= outsourcing):
 - o the radiologist making the 2D images being used for the 3D printing ≠ manufacturer of a finished product => no liability as producer → liability under common civil law;
 - o the surgeon fine-tuning the design together with the engineer of the 3D printing company ≠ putting the product into circulation → no liability as producer → liability under common civil law;
 - o the engineer of the 3D device manufacturer/supplier helping the surgeon to align medical issues with technical ones ≠ putting the product into circulation → no liability as producer → liability under common civil law;
 - as 3D printing institution (= in-house):
 - o the person pushing the button of the 3D printer ≠ putting the product into circulation → no liability as producer → liability under common civil law;
 - o the hospital running the 3D printer = manufacturer of a finished product (= 3D printed device) = producer.
 - o the surgeon fine-tuning the design together with the engineer of the hospital ≠ putting the product into circulation → no liability as producer → liability under common civil law;
 - o the engineer of the hospital helping the surgeon to align medical issues with technical ones ≠ putting the product into circulation → no liability as producer → liability under common civil law;
- the hobbyist:
 - o the hobbyist inventor who created and sold the defective 3D printed product ≠ in the course of his business = no liability as producer → liability under common civil law.



The RD Medical Devices defines a “manufacturer”¹²⁰ as follows: “the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this decree to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient”.¹²¹ The definition of a “manufacturer” in the RD In-vitro Devices is similar to this definition.¹²²

If a person is considered a “manufacturer” in the meaning of the RD Medical Devices or the RD In-vitro Devices, it is very likely that this person is also considered a “producer” in the meaning of the Product Liability Law. The fact that a natural or legal person is considered a “manufacturer” is thus an important element when considering if that person is a “producer” according to the Product Liability Law.

5.6.2.2 No-fault liability

The Product Liability Law further proclaims the principle of **no fault-liability** of the producer. The injured person will not have to prove the producer committed a fault. The injured person will only have to prove: the **damage** he or she suffered, the **defect** of the product and the **causal relationship** between the defect and the damage.¹²³ If the injured person can prove all this, the producer will be held liable for the damage caused by the defective product.

If, according to the Product Liability Law, two or more persons are held liable for the same damage, they shall be liable jointly and severally.¹²⁴

The liability of the producer arising from the Product Liability Law may **not**, in relation to the injured person, be **limited** or **excluded** in an agreement. The liability of the producer may however be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by a fault of the injured person or any person for whom the injured person is responsible.¹²⁵ So, if a patient is injured by a defective 3D printed implant because the patient did not follow the instructions from the doctor (who implanted the device), the liability of the producer of the defective 3D printed implant may be reduced or disallowed. The liability of the producer is however not reduced when the damage is caused both by a defect in the product and by the act or omission of a third party. The producer will thus remain liable for the damage caused to a patient by a (defective) 3D printed implant that was implanted incorrectly by the doctor or that was implanted by a doctor who should have seen that the 3D printed implant was defective.

The **producer** can escape from the no fault-liability and will **not** be held **liable** if he proves¹²⁶:

- that he did not put the product into circulation¹²⁷
 - o for example: a defective 3D printed medical device that is only used as part of an experiment; or
- that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards

¹²⁰ A. VIJVERMAN, “Hergebruik van voor eenmalig gebruik bestemde medische hulpmiddelen: nood aan een duidelijke regeling”, *T.Gez.* 2008-09, afl. 1, 20.

¹²¹ Article 1, §2, 6° RD Medical Devices.

¹²² Article 1, §2, 10° RD In-vitro Devices.

¹²³ Article 7 Product Liability Law.

¹²⁴ Article 9 Product Liability Law.

¹²⁵ Article 10 Product Liability Law.

¹²⁶ Article 8 Product Liability Law.

¹²⁷ Article 6 Product Liability Law defines “put into circulation” as the first act from which the intention of the producer turns out to provide to the product the destination which he gives to that product by transfer to third parties or by use to the benefit of the latter.



- o for example: a non-defective 3D printed device that becomes defective during its transport to the hospital; or
- that the product was neither manufactured by him for sale or any form of distribution for economic purpose, nor manufactured or distributed by him in the course of his business
 - o for example: a defective 3D medical device printed by a hobbyist; or
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities
 - o for example: a 3D printed medical device that has become defective due to its compliance with careless government standards; or
- that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered
 - o for example: a 3D printed medical device that became defective due to the wrong choice of 3D printing material (= input material) and at the time of putting the medical device into circulation it was not known that this type of 3D printing material was not strong enough for the desired or intended type of medical use; or
- in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product
 - o for example: manufacturer of a component part of a 3D printed medical device that was defective due to the design of the medical device.

The Product Liability Law does not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability.¹²⁸ An injured person can thus also claim compensation from the same “*producer*” based on the principles of contractual or non-contractual

liability law (see following sections). However, the burden of proof will be heavier under the contractual or non-contractual liability rules.

5.6.2.3 Article 1382 Civil Code

Article 1382 of the Belgian Civil Code (“CC”) stipulates that any act of a person which causes damage to another makes him by whose fault the damage occurred liable to make reparation for the damage. This liability of article 1382 CC is a **non-contractual liability**.

To be able to claim compensation the injured person (in most cases the patient) will have to prove:

- that **damage** was caused;
- by the **fault** of a person; and
- that a **causal relationship** exists between the concerned damage and fault.

Applied to the context of 3D printing damage can be caused by multiple persons: the “digital designer” who wrote the code being used to instruct the printer what to print; the developer of the website where the software was downloaded from; the person implementing the digital design; the developer of the blueprint; the manufacturer or supplier of the bulk printing material; the manufacturer of the 3D printer being used to “print” the (defective) medical device; the person operating the printer (this can be the “traditional” manufacturer or a doctor, pharmacist, hospital employee, etcetera); the person pushing the button of the printer; the hospital running the printer; the hobbyist inventor who created and sold the defective 3D printed product; etcetera.

If a patient can prove a fault committed by any or several of these persons and can prove that he suffered damage as a consequence of that fault, the conditions of article 1382 CC are fulfilled and the patient can claim compensation from all persons having committed such fault. The scope of this article 1382 CC is thus broader than the scope of the Product Liability Law. All these persons can be held liable according to article 1382 CC without them having to be qualified as producer, whereas only some of them

¹²⁸ Article 13 Product Liability Law.



(only the persons who can qualify as producer) could be held liable according to the Product Liability Law. But the patient will have to prove a fault if he wants to be compensated under article 1382 CC, whereas the patient will not have to prove any fault if he wants to be compensated under the Product Liability Law (= a no fault-liability = a less heavy burden of proof).

Finally, it should be repeated that both options to claim compensation could be combined (see article 13 of the Product Liability Law: the Product Liability Law does not affect any rights which an injured person may have according to the rules of contractual or non-contractual liability law).

5.6.2.4 Article 1384, section 1 Civil Code

According to article 1384, section 1 CC a person is liable not only for the damage he causes by his own act, but also for the damage caused by the acts of persons for whom he is responsible or by objects he has under his care. If we apply these rules to 3D printing causing damage to a patient, the patient would have to prove the following in order to be able to claim compensation based on this article 1384, section 1 CC:

- **damage;**
- a **defect** in a **product** (that is under the custody of a person); and
- a **causal relationship** between the defective product and the damage.
- This article 1384, section 1 CC could be applied by a patient suffering e.g. damage caused by a defective 3D printed medical device and/or a defective 3D printer for which the owner of the 3D printer could be considered the custodian; if damage would be caused by a defective 3D printer owned by the hospital, it is most likely that the hospital (and not

the physician who implanted the device) would be considered the custodian of the 3D printer.¹²⁹

- This liability of the custodian for the objects (and persons) he has under his care, is a **non-contractual liability**.¹³⁰ As patients, in most cases, will have a contractual relationship with their hospital/doctor, the scope of this article 1384, section 1 CC is limited in the relationship patient ~ hospital/doctor. This article 1384, section 1 CC will however be relevant towards a hospital/doctor if a 3D printed medical device was implanted in a public hospital (e.g. UZ Gent), by a doctor-assistant or in situations where the patient has not given his consent (for instance when the patient is in coma)¹³¹ because in these situations there is supposed to be no contractual relationship between the patient and the hospital/doctor, being the custodian of the defective device or printer having caused the damage.

5.6.2.5 Contractual liability (patient ~ hospital/doctor)

In the medical context, a **contractual relationship** will mostly exist between the **patient** and the **hospital** and/or **doctor**. As a consequence the hospital and/or doctor can be held contractually liable for the damage they caused to the patient when using e.g. defective products. The mere fact that the hospital or doctor is using a defective product could indeed be considered a breach of contract as the hospital/doctor, by using such defective product, cannot achieve the guaranteed result, i.e. a certain level of safety. In those cases the hospital or doctor violates his/her obligation of result.

In the Belgian doctrine the generally accepted principle indeed is that the hospital/doctor has an **obligation of result** not to use defective products.¹³² This has also been confirmed by the Belgian jurisdiction.¹³³ The objective of

¹²⁹ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1502, nr. 3103.

¹³⁰ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1501, nr. 3101.

¹³¹ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1501-1502, nr. 3102.

¹³² T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1490, nr. 3083.

¹³³ For an overview of this Belgian jurisdiction see: T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1490-1491, nr. 3084.



this obligation of result (also called: “*safety obligation*”) is that the hospital/doctor uses sound and safe material when treating his patients.

It is clear that it will not be easy for the patient to prove that the hospital/doctor violated this obligation of result. To hold the hospital/doctor liable the patient will have to prove the defect of the product (3D printed medical device), the damage and the causal relationship between defect and damage. The hospital/doctor can escape from this liability by proving that the product (3D printed medical device) was not defective, or that the damage was caused by force majeure, by a fault of a third party or by a fault of the injured patient himself. Moreover, the hospital/doctor can take recourse against the distributor or the producer of the defective product (for instance the 3D printing company).¹³⁴

Such contractual liability could however also be withheld if damage is caused by the hospital or doctor due to a lack of care on the part of the hospital/doctor, when e.g. using the (not necessarily defective) 3D printed medical device (= product) or when performing 3D printing itself (= activity). In those cases the hospital or doctor violates his or her **obligation of effort/means**.

This contractual liability of the hospital/doctor is not stipulated/regulated in the Belgian legislation. Moreover, there is disagreement in the Belgian doctrine about the legal basis/application of this contractual liability for defective products.¹³⁵

5.6.2.6 Contract/agreement (hospital/doctor ~ producer)

In reality the **producer** (manufacturer) of 3D printed medical devices will often conclude an **agreement** with the party who ordered or requested to print a certain 3D printed medical device, such as a **hospital** or **doctor**. In this agreement parties will almost always make arrangements concerning the liability (and accompanying insurance) obligations of each of the parties.

In this agreement the producer (manufacturer of the 3D printed medical devices) will also often limit or exclude his liability (and insurance obligations) with regard to the hospital or doctor. **It is however important to note that the liability of the producer may never be limited or excluded contractually in relation to the injured person.**¹³⁶

Apart from that, parties are free to determine what they stipulate in the agreement¹³⁷, as long as they both agree on the content of the agreement. **Parties are thus absolutely free to determine which party is liable for which liability aspects of the collaboration (as long as the rules of the Product Liability Law are not violated – see section 5.6.2.1).** Despite the fact that software cannot be considered a product (according to the Product Liability Law), it can be stipulated contractually that the product liability legislation will apply to the developer of the software anyway. But if no contract is concluded, common civil law will apply and in that case the patient will be in a weaker position as the patient cannot rely on the no-fault liability as foreseen in the product liability legislation. This pleads at the same time for good rules on software validation. It could be considered a duty of the government to develop these software validation rules.

Each agreement can be different depending on the specific circumstances of the collaboration. There does not exist something like a “standard” liability (and insurance) clause, but in practice it seems logic to agree as follows:

- hospital (doctor): provision of 2D images (3D-scanning information); taking the medical decisions;
- producer (manufacturer/engineer): converting 2D images into 3D image; choice of input material; choice of type of printer/printing technique; taking the technical/mechanical decisions.

If the patient claims compensation from the hospital and/or doctor based on the contractual relationship between them (see section 5.6.2.5), this patient

¹³⁴ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1492-1493, nrs. 3086-3087.

¹³⁵ T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht*, I, Zorgverleners: statuut en aansprakelijkheid, Antwerp, Intersentia, 2014, p. 1497, nr. 3096 and A. VIJVERMAN, “Hergebruik van voor eenmalig gebruik

bestemde medisch hulpmiddelen: nood aan een duidelijke regeling”, *T.Gez.* 2008-09, afl. 1, 23.

¹³⁶ Article 10 Product Liability Law.

¹³⁷ Except for contractual clauses who are in conflict with mandatory law and public order law.



cannot, at the same time, claim compensation from the producer based on the non-contractual relationship he has with the producer (engineer). Such combination of a claim based on contractual liability and a claim based on a non-contractual liability, is prohibited in Belgium (on the basis of case-law of the Court of Cassation).¹³⁸

5.6.2.7 Article 1641 Civil Code

According to article 1641 CC the seller is bound by the guarantee covering hidden defects in the item sold which render said item unfit for the use for which it was intended, or which diminish this use to such a degree that the buyer would not have bought said item or would only have paid a lower price for it if the faults had been known. This liability of the seller is a **contractual liability** towards the buyer of the item.

If the patient or a doctor/hospital buys a defective 3D printed medical device, the patient/doctor/hospital will be able to rely on this article 1641 CC towards their respective seller in order to get compensation from this seller for the defective 3D printed medical device. The party having suffered damage will have to prove that the conditions of article 1641 CC are fulfilled:

- a (hidden) **defect**;
- the fact that the (hidden) defect existed **at the moment of sale**;
- the fact that the (hidden) defect made the item (product) **unfit for the use for which it was intended**; and
- the fact that the defect was **sufficiently serious**.
- The party having suffered damage will **not** have to prove any **fault** of the seller (= no fault-liability).¹³⁹ To claim compensation the party having suffered damage will however still have to prove this damage and the causal relationship between the defect and this damage.

In case of a defective 3D printed medical device the patient would thus be able to claim compensation from the doctor or hospital having sold (and implanted) the medical device to the patient. And the doctor or hospital would, in their turn, be able to claim compensation from the producer-seller of the 3D printed medical device from whom they bought the medical device. These claims will of course only result in an effective compensation of the party having suffered damage if all the conditions of article 1641 CC are fulfilled.

5.6.2.8 Medical Accidents Law

With the Medical Accidents Law of 31 March 2010¹⁴⁰ the Belgian legislator created a second pathway (besides common law) for patients who are looking for compensation for the damage they suffered as a result of a medical accident. If the conditions laid down in this Medical Accidents Law are fulfilled patients can be compensated by the Medical Accidents Fund that was created as a result of this Law. New in this Medical Accidents Law is that patients can be compensated for the damage they suffered as a result of a medical accident without even having to prove any liability of e.g. the doctor or the hospital.

In principle all health care acts fall under the scope of the Medical Accidents Law. The Medical Accidents Law should thus in principle also be applicable to damage caused by a health care act during which (defective) products (such as medical devices) were used. However in the Preparatory works of the law it was stipulated that **damage as a result of a defective product used during a health care act does not fall under the scope of the Medical Accidents Law**. The reason given for this exclusion is that the Belgian legislation already contains a no fault liability system for damage caused by defective products, more particularly the Product Liability Law (see section 5.6.2.1).¹⁴¹ It was thus considered as unnecessary to incorporate/put liability resulting from defective products, under the scope of the Medical Accidents

¹³⁸ See the important “Stuwadoors-judgement” of the Court of Cassation, dated 7 December 1973. For a detailed explanation of this “prohibition of coexistence” see: T. VANSWEEVELT and B. WEYTS, *Handboek Buitencontractueel Aansprakelijkheidsrecht*, Antwerp, Intersentia, 2009, p. 97-106.

¹³⁹ A. VIJVERMAN, “Hergebruik van voor eenmalig gebruik bestemde medisch hulpmiddelen: nood aan een duidelijke regeling”, *T.Gez.* 2008-09, iss. 1, 22.

¹⁴⁰ Law of 31 March 2010 concerning the compensation of damage as a result of health care, *B. Off. J.* 2 April 2010 (“Medical Accidents Law”).

¹⁴¹ Report BURGEON, *Doc. Parl.*, Ch., 2009-2010; 2240/006, p. 87.



Law^{142, 143} As software (contrary to the 3D printer, input material and 3D printed medical devices) does not fall under the no fault liability system of the Product Liability Law (software is not considered a product), the damage caused by this software could thus fall under the scope of the Medical Accidents Law. A patient claiming compensation based on this Medical Accidents Law will however still have to prove that the conditions of the Medical Accidents Law are fulfilled.

Despite this, the Medical Accidents Law can be of a certain use for patients suffering damage as a result of e.g. a defective 3D printed implant. In some cases it might be difficult or unclear to define the exact cause of the damage (the damage suffered by the patient could be caused by multiple reasons, one of them being a defective product but there could also be other reasons, such as a fault committed by the treating physician (e.g. a wrong diagnosis/treatment of the patient). In case of such uncertainty the patient can nevertheless submit an application for compensation to the Fund and only if the experts of the Fund would judge that the damage is not caused by a medical accident but by a defective product, the Fund would not compensate the patient but the patient then obviously has an important argument to claim compensation from the producer (based on the Product Liability Law).¹⁴⁴

5.6.2.9 Law on Experiments

It is also relevant to refer to the Law on Experiments¹⁴⁵. The definition of an experiment in this Law is very broad: “every test, study or research executed on the human person, with the objective of the development of knowledge peculiar to the execution of health care professions in the meaning of the royal decree n° 78 of 10 November 1967 concerning the execution of health care professions”¹⁴⁶.

As a consequence experiments with medical devices (such as 3D printed medical devices) do fall under the scope of the Law on Experiments.

According to article 29 of the Law on Experiments the **sponsor** of the experiment is **liable**, even **without fault**, for the damage caused to the participant, and directly or indirectly related to the experiment. To claim compensation from the sponsor the injured patient (or in case of death, his rightful claimants) will thus have to prove:

- the **damage** suffered;
- a direct or indirect **link between the damage and the experiment**.¹⁴⁷

Every contractual limitation of this liability of the sponsor is considered void.

The sponsor is also legally obliged to take an insurance covering this no fault-liability as sponsor of the experiment. Is considered “*sponsor*” in the meaning of the Law on Experiments: “*an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of an experiment*”.¹⁴⁸

If 3D printed medical devices are used as part of an experiment, the patients participating to that experiment could thus, in case of damage (directly or

¹⁴² Damage patients suffer as a result of their participation to an experiment is excluded from the Medical Accidents Law for the same reason; the Law of 7 May 2004 contains a no fault-liability for the sponsor of the experiment.

¹⁴³ T. VANSWEEVELT, “De Wet Medische Ongevallen”, *T.Gez.* 2010-11, iss. 2, 96.

¹⁴⁴ T. VANSWEEVELT, “De Wet Medische Ongevallen”, *T.Gez.* 2010-11, iss. 2, 96.

¹⁴⁵ Law of 7 May 2004 concerning experiments on the human person, *B. Off. J.* 18 May 2004 (“Law on Experiments”).

¹⁴⁶ Article 2, 11° Law on Experiments.

¹⁴⁷ T. VANSWEEVELT, “De wet experimenten op de menselijke persoon: objectieve aansprakelijkheid en verzekering”, *T.Gez.* 2005-06, afl. 1, 22-32; K. WOUTERS, “De foutloze aansprakelijkheid in de Wet van 7 mei 2004 inzake experimenten op de menselijke persoon”, *TBBR* 2010, 156-181; A. VIJVERMAN, “De Wet Experimenten op de menselijke persoon” in T. VANSWEEVELT and F. DEWALLENS (eds.), *Handboek Gezondheidsrecht, II, Rechten van patiënten: van embryo tot lijk*, Antwerp, Intersentia, 2014, 1055-1117.

¹⁴⁸ Article 2, 21° Law on Experiments.



indirectly) related to the experiment, claim compensation from the sponsor of that experiment. This sponsor could e.g. be the company developing and experimenting with a new 3D printed medical device.

5.6.2.10 Liability of the government

It cannot be discussed that also the government can be held liable if the government commits a fault. The **government** has the obligation to **take sufficient quality and safety measures**. These measures can be taken in the form of legislation or regulation, but also, for instance, by providing additional funding (e.g. subsidies) or organizing prevention campaigns. If the government does not take sufficient quality and safety measures, she commits a fault and she can be held liable for the damage caused by this fault.

This possible liability of the government is also applicable to the domain of 3D printing and 3D printed medical devices. As a consequence, the Belgian government is obliged to take sufficient action to guarantee a safe and high-quality use of 3D printed medical devices.

This principle of liability of the government must however be put in perspective. In first instance this “*general standard of care*” implies that the government must be given a sufficient broad margin of appreciation (e.g. for the allocation of scarce resources). If not, one would come too often to the conclusion that the government committed a fault. Secondly, it must be taken into account that the Belgian government did already take important steps to assure quality and safety in the field of medical devices, more particularly by securely implementing the European directives and guidelines concerning medical devices into Belgian law. Finally, it must be noted that it will probably not be easy to prove the causal relationship between the negligence (fault) of the government by not issuing sufficient quality and safety rules on the one hand and the damage caused e.g. by a defective 3D printing process/3D printed medical device on the other hand.¹⁴⁹

5.6.2.11 Criminal liability

Damage caused in the framework of 3D printed medical devices, can lead to civil liability but also to criminal liability.

If the use a defective 3D medical device would cause damage to the patient, this could more particularly be considered **involuntary assault and battery** (art. 418-420 Criminal Code) and thus lead to criminal sanctions.

If a patient starts a procedure based on these articles of the Criminal Code, that patient will have to prove a **fault** was committed by the offender. This fault could be:

- a violation of the data protection rules (e.g. not informing the patient about the transfer of his personal data to the 3D printing company);
- doing a medical intervention without obtaining the patients informed consent (e.g. implanting a 3D printed medical devices without having informed the patient about this);
- a violation of the medical regulation concerning medical devices (e.g. the Law of 15 December 2013 relating to medical devices¹⁵⁰);
- a violation by the doctor of his medical secrecy (article 458 Criminal Code).

If a patient can also prove he suffered damage as a consequence of the involuntary assault and battery, he/she can also claim compensation for the damage he or she suffered.

5.6.2.12 Insurance

With the exception of the experimental context (see section 5.6.2.9), there is no legal obligation in Belgium to provide insurance coverage for one of the above mentioned liabilities.

Off course, the obligation to take an insurance coverage can, and will often, be stipulated in an agreement between parties. If this is the case, parties are obliged to have an insurance coverage for their possible liabilities.

¹⁴⁹ Compare: N. BROECKX, *Orgaantransplantatie. Een juridische analyse*, University of Antwerp, doctoral thesis, 2016, p. 797-798.

¹⁵⁰ B. Off. J. 20 December 2013



The premiums for insurance coverage in the context of 3D printing are likely to be high, as the risks to be insured will be considered relatively unknown by the insurers. In this regard, reference can be made to the insurance the sponsor of an experiment is obliged to take. It is known that the premiums to be paid by the sponsors of experiments are often “*huge*”. There is however an important difference between the insurance coverage for experiments and the insurance coverage in the framework of 3D printing: the sponsor of an experiment is obliged by law to take an insurance for his liability as sponsor, whereas all the other persons involved in the domain of 3D printing are not obliged to do so. Another difference between these two situations is that the insurance for experiments is an insurance which -per definition- has to cover a no-fault liability of the sponsor, whereas the insurance coverage in the framework of 3D printing not necessarily concerns a no-fault liability.

Key points

- **The current Belgian liability system offers a sufficient framework for the patient suffering damage as a result of a 3D printed medical device.**
- **In case of liability claims the Product Liability Law will play a key role. But also the contractual and non-contractual general liability principles can be applied in case of damage caused in the framework of the use of a 3D printed medical device.**
- **3D printed medical devices do not fall under the scope of the Medical Accidents Law.**
- **From a patient protection point of view it is recommended that a contract is concluded between the hospital/doctor and the manufacturer/supplier which determines the responsibilities and liabilities of each party.**

5.6.3 Conclusion

The European and Belgian legislation does not contain any specific liability system for 3D printing. As a consequence, cases of liability caused by 3D printing fall under the common liability rules. These liability rules differ from Member State to Member State; except for the product liability rules which are more or less the same in all European countries as they are all based on the European Product Liability Directive.

The fact that there are no specific liability rules for damage caused by 3D printed devices, does not mean that it will be (unreasonably) difficult for the patient (victim) to claim compensation. In case of product liability claims, the injured person will only have to prove damage, the defect of the product and the causal relationship between the damage and the defect. As the Product Liability Directive is based on the principle of no fault liability, it is made easier for the patient to claim compensation.

It is thus not necessary to amend the European or Belgian legislation in order to provide an appropriate liability system specifically for 3D printing. Only for intangible products, like the design- and the CAD files and the software, it seems that they do not fall under the Product Liability legislation as such. But such defects in the design or the software will probably make the final 3D printed device defective too. This way, the product liability legislation would nevertheless apply. Moreover in these cases an injured person can also claim compensation based on the principles of contractual or non-contractual liability law; only the burden of proof will be heavier.



5.7 Data protection issues associated with 3D printed medical devices

The process of **3D printing patient specific products** evidently requires the electronic processing of reliable patient data. The patient's 2D medical imaging (e.g. CT-scans) first has to be converted to 3D imagery. Along with other useful patient data (e.g. regarding the patient's condition or behaviour), the 3D images can then be edited by physicians (e.g. radiologists or surgeons) and engineers with the use of computer aided design (CAD) software according to the instructions of the healthcare professionals. The CAD-file will eventually be uploaded to the 3D printer that will print a medical device or model that reflects the patient's morphology. All types of information relate to the patient's health status and should thus be considered highly sensitive data which merits adequate privacy protection throughout all the stages of the 3D printing process.

The patient data gathered for the 3D printing process might also be further used for **other purposes besides 3D printing**. Such purposes may include for instance scientific research (e.g. to study the effectiveness of 3D printed medical devices or the efficacy of the 3D printing process), profiling of the patient for (direct) marketing purposes or even taking insurance policy premium decisions. Using the patient's health data for such purposes rather than for his own medical treatment seems to merit an even stricter privacy protection.

In the sections below, we will outline the European and national data protection requirements with regard to the processing of the patient's health data for both 3D printing purposes as well as for the above mentioned secondary purposes.

5.7.1 EU

5.7.1.1 The Personal Data Protection Directive

Currently, the EU regulatory framework on data protection is primarily based on European Directive 95/45/EC on the protection of personal data¹⁵¹ ("PDPD"). All EU member states currently have a data protection regime in place based on the PDPD with a view of its implementation into national law. According to the PDPD, several data protection requirements must be met before personal data can be processed. In order to allow us to determine how the PDPD will apply to data processing with regard to 3D printing of medical devices and models, it will first be examined which data classifies as personal data and who is responsible for compliance with the applicable data protection requirements. Next, the most important data protection requirements will be outlined.

The PDPD only protects the **processing of personal data**. These terms are to be interpreted very broadly. Pursuant to article 2(a) PDPD personal data is defined as:

"any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity."

Recital 26 PDPD further states:

"whereas to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person; whereas the principles of protection shall not apply to data rendered anonymous in such a way that the data subject is no longer identifiable (...)."

¹⁵¹ Directive 95/45/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of

personal data and on the free movement of such data, *Off. J.* 23 November 1995, L281/31.



It is clear that “*personal data*” also encompasses data concerning health, because the PDPD imposes strict requirements for the processing of this type of sensitive data.¹⁵² Although “*data concerning health*” is not defined by the PDPD, the European Court of Justice already considered that this term should be given a wide interpretation so as to include information concerning all aspects, both physical and mental, of the health of an individual.¹⁵³ It is said that even administrative data such as the data of admission to the hospital qualifies as health related data.¹⁵⁴ This wide interpretation has been confirmed by the General Data Protection Regulation (GDPR) which now explicitly defines “*data concerning health*” as such (see section 5.7.1.2.below).

It follows from the definition of personal data that the PDPD even applies to encoded (health related) personal data. Only after anonymization the health related data will no longer be considered personal data. This means that - without anonymization-¹⁵⁵ the following information must for instance be considered personal data:

- patient scans, information on the patient’s condition and behaviour contained within the CAD-file; and
- even the patient-specific model/medical devices themselves, provided they contain information that identifies the patient or that can be reasonably used to identify the patient (e.g. when accompanied by a name tag or a code that refers to the patient).

Pursuant to article 2(b) PDPD personal data is “*processed*” if it is the subject of any (set of) operations whether or not by automatic means (e.g. collection, recording, organization, storage, adaptation, alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise

making available, alignment or combination, blocking, erasure or destruction). This means that *inter alia* the creation of patient scans, the transfer of the scanned data to the manufacturer (inside or outside the hospital – see below), creating the CAD-file¹⁵⁶, the actual 3D printing on the basis of patient related data and even the use of the patient-specific model or medical device may all encompass a form of personal data processing.

Data controller and data processor

To protect the personal data during processing, the PDPD imposes several requirements. The fulfilment of these requirements is mainly the responsibility of the **data controller**. Pursuant to article 2(d) PDPD the controller is defined as:

“the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; (...)”

The capacity to determine the purposes and means of the personal data processing must always be evaluated on a case by case basis, taking into account elements such as the level of factual influence and control by a party, contractual relations and the visibility towards the data subject. It must be kept in mind that there can be more than one controller.¹⁵⁷

As a general rule it can be assumed that the **hospital who gathers the patient data (possibly through the treating physician), possibly 3D prints the medical device or model itself and afterwards uses the device or model (through the treating physician)**, must be considered the **controller**. This follows from the fact that the hospital decides which patient data is processed for which purpose, how the final design of the 3D

¹⁵² Art. 8 PDPD. See more on these requirements below.

¹⁵³ ECJ 6 November 2003, nr. C-101/01, *Bodil Lindqvist*, para. 50.

¹⁵⁴ Working document of the article 29 Data Protection Working Party on the processing of personal data relating to health in electronic health records (HER), <http://ec.europa.eu>, p. 7.

¹⁵⁵ Anonymization means that the personal data should be stripped of sufficient elements (e.g. through generalization or randomization) such that the patient can no longer be identified from that point on (irreversible de-identification). According to recital 26 PDPD the data is sufficiently anonymized if the data

can no longer be used to identify the patient by using “*all the means likely reasonably used*” by either the controller or any other person. It is important to note that the act of anonymization of personal data is still a form of (further) personal data processing and must therefore satisfy with the PDPD requirements. Cf. Opinion 05/2014 of the article 29 Data Protection Working Party on Anonymisation Techniques, <http://ec.europa.eu>, p. 5 and 7.

¹⁵⁶ Provided that this entails the input of personal data.

¹⁵⁷ Opinion 1/2010 of the article 29 Data Protection Working Party on the concepts of “controller” and “processor”, <http://ec.europa.eu>, p.32-33.



printed product should look like and how the 3D printed product is eventually used. Furthermore, the hospital is in direct contact with the data subject (*i.e.* the patient). Even if the same could be said about each individual health care professional involved, preference should nevertheless be given to qualifying as controller the institution as such rather than a specific person within the institution.¹⁵⁸

If a third party manufacturer prints the medical device or model (= outsourcing by the hospital or physician), the patient data will be processed outside the hospital for the creation of the CAD-file and for the actual 3D printing. The question then arises whether this outsourced manufacturer acts as a second controller or only as a “processor” who merely processes the personal data on the hospital’s behalf in the meaning of article 2(e) PDPD. There are enough arguments to say that the **outsource manufacturer** generally will qualify as a mere **processor**. The manufacturer would not process the patient data were it not for his contractual engagement to the hospital.¹⁵⁹ In doing so the manufacturer follows the instructions of the hospital’s healthcare professional in designing the 3D printed device or model. Moreover, the manufacturer does not directly come into contact with the patient. Even if the outsource manufacturer has quite some input on the means of the data processing, it is nevertheless advisable to attach more weight to determining the purposes of the data processing on which the manufacturer does not have any control.¹⁶⁰

Data protection requirements

Health related personal data and thus also personal data related to 3D printing can only be processed on a **legitimate basis**. According to the PDPD, the controller can legitimately process personal data either on the basis of the patient’s informed consent or on one of several other legitimate bases as specifically defined in the PDPD:

- one of the legitimate bases defined in the PDPD for which the controller does not need the patient’s consent is the processing of health related data “*required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy*”.¹⁶¹ This provision can act as a legitimate basis for the processing of the patient’s health related personal data required for the 3D printing of medical devices and models. This is obviously the case for the 3D printing of a medical device that is to be used for the diagnosis or treatment of that patient (*e.g.* an implant or a surgical guide); or for the 3D printing of a patient specific model that is to be used for planning a diagnostic or treatment procedure on that patient. In these cases the patient will not have to consent to the data processing as such.¹⁶²
- for other types of health related data processing, the controller will have to obtain the patient’s explicit informed consent.¹⁶³ This will *e.g.* be the case for the processing of health related data that is not strictly required for the 3D printing process as such or in case of processing health related data of a patient allowing the use of a patient specific model for scientific or educational purposes.

Regardless whether the legitimate basis is consent-based or not, the controller has the **duty to provide certain information** to the patient with regard to the data processing.¹⁶⁴ This duty entails at least the following information:

- the identity of the controller (or his representative);
- the purposes of the processing (*e.g.* the design, the printing and/or the use of 3D printed medical devices or models). As a general rule the

¹⁵⁸ Opinion 1/2010 of the article 29 Data Protection Working Party on the concepts of “controller” and “processor”, <http://ec.europa.eu>, p.32.

¹⁵⁹ Compare: V. HORDERN, “Data Protection Compliance in the Age of Digital Health”, *EJHL* 2016, (248) 254.

¹⁶⁰ Opinion 1/2010 of the article 29 Data Protection Working Party on the concepts of “controller” and “processor”, <http://ec.europa.eu>, p. 13.

¹⁶¹ Art. 8, para. 3 PDPD.

¹⁶² The patient must however still consent to the diagnostic or treatment procedure beforehand. See section 4.3 on patients’ rights.

¹⁶³ Art. 8, para. 2(a) PDPD.

¹⁶⁴ Art. 10 and art. 11 PDPD



personal data can only be collected for a specified, explicit and legitimate purpose and cannot be processed any further in a way that is incompatible with those purposes. No more data should be collected or kept if it is not necessary for these purposes (proportionality principle);¹⁶⁵

- any further information if necessary to guarantee a fair processing in respect of the data subject, such as the (categories of) data recipients (e.g. a third party manufacturer) and the existence of the patient's rights of access and of rectification to/of his personal data.

The controller is however exempt from his information duty when the patient already has all of this information. In case the controller did not himself obtain the data from the data subject (e.g. data obtained from another hospital), then he is also exempt from the information duty if the provision of this information is impossible or requires a disproportionate effort or if the recording/disclosure is expressly laid down by law.

In case of **outsourcing** of 3D printing by the hospital or physician to a 3D manufacturer, the processing of the health related personal data by the manufacturer-data processor must always be governed by a written contract with the hospital-controller.¹⁶⁶ According to the proportionality principle,¹⁶⁷ the hospital or physician can only provide data which is absolutely necessary for the manufacturer to perform its 3D printing tasks (e.g. only encoded data). The data processing contract between the manufacturer and hospital must at least stipulate that:

- the processor shall act only on instructions from the controller. As a general rule neither the processor (including the person's acting under his authority) nor the persons acting under the authority of the controller can process personal data except on instructions from the controller;¹⁶⁸
- the processor will implement appropriate technical and organizational measures to protect data against accidental or unlawful destruction or accidental loss, alteration unauthorized disclosure or access, in

particular for transmission over a network. The hospital can only choose a manufacturer-data processor who provides sufficient guarantees in respect of the technical security measures and organizational measures and must ensure compliance with those measures.¹⁶⁹ Evidently, the controller must implement the appropriate technical and organizational measures for his own data processing as well.¹⁷⁰

Member states must furthermore provide for **liability of the controller** to compensate any damage resulting from an unlawful processing operation or from an act incompatible with the national provisions adopted pursuant the PDPD. The controller may however be (wholly or partly) exempt from this liability if he proves that he is not responsible for the event giving rise to the damage.¹⁷¹ Moreover, member states must lay down **penalties** in case of infringement of the provisions adopted pursuant to the PDPD.¹⁷²

The controller must also **notify the national public supervisory authority** according to the provisions of national law before carrying out any (wholly or partly) automatic (set of) processing operations intended to serve a single purpose or several related purposes (e.g. for the purpose of 3D printing of a medical device or model).¹⁷³

If the patient's personal data is further processed for **other secondary purposes besides 3D printing** without anonymization later on, then the afore-mentioned requirements will apply as well. It must be kept in mind that the controller for this further processing is not necessarily the original controller if the original controller no longer determines the secondary purpose and the means for processing (see the subsection on data controller and data processor above). With regard to the need for a legitimate basis the (new) controller must examine whether the processing for these secondary purposes is already covered by the patient's prior consent. If these purposes are not yet specifically covered by the patient's consent, the following rules will then apply for the further processing of the patient's personal data, including his health related personal data:

¹⁶⁵ Art. 6(b)(c) and (e) PDPD.

¹⁶⁶ Art. 17, para. 3 and 4 PDPD.

¹⁶⁷ Art. 6, sec. 1(c) PDPD.

¹⁶⁸ Art. 16 PDPD.

¹⁶⁹ Art. 17, para. 2 PDPD.

¹⁷⁰ Art. 17, para. 1 PDPD.

¹⁷¹ Art. 23 PDPD.

¹⁷² Art. 24 PDPD.

¹⁷³ Art. 18 PDPD.



- further processing for *scientific research* is considered compatible with the purpose for which the patient data was legitimately obtained (either through consent or any other legitimate basis defined in the PDPD) provided that the EU member state establishes appropriate safeguards¹⁷⁴ and the controller respects the national law that governs the further processing for scientific purposes;
- further processing for *marketing purposes* will normally require a (new) specific informed consent of the patient-data subject, if the patient did not already consent to the processing for marketing purposes when he gave his consent to the processing for 3D printing a medical device or model. The PDPD specifically states that member states must grant each data subject the right to object (on request and free of charge) to the processing of personal data for direct marketing purposes and to inform the data subject of this right¹⁷⁵;
- processing for *insurance purposes* depends on the type of insurance purpose. Processing for purposes of the patient's health insurance can be performed without the patient's consent if this processing is required for "*the management of healthcare services*" which constitutes a PDPD defined legitimate basis.¹⁷⁶ Processing for the performance of a legal insurance policy can also be performed without the patient's consent in so far the processing of health data is "*necessary for the establishment, exercise of defence of legal claims*", which constitutes a PDPD defined legitimate basis as well;¹⁷⁷
- processing for other insurance purposes (e.g. defining the insurance premium albeit for a health or legal insurance or otherwise) will normally require a (new) specific informed consent of the patient-data subject, if the patient did not already consent to the processing for such insurance

purposes when he gave his consent for the processing for 3D printing a medical device or model;¹⁷⁸

- for any insurance it can be argued that the controller must reasonably inform the patient on the possible effects of the data transfer for the insurance policy premium, as this information can be considered "*necessary to guarantee a fair processing in respect of the data subject*".¹⁷⁹

The PDPD requirements apply within the EU. If at any point the patient data is to be **transferred to a country outside the EU** (e.g. 3D printing facilities outside the EU), then this third country must first ensure an adequate level of data protection.¹⁸⁰ There are different ways to guarantee an adequate data protection under the PDPD, e.g. through binding corporate rules,¹⁸¹ through model contractual clauses recognized by the European Commission,¹⁸² under the framework of the EU-US Privacy Shield or following a binding decision of the European Commission that recognizes the third country as a country that provides an adequate level of data protection.¹⁸³ The PDPD also allows the transfer without the assurance of adequate data protection under certain legally defined conditions, such as the patient's unambiguous consent to such transfer or the fact that the transfer is necessary for either the performance of a contract between the patient and the controller or the protection of the patient's vital interests.¹⁸⁴

¹⁷⁴ Art. 6, para. 1(b) and (e) and art. PDPD

¹⁷⁵ Art. 14(b) PDPD.

¹⁷⁶ Recital 34 and art. 8, para. 3 PDPD.

¹⁷⁷ Art. 8, para. 2(e) PDPD.

¹⁷⁸ Art. 8, para. 2(a) PDPD.

¹⁷⁹ Art. 10(c) and 11, para. 1(c) PDPD.

¹⁸⁰ Art. 25 PDPD.

¹⁸¹ These are considered "*adequate safeguards*" within the meaning of art. 26, para. 2 PDPD.

¹⁸² Art. 26, para. 4 PDPD.

¹⁸³ Art. 25, para. 6 PDPD. The European Commission already recognized several countries providing adequate data protection. See: http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm.

¹⁸⁴ Art. 26 PDPD.



Key points

- Medical 3D printing requires the processing of personal data and is therefore subject to the privacy protection offered by the PDPD.
- The hospital will generally qualify as the data controller who is responsible for meeting most of the PDPD requirements. The outsource manufacturer will then qualify as a mere processor. The hospital and the outsource manufacturer must enter into a processing agreement which must contain certain provisions concerning the respective responsibilities of both parties.

The processing of the patient's data for 3D printing purposes is justified according to the PDPD, even without patient consent, as long as the 3D printing is required for the diagnosis or treatment of the patient or for health insurance or legal insurance purposes. The processing for other 3D purposes will normally require the patient's consent. In both cases, the patient is entitled to certain information regarding the data processing.

- The further processing of the patient's data for other purposes than 3D printing medical devices (especially scientific, marketing and insurance purposes) is also subject to the protection offered by the PDPD. This means that 3D printing does not create an additional privacy hazard in case of further processing of the patient data collected for 3D printing purposes.

- A national public supervisory authority must supervise the data processing for 3D printing purposes.
- The transfer of the patient's data to a third country outside the EU (e.g. to 3D printing facilities abroad) normally requires that this country ensures an adequate level of data protection. The assurance of such adequate protection level is however not required in some well defined cases (e.g. patient consent, protection of the patient's vital interests).

5.7.1.2 The General Data Protection Regulation

As of 25 May 2018 the EU regulatory framework on data protection will be governed by the General Data Protection Regulation ("GDPR").¹⁸⁵ The GDPR will have direct effect in the EU member states. It will be discussed below how the GDPR will change the current data protection regimes with specific attention to 3D printing of medical devices.

Like the PDPD, the GDPR only protects **the processing of personal data**. Pursuant to its article 4, 1) and 2) the GDPR defines "*personal data*"¹⁸⁶ and the "*processing*" thereof in the same way as under the PDPD.¹⁸⁷ Unlike the PDPD, the GDPR also provides a specific definition of "*data concerning health*" for which strict processing requirements apply. Pursuant to article 4(15) GDPR it is specified that "*data concerning health*" means:

¹⁸⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, O.J.L. 4-5-2016, L119/1.

¹⁸⁶ Building on recital 26 PDPD, the GDPR further elaborates in its recital 26 when a person is considered "identifiable": "To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the

amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments. The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."

¹⁸⁷ Although the definition of "*personal data*" is slightly modified as it now also explicitly mentions "*location data*" and "*online identifiers*" as possible elements by which a person can be considered identifiable.



“personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.”

In recital 35 GDPR it is further specified that this includes *inter alia*:

“information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person”. According to Directive 2011/24/EU¹⁸⁸ such health care services include the prescription, dispensation and provision of medical devices¹⁸⁹;

“a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples”; and

“any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.”

It is clear from this definition that the GDPR basically interprets “data concerning health” very widely as is already the case under the PDPD. This means that also under the GDPR *e.g.* the creation of patient scans, the transfer of the scanned data to the manufacturer, the use of other patient data such as information on the patient’s condition or behaviour, the creation of the CAD and the actual 3D printing or even the use of certain patient-specific models or medical devices will qualify as health related personal data for which strict processing requirements apply (see section 5.7.1.1.).

Furthermore, the GDPR explicitly expands the strict requirements for processing health related data to the processing of “genetic data” and “biometric data”. These types of data might also be processed in the context

of 3D printing medical devices. The GDPR provides a specific definition of both “genetic data” and “biometric data”:

- in article 4(13) GDPR it is specified that “genetic data” means:
“personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question”;
- in article article 4(14) GDPR it is specified that “biometric data” means:
“personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data.”

Unlike the PDPD, the GDPR also contains specific requirements for “profiling”. Pursuant to art. 4(4) GDPR, “profiling” is defined as “any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person’s performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.” The 3D printing of medical devices might entail such profiling, *e.g.* automatically correcting the CAD based on an assessment of the patient’s health behaviour to determine its effects on the 3D printed medical devices.

Data controller and data processor

Like the PDPD, the GDPR considers the fulfilment of the data protection requirements mainly the responsibility of the **data controller**. Pursuant to article 4, 7) GDPR the controller is defined in the same way as under the PDPD. This means that -as a rule of thumb- the hospital can be considered the controller whereas an outsourced manufacturer will normally qualify as a mere processor (see section 5.7.1.1.).

¹⁸⁸ Directive 2011/24/EU of the European Parliament and the European Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare, OJ. L of 4 April 2011, iss.88/, 45

¹⁸⁹ Art. 3(a) Directive 2011/24/EU.



Data protection requirements

The GDPR greatly strengthens the current processing requirements for (health related) personal data and also adds several new requirements. In general this will lead to a better protection of the data subject (*i.e.* the patient), but also to a more expensive and administrative burdensome data protection regime for the hospital-controllers and even the outsource manufacturer-processors. The most important changes with regard to data processing for 3D printing will be outlined below.

A **legitimate basis** is still required for the processing of health related personal data:

- like under the PDPD, the treatment of the patient is still a legitimate basis that allows the processing of health related data under responsibility of a health care professional with professional secrecy without the patient's consent (see section 5.7.1.1.).¹⁹⁰ The same goes for biometric data that is processed for uniquely identifying the patient;
- the GDPR now also considers the processing of health related data (and biometric data processed for uniquely identifying the patient) legitimate if this is necessary for "*reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy*".¹⁹¹ **This e.g. provides a clear basis to process the patient's personal data for traceability purposes regarding (3D**

printed) medical devices (see section 5.9. below on traceability issues);

- in all other cases the hospital-controller has to obtain the explicit consent of the patient.¹⁹² Under the GDPR the consent requirements are somewhat stricter than under the PDPD. The controller bears the onus of demonstrating that this consent was actually given.¹⁹³

The hospital-controller still has a **duty to provide certain information** to the patient. Under the GDPR this duty is more elaborate as it entails new types of information to be provided,¹⁹⁴ such as contact data of the controller's data protection officer,¹⁹⁵ the legal basis of the processing (*e.g.* consent), the intention to transfer data to a third country or international organization, the (criteria to determine) the period for which the data is stored, the data subject's rights (including his or her right of portability of his or her data allowing him or her to transmit the data to another controller (*e.g.* another hospital), his or her right to lodge a complaint with a supervisory authority, his or her right to withdraw consent (without however affecting the lawfulness of the consent based processing before the withdrawal), information on whether the data is required or not to enter in to a contract (*e.g.* a treatment contract), as well as the existence of profiling¹⁹⁶.

In case of **outsourcing**, the hospital-controller still has to make sure that its relation with the manufacturer-data processor is governed by a written contract on data processing. Under the GDPR, this contract must set out quite some additional aspects when compared to the PDPD,¹⁹⁷ including the subject-matter and duration of the processing, an obligation of confidentiality for the processor's personnel, a more specific obligation to take the necessary safety measures,¹⁹⁸ conditions for engaging another processor,¹⁹⁹ assistance to the controller for complying with the required

¹⁹⁰ Art. 9, para. 2(h) and para. 3 GDPR.

¹⁹¹ Art. 9, para 2, i) GDPR.

¹⁹² Art. 9, para. 2, a) GDPR.

¹⁹³ Art. 4, 11) and art. 7, para. 1 GDPR.

¹⁹⁴ Art. 13 and 14 GDPR.

¹⁹⁵ A data protection officer is basically a person who is responsible for advising on the implementation of the GDPR requirements and for supervising the implementation thereof (*cf.* art. 39 GDPR).

¹⁹⁶ Pursuant to art. 22, para. 1 GDPR, the patient has to right not to be subject to a decision based solely on profiling.

¹⁹⁷ Art. 28, para. 3 GDPR.

¹⁹⁸ *Cf.* art. 32 GDPR.

¹⁹⁹ *Cf.* art. 28, para. 2 GDPR.



technical and organizational safety measures and deletion of the data held by the processor after the end of its services. In case there are two or more joint controllers, they should determine their respective responsibilities for compliance with the obligations under the GDPR in an arrangement between them, although the data subject may exercise his or her rights against each of the controllers irrespective of this arrangement.²⁰⁰

The hospital-controller will also have to perform a **data protection impact assessment** with regard to the processing of health related data and biometric data of patients prior to this processing.²⁰¹

Under the GDPR the **liability** for compensation of any damage resulting from an infringement of the GDPR is further elaborated. The focus not only lies on the liability of the controller but also on the (less extensive) liability of the processor. The data subject can however address both the controller and the processor for compensation of the entire damage if they are both liable with regard to the same processing.²⁰² Moreover, the GDPR provides that the national supervisory authorities can impose significant **administrative fines** in case of infringement of the GDPR. Some of these fines can constitute a percentage of the undertaking's worldwide annual turnover.²⁰³ It is still left up to the EU member states to determine the **penalties** applicable to the infringement of the GDPR.²⁰⁴

Unlike the PDPD, the GDPR no longer requires the controller to notify the supervisory authority for carrying out automatic operations. Instead, the hospital-controller must **maintain a record of processing activities** which contains information such as the controller's contact data, the purposes of the processing and the categories of data, data subjects and recipients. The outsource manufacturer-processor must maintain a similar record of all categories of processing activities.²⁰⁵

With regard to the further processing of the patient's personal data for **other secondary purposes beside 3D printing**, the controller must again examine whether the processing for these purposes is already covered by

the patient's consent. According to the new consent requirements, the patient's consent to processing of personal data for 3D printing will only cover a secondary purpose beside 3D printing if in the initial consent this other purpose was clearly distinguished from the initial 3D printing purpose.²⁰⁶ If the patient did not already give a valid consent for the secondary purpose(s), then similar requirements for further processing of the patient's personal data (including health related data and biometric data) as under the PDPD will apply. The GDPR did however also further elaborate on these requirements:

- in order to facilitate scientific research,²⁰⁷ further processing for *scientific research* is considered compatible with the initial purpose for which the patient data was legitimately obtained (either through consent or any other legitimate basis defined in the GDPR) provided that the conditions of article 89, section 1 are met.²⁰⁸ This provision requires that the further processing for scientific research should not permit the identification of the data subject if the research can be performed this way. Otherwise, the processing for scientific research requires technical and organizational measures to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that the research can be fulfilled in that manner;
- as under the PDPD, the further processing for *marketing purposes* will normally require a(n) (separate) informed consent. The GDPR explicitly states that the data subject has the right to object at any time to the further processing for direct marketing, including profiling for direct marketing. This right must be explicitly brought to the attention of the data subject and be presented clearly and separately from any other information no later than the first communication with the data subject²⁰⁹;

²⁰⁰ Art. 26 GDPR.

²⁰¹ Art. 35, para. 3(b) GDPR.

²⁰² Art. 82 GDPR.

²⁰³ Art. 83 GDPR.

²⁰⁴ Art. 84 GDPR.

²⁰⁵ Art. 30 GDPR.

²⁰⁶ Art. 7, para. 2 GDPR.

²⁰⁷ Recital 157 GDPR.

²⁰⁸ Art. 5, para. 1, b) GDPR.

²⁰⁹ Art. 21, para. 2 to 4 GDPR.



- with regard to the further processing for *insurance purposes*, the requirements do not appear to differ from the current PDPD regime.

The requirements for **transfer of personal data to third countries or even international organisations** is also further elaborated under the GDPR. Such transfer is only allowed under specifically defined conditions such as an adequacy decision of the European Commission, appropriate safeguards or explicit informed consent of the data subject.²¹⁰ These requirements might prove especially important in case of 3D printing as a “*distance sale*” (see section 5.4.2.1.)²¹¹ under the future MDR.

Key points

- **The GDPR does not bring any fundamental changes with regard to either the qualification of patient data collected for 3D printing purposes as personal data or with regard to the qualification of the hospital as the data controller (and the outsource manufacturer as data processor).**
- **The GDPR greatly strengthens the current processing requirements for (health related) personal data and also adds several new requirements (e.g. for “profiling”, a form of data processing that might also take place with regard to the 3D printing of medical devices). In general this will lead to a better protection of the data subject (i.e. the patient), but also to a more expensive and administrative burdensome data protection regime for the hospital-controllers and even the outsourced manufacturer-processors.**

5.7.2 Belgium

5.7.2.1 Current Belgian data protection regime

The current Belgian regime for protecting the privacy of patient's health related personal data is mainly based on the legal obligation of professional secrecy of health care providers²¹² on the one hand and on the Belgian Act of 8 December 1992 on the protection of privacy in relation to the processing of personal data²¹³ (“*Privacy Act*”), as well as the Royal Decree of 13 February 2001²¹⁴ (“*RD 13 February 2001*”) on the other hand.

In short, the obligation of **professional secrecy** prohibits the patient's healthcare provider to release patient data to third parties (e.g. the outsourced manufacturer, non-healthcare professionals or even other healthcare professionals) for 3D printing purposes. The processing (transfer) of this patient data is nevertheless allowed if the processing complies with the requirements of the Privacy Act.²¹⁵

For purposes of implementing the PDPD into Belgian national law, the **Privacy Act** has copied the PDPD's **definitions** of “*processing personal data*” and “*controller*” (see section 5.7.1.1.). This means that -without anonymization- the 2D patient scans, the information on the patient's condition and behaviour, the CAD and the patient specific model/medical devices themselves are also considered personal data under Belgian law. It also means that, as a rule of thumb, the hospital will act as the data controller,²¹⁶ whereas an outsource manufacturer of 3D printed products will act as a mere processor.

Both the Privacy Act and RD 13 February 2001 implement the **data protection requirements** of the PDPD concerning *inter alia* the need for a

²¹⁰ Art. 44 to 49 GDPR.

²¹¹ Art. 6 MDR.

²¹² Art. 458 Penal Code.

²¹³ B. Off. J. 18 March 1993.

²¹⁴ Royal Decree of 13 February 2001 implementing the Act of 8 December 1992 on the protection of privacy in relation to the processing of personal data, B. Off. J. 13 March 2001.

²¹⁵ E. DELBEKE en A. VIJVERMAN, “De uitwisseling van gezondheidsgegevens uit het elektronisch patiëntendossier”, *T. Gez.* 2012-2013, (104) 106 en 109-111.

²¹⁶ See also: T. VANSWEEVELT, “Rechten met betrekking tot het patiëntendossier” in T. VANSWEEVELT en F. DEWALLENS (eds.), *Handboek Gezondheidsrecht. Volume II*, Antwerpen, Intersentia, 2014, (429) 467, where reference is made to the general and final responsibility of the hospital management for hospital activities (art. 16 Hospital Act).



legitimate basis,²¹⁷ the duty to inform the data subject,²¹⁸ the rights of the data subject of access and of rectification to/of his/her data,²¹⁹ the outsourcing to a processor,²²⁰ controller liability²²¹ and notification of the supervising authority²²² (see already section 5.7.1.1.). They have further elaborated these requirements in accordance with the PDPD. The most important Belgian specifications that are relevant for the processing of health related personal data for the purpose of the **3D printing** of medical devices and models are outlined below:

- for any processing of the patient's health related personal data, albeit consent-based or not, the controller must see to it that he (or the processor) precisely describes the function of the persons who have access to this data. He must make a list of the categories of such persons.

The controller must also ensure that these persons are bound by law, articles of association or contract to respect the confidential nature of the data.²²³ This requirement is evidently met with regard to staff members that are bound by the legal duty of professional secrecy²²⁴ (all persons who are a "necessary confidant" according to law, common practice or morals, e.g. physicians, nurses, paramedics and certain administrative personnel).²²⁵ With regard to 3D printing, it can be argued that the technical engineer who is part of the hospital's medical team, is also a necessary confidant and is therefore bound by the duty of professional secrecy. The persons who are bound by this duty can share the confidential patient information between themselves, as long as they each are involved in the patient's treatment, act in the therapeutic interests of the patient and do not share more information than necessary (concept of shared professional secrecy). With regard

to staff members to whom the concept of (shared) professional secrecy does not apply or does not apply with certainty, a contract containing a confidentiality clause is of course very important;

- if the processing of the patient's health related personal data is to be based on the patient's consent (e.g. processing for the purpose of 3D printing of models for educational purposes), then this consent needs to be in writing.²²⁶ In order to obtain a proper informed consent, the controller must also see to it that, apart from the information already mentioned in the PDPD, the patient is additionally informed on the reasons for the processing (e.g. why the data is required for the purpose) and the list of categories of persons who have access to his personal health data;²²⁷
- the controller must also see to it that the patient's health related personal data is processed under the responsibility of a healthcare professional, whether or not this processing is based on the patient's consent. The controller is however exempt from this obligation if the patient has provided his or her specific written consent for processing under the responsibility of non-healthcare professionals (e.g. personnel of an outsourced manufacturer of 3D printed products) or if the processing is necessary for prevention of an imminent danger.²²⁸ Every person who processes the patient data must nevertheless be bound by a duty of confidentiality, as already mentioned;²²⁹
- with regard to the mandatory contract governing the collaboration between the controller and processor, the Privacy Act specifies that this

²¹⁷ Art. 4, 2° and art. 7 Privacy Act.

²¹⁸ Art. 9 Privacy Act.

²¹⁹ Art. 10 and 12 Privacy Act

²²⁰ Art. 16 Privacy Act.

²²¹ Art. 15bis Privacy Act.

²²² Art. 17 Privacy Act.

²²³ Art. 25, 1°, 2° and 3° RD 13 February 2001.

²²⁴ Art. 458 Penal Code.

²²⁵ A. DIERICKX, J. BUELENS and A. VIJVERMAN, "Het recht op de bescherming van de persoonlijke levenssfeer, het medisch beroepsgeheim en de verwerking van persoonsgegevens" in T. VANSWEEVELT en F. DEWALLENS (eds.), *Handboek Gezondheidsrecht. Volume II*, Antwerpen, Intersentia, 2014, (583) 611 et seq.

²²⁶ Art. 7, §2, a) Privacy Act.

²²⁷ Art. 26 RD 13 February 2001.

²²⁸ Art. 7, §4 Privacy Act.

²²⁹ Art. 25, 3° RD 13 February 2001.



contract must also determine the liability of the processor towards the controller in addition the stipulations mentioned in the PDPD;²³⁰

- the Privacy Act further specifies that the Belgian Privacy Commission should be notified by the controller prior to any (wholly or partly) automatic (set of) operations intended to serve a single purpose or several related purposes.²³¹ Each transfer of health related data also requires the authorization of the Sector Committee for Social Security and Healthcare, except in certain legally defined cases.²³² For example, an authorization is not required when the transfer is already authorized by law or decree issued after an advice of the Privacy Commission (e.g. the transfer of data by the controller to a processor under article 16 Privacy Act);
- the data protection requirements are to be complied with on penalty of fines or even confiscation of the data carrier (e.g. a patient specific model or medical device that is not implanted in the patient and in itself contains identifiable information).²³³

With regard to the requirements concerning the further processing of the patient's personal data for **other secondary purposes beside 3D printing**, the following Belgian specifications are also relevant:

- further processing for *scientific research* is allowed under the conditions set forth in the RD 13 February 2001.²³⁴ It states that in principle the further processing for scientific purposes is only allowed after anonymization of the data;

If the intended scientific study is not feasible with anonymous data, then the processing can take place with encoded data, provided that certain conditions are met (e.g. the duty for the original controller to inform the patient on several items including his right to object against the further processing for scientific research). If the study is not feasible even with

encoded data, then the processing can take place with non-encoded data, provided that even stricter conditions are met (e.g. the duty of the original controller to inform the patient on several items and to obtain his explicit informed consent to the processing for scientific purposes). The (original) controller may however be exempt by the Belgian Privacy Commission from his duty to inform the patient on the further scientific use of his encoded or non-encoded data (and to obtain the patient's consent with regard to non-encoded data) if this obligation is impossible (e.g. the patient is deceased) or would require a disproportionate effort;

- with regard to the further processing for *marketing purposes* the Privacy Act specifies that the controller must inform the patient of his right to object against the processing of his data for direct marketing purposes no later than the moment he obtains this data or, if the data is not collected from the data subject, no later than the moment this data is provided to a third party or used on behalf of a third party.²³⁵ In each case the controller must also explicitly ask the patient whether he wants to exercise his right to object against the processing for direct marketing purposes²³⁶;
- with regard to the further processing for *health insurance purposes* the Belgian Privacy Act explicitly considers the processing "*necessary to comply with social security laws*" as a legitimate basis for which no patient consent is required.²³⁷ The Belgian social security concerning the mandatory health insurance itself explicitly states that hospitals, health care professionals and even manufacturers or suppliers of medical devices also have an obligation to provide the inspectors of the Federal Service for Health Insurance and Benefits with all data necessary for their audit²³⁸;

For other insurance policies the general Belgian insurance law states that a physician can only provide statements to the patient himself at

²³⁰ Art. 16, §1, 3° Privacy Act.

²³¹ Art. 17 Privacy Act.

²³² Art. 42, §2, 3° Law of 13 December 2006 on various provisions regarding health, *B. Off. J.* 22 December 2006.

²³³ Art. 37 *et seq.* Privacy Act.

²³⁴ Art. 2 to 24 and art. 28 to 31 RD 13 February 2001.

²³⁵ Art. 9, §1, c) and §2, c) Privacy Act.

²³⁶ Art. 34 and 35 RD 13 February 2001.

²³⁷ Art. 7, §2, c) Privacy Act.

²³⁸ Art. 150 Act of 14 July 1994 on the mandatory insurance for healthcare and benefits, *B. Off. J.* 27 August 1994.



the request of the patient on the patient's health status in so far this is necessary for the conclusion or performance of the insurance policy or, with the patient's informed consent,²³⁹ to the advising physician of the insurance company. This advising physician may not provide the insurance company itself with information that is irrelevant to the insured risk.²⁴⁰

5.7.2.2 Future Belgian data protection regime

As of 25 May 2018 the GDPR will apply directly in Belgium. This will imply that Belgium will have to amend the Privacy Act on certain points, further elaborate certain requirements (e.g. additional conditions for the processing of health related data²⁴¹) or possibly provide for national exemptions to some of the GDPR requirements.²⁴² In the meanwhile, the Belgian Privacy Commission has issued a 13 step roadmap for companies to prepare for the GDPR.²⁴³

Key points

- **The Belgian data protection regime is currently in accordance with the European data protection regime. The requirements of the PDPD have been implemented and further elaborated. These elaborations merely strengthen the privacy protection of the patient and do not appear to present any specific problems with regard to the 3D printing of medical devices.**
- **The Privacy Commission supervises the processing activities concerning personal data, including data processed for 3D printing medical devices.**

5.7.3 Conclusion

There are no specific EU or national data protection rules for the 3D printing of medical devices. The general data protection regime applies. The (non-anonymized) patient data will qualify as 'personal data'. As such, the processing of this data for 3D printing purposes and the further processing of this data for other purposes is subject to strict data protection requirements. As of 25 May 2018, these requirements will be even stricter under the GDPR. The fulfilment of these requirements does not seem to pose any specific issues with regard to the 3D printing of medical devices.

The most important issue is determining who is 'controller' of the data processing for 3D printing purposes. It is the controller who bears the responsibility for meeting most data protection requirements. This is especially important if the hospital outsources the 3D printing to a third party manufacturer. Although this must always be determined on a case-by-case basis, it can be concluded that the hospital will generally qualify as controller. The outsource manufacturer will thus merely act as a 'processor'. This view finds support in Belgium, as well France, the Netherlands, the UK and in the USA (see appendix 3). We have no reason to expect that this will change under the GDPR. To avoid discussion, it is recommended that hospitals and manufacturing companies clearly outline their respective responsibilities in the (data processing) agreement.

²³⁹ T. Vansweevelt and B. Weyts, "Medische informatie" in T. Vansweevelt and B. Weyts (eds.), *Handboek Verzekeringsrecht*, Antwerp, Intersentia, 2016, (412) 417-418.

²⁴⁰ Art. 61 Act of 4 April 2014 on insurances, *B. Off. J.* 30 April 2014.

²⁴¹ Art. 9, para. 4 GDPR.

²⁴² D. DE BOT, "De uitvoering van de algemene verordening gegevensbescherming – enkele bemerkingen bij de Belgische context", *TvW* 2016, afl. 3, (218) 223 et seq.

²⁴³ Can be found at: <https://www.privacycommission.be>.



5.8 Patients' rights issues associated with 3D printed medical devices

Patients' rights are an important aspect of the relationship between the patient on the one hand and the healthcare professionals or health institution on the other hand. This relationship is often characterised by an imbalance, especially in terms of a lack of (medical) knowledge on the patient's end. Patient's rights are generally intended for restoring this imbalance by strengthening the patient's position. It must be examined whether the existing patients' rights are adequate to achieve this goal with regard to the use of 3D printed medical devices as well.

The most important patients' right that is also most relevant here is definitely the **right to free and informed consent**. This widely recognized right allows the patient (or his representative) to choose at any time whether or not to undergo a medical procedure. This protects and promotes the patient's autonomy. In order to attain true autonomy, this right requires that the patient (or his representative) is properly informed before making a choice. The introduction of 3D printed medical devices might present problems with regard to this right.

- There is still a *lack of appropriate and correct evidence* on the effectiveness of most 3D printed medical devices, as the 3D printing of medical devices is a relatively new technology.²⁴⁴ This begs the question whether a sufficient informed consent as to treatment with a 3D printed medical device is still possible and, if so, how this can be achieved. Anyhow, the patient should be informed on the fact that evidence may be lacking and on appropriate existing alternatives to allow an informed choice.
- The manufacturing of patient specific 3D printed medical devices (including medical imaging, design, printing) takes time. In the meanwhile, the patient might change his mind and *withdraw his consent* to treatment (with a 3D printed medical device). Seeing that the medical device is patient specific device, it will normally not be possible to use

the device for another patient. This means that costs have been made for nothing. This begs the question to what extent the patient should pay for these costs.

Of course, the introduction of 3D printed medical devices might present problems with regard to **other patients' rights** as well. For example, 3D printed medical devices are usually based on medical imaging of the patient. Later on, the patient might want to access this imaging (e.g. for liability purposes). This relates to the right to (access to) the patient's medical record. It is important the check for problems with regard to such other rights as well.

5.8.1 EU

5.8.1.1 Informed consent

The EU regulatory framework clearly recognizes a right to informed consent:

- the right to free and informed consent is established as a fundamental right in article 3, sec. 2(a) of the European Charter of Fundamental Rights. This provision merely states that this right should be exercised "*according to the procedures laid down by law*";
- the right to informed consent is further elaborated in European Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.²⁴⁵ This directive applies to the provision of healthcare within the EU and explicitly includes the prescription, dispensation and provision of medical devices (which includes 3D printed medical devices).²⁴⁶ According to Directive 2011/24/EU healthcare providers must provide the patient with relevant information to help make an informed choice, including information on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and they must also provide clear invoices and clear information on prices, as well as information on their authorisation or registration status, their insurance coverage or other

²⁴⁴ H. BAEYENS, C. POUPPEZ, P. SLEIGERS, I. VINCK, F. HULSAERT and M. NEYT, *Towards a guided and phased introduction of high-risk medical devices in Belgium*, Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE), 2005, KCE Reports 249, D/2015/10.273/63, p. 57.

²⁴⁵ Directive 2011/24/EU of the European Parliament and the European Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ. L of 4 April 2011, iss.88/, 45.

²⁴⁶ Art. 3(a) Directive 2011/24/EU.



means of personal or collective protection with regard to professional liability.²⁴⁷ It is up to the member states to implement this right into national law.

It is certainly worth mentioning that Directive 2011/24/EU also promotes the establishment of European reference networks. The objectives of such networks are *inter alia* highly specialized care by exploiting innovations in medical science and health technologies, as well as research and knowledge sharing.²⁴⁸ This might provide a good platform for increasing scientific evidence on 3D printed medical devices. But in practice, the European reference networks are, so far, only aimed at specific diseases rather than devices;

- provided that 3D printed medical devices are custom-made devices, the patient must receive the Annex VIII Statement for 3D printed medical devices of classes IIa, IIb and III (Annex XIII Statement under the MDR).²⁴⁹ This declaration contains the identity of the manufacturer and of the healthcare professional, as well as the specific characteristics of the medical device itself. This declaration however does not contain sufficient information for a proper informed consent (e.g. benefits and risks, alternatives, financial information).²⁵⁰ It is moreover not clear whether this information should be provided to the patient before the intervention or afterwards.

Specifically for (3D printed) implantable medical devices, the MDR additionally requires that in the future the patient is provided with an implant card.²⁵¹ This implant card must contain information for the identification of the implant (e.g. device name, serial number, UDI, name of the manufacturer), as well as information regarding the (safe) use of the implant. The implant card however presents the same problem for informed consent as does the aforementioned EC-conformity declaration for custom-made devices: the information on the card is not

enough for a proper informed consent and the card must only be provided to the patient after implantation;

- in the future, both the MDR and the IVDR will also provide for more elaborated informed consent requirements with regard to clinical investigation/performance studies concerning medical devices (e.g. written informed consent, information on benefits and risks, information on the conditions of the investigation and on applicable damage compensation systems, as well as informed consent procedures for minors, incapacitated subjects and for emergency situations).²⁵²

5.8.1.2 Other patients' rights

Directive 2011/24/EU also contains provisions on other patients' rights, namely the right to quality and safety, the right to complaints procedures and to remedies for harm resulting from healthcare and the right to (access to and copy of) a medical record.²⁵³ Specifically for cross-border care, Directive 2011/24/EU also provides a right to the recognition of a prescription for, amongst others, a medical device coming from another member state.²⁵⁴ These rights do not seem to pose specific problems with regard to 3D printed medical devices.

- **EU law recognizes the right to informed consent but does not provide clear guidance on how to implement this right with regard to innovative devices or techniques such as 3D printing medical devices.**
- **The concept of EU reference networks in Directive 2011/24/EU on the application of patient's rights on cross border care might provide a good platform for increasing knowledge on 3D printed medical devices. This would help to inform patients in the context of obtaining informed consent.**

²⁴⁷ Art. 4, para. 2(b)

²⁴⁸ Art. 12, para. 2(a), (e) and (f) Directive 2011/24/EU.

²⁴⁹ Art. 4, sec. 2 MDD; art. 21, sec. 2 MDR.

²⁵⁰ Cf. H. BAEYENS, C. POUPPEZ, P. SLEGGERS, I. VINCK, F. HULSTAERT and M. NEYT, *Towards a guided and phased introduction of high-risk medical devices in*

Belgium, Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE), 2005, KCE Reports 249, D/2015/10.273/63, p. 66.

²⁵¹ Art. 18 MDR.

²⁵² Art. 63, 64, 65 and 68 MDR; art. 59, 60, 61 and 64 IVDR.

²⁵³ Art. 4, para. 1 and 2 Directive 2011/24/EU.

²⁵⁴ Art. 11, para. 1, sec. 5 and 6 Directive 2011/24/EU.



5.8.2 Belgium

5.8.2.1 Informed consent

In Belgium, the right to free, informed consent is laid down in article 8 of the Patients' Rights Act.²⁵⁵ This right applies to every "intervention" by a qualified healthcare professional.²⁵⁶ This obviously also includes the use of 3D printed medical devices such as implants, prostheses and surgical guides on patients, as well as the imaging procedures for making 3D printed devices and models. Proceeding with an intervention without the patient's prior informed consent constitutes a fault, which could lead to the liability of the healthcare professional for harm resulting from this intervention.

The provision of **information** to the patient prior to the intervention is a crucial aspect of the right to informed consent:

- according to the Patients' Rights Act, the patient must be informed beforehand on the purpose, the nature, the urgency, the duration, the frequency, the relevant contra-indications, side effects and risk related to the intervention, the aftercare, the possible alternatives, the financial consequences, the consequences in case of refusal, the health care professional's authorisation or registration status and liability insurance status, as well as all other relevant clarifications (including legal provisions relating to the intervention if necessary).²⁵⁷ Some of these information categories merit closer attention with regard to interventions with 3D printed medical devices, namely the relevant risks, the possible alternatives and the financial consequences:

- o evidently, the use of 3D printed medical devices can present risks to the patient. Under the Patients' Rights Act, the patient should only be informed on *relevant risks*, i.e. every risk that is relevant for a normal, reasonable patient, taking into account the risk frequency, the seriousness of the risk and the individual patient's characteristics. Therefore, the question rises how to inform the patient when not much is known about these risks. According to the Belgian case law and doctrine, it is still possible to obtain an informed consent in this kind of situation, as long as the healthcare professional is transparent on the lack of knowledge.²⁵⁸ The patient thus has to be informed on the fact that there is scientific uncertainty and has to be informed as far as possible on the (known) relevant risks.²⁵⁹ The greater the uncertainty, the more elaborate the provision of information should be;²⁶⁰
- o a 3D printed medical device will usually be considered an *alternative* to a traditionally manufactured medical device. It is accepted that the healthcare professionals should only inform the patient on the reasonable treatment alternatives, i.e. the (medically indicated) alternatives that entail different risks or chances of success.²⁶¹ This means that the healthcare professionals who plan on using a 3D printed medical device should therefore still inform the patient on such reasonable alternatives, both traditionally manufactured and 3D printed ones, if any;
- o some 3D printed custom-made implants or non-implantable invasive devices will not be reimbursed by the NIHD. In case of 3D printed custom-made implants the reason for non-reimbursement will, as mentioned below, often relate to the lack of evidence on

²⁵⁵ Act of 22 August 2002 on patients' rights, *B. Off. J.* 26 September 2002.

²⁵⁶ Art. 8, §1 Patients' Rights Act.

²⁵⁷ Art. 8, §2, art. 8/1 and art. 8/2 Patients' Rights Act.

²⁵⁸ Cf. Trib. Brussels 21 March 2006, *T. Gez./Rev. Dr. Santé* 2009-10, 137: a physician commits a fault if he misrepresents a scientifically non-validated procedure as a minimal procedure.

²⁵⁹ Compare: I. VRANCKEN, "Jurdische aspecten van het off-label voorschrijven van geneesmiddelen", *T. Gez. /Rev. Dr. Santé* 2015-2016, (197) 206.

²⁶⁰ T. VANSWEEVELT, *De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis*, Antwerpen, Maklu, 1992, nr. 362; H. BAEYENS, C. POUPPEZ, P. SLEGERS, I. VINCK, F. HULSAERT and M. NEYT, *Towards a guided and phased introduction of high-risk medical devices in Belgium*, Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE), 2005, KCE Reports 249, D/2015/10.273/63, p. 57 and 66.

²⁶¹ S. TACK and T. VANSWEEVELT, "Het recht op gezondheidstoestandinformatie en geïnformeerde toestemming" in T. VANSWEEVELT and F. DEWALLENS, *Handboek Gezondheidsrecht. Volume II*, Antwerp, Intersentia, 2014, (331) 368.



safety, quality and effectiveness or a too high price. In some cases the cost for non-reimbursed custom-made implants, can be legally charged to the patient (for more details see chapter 5.10.2.1. on reimbursement). Although the healthcare practitioner may be convinced that the 3D printed device is the best option, patients should be able to make an informed choice. Therefore healthcare professionals are held to inform patients on the costs and the evidence related to different options.

- additional information requirements exist outside the Patients' Rights Act for certain 3D printed medical devices:
 - o like under the MDD and the MDR, the patient must receive the Annex VIII Statement for 3D printed custom-made medical devices of classes IIa, IIb and III (Annex XIII Statement under the MDR).²⁶² Like under the MDR, the Belgian law also requires for (3D printed) medical devices that the patient is provided with an implant card.²⁶³ As already mentioned, the information on this declaration and implant card is however not sufficient for a proper informed consent (see section 5.8.1.1.)²⁶⁴;
 - o in case of 3D printed implants for plastic surgery or other aesthetic medical procedures, the patient must be informed about the name of the implant, its properties (volume, dimensions, quantity) and its manufacturer/importer.²⁶⁵

- o in case of 3D printed medical devices used in the context of an experiment, some specific information requirements for experiments in general apply;²⁶⁶

- the right to informed consent must be distinguished from the right to health status information. Each patient has a right to information on his health status, even without the prospect of an intervention.²⁶⁷ This information also includes the diagnostic results after using a 3D printed diagnostic medical device.
- in general, patient specific 3D printed models can help the health care professional to inform the patient on the intervention.

The patient remains **free to refuse or withdraw his consent** at any time.²⁶⁸ As said already, this is problematic when the production process of a patient specific 3D printed medical device has already started. Although the patient cannot be forced to go through with the procedure, the question does rise whether the patient should pay for the production costs that have already been made. According to Belgian law, it can be argued that the patient should indeed pay these costs if he consented to the production of the 3D printed medical device and was informed on the possible compensation costs and on the other relevant aspects of the use of 3D printed devices. In that case, it is not considered unlawful to ask the patient for compensation if he does not want to continue with the procedure, as long as this compensation is limited to the actual cost.²⁶⁹

²⁶² Art. 8 RD Medical Devices.

²⁶³ Art. 53 Law of 15 December 2013 with regard to medical devices, *B. Off. J.* 20 December 2013; Explanatory memorandum on the bill concerning various provisions with regard to medical devices, *Doc. Parl.* Ch. 2013-2014, nr. 3057/001, p. 42

²⁶⁴ Cf. H. BAEYENS, C. POUPPEZ, P. SLEGGERS, I. VINCK, F. HULSAERT and M. NEYT, *Towards a guided and phased introduction of high-risk medical devices in Belgium*, Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE), 2005, KCE Reports 249, D/2015/10.273/63, p. 66.

²⁶⁵ Art. 18, §1, 3° and 4° Act of 23 May 2013 on the required qualifications to perform non-surgical aesthetic medical procedures and plastic surgery and on advertising and information on such procedures, *B. Off. J.* 2 July 2013.

²⁶⁶ Art. 6 Act of 7 May 2004 on experiments on human beings, *B. Off. J.* 18 May 2004.

²⁶⁷ Art. 7 Patients' Rights Act.

²⁶⁸ Art. 8, §4 Patients' Rights Act.

²⁶⁹ Compare with regard to patients not showing up to an appointment: T. VANSWEEVELT, "Het recht op een honorarium" in T. VANSWEEVELT and F. DEWALLENS, *Handboek Gezondheidsrecht. Volume I*, Antwerp, Intersentia, 2014, (1099) 1105-1106.



5.8.2.2 Other patients' rights

Apart from the right to a free and informed consent, the Patients' Rights Act also provides for a right to qualitative healthcare, a right to free choice of healthcare professional, a right to (access to and copy of) the patient's medical record, a right to privacy (see also section 5.7. more extensively on privacy protection) and a right to file a complaint with the hospital's ombudsfunction about the exercise of his patients' rights.²⁷⁰ The compliance with these patients' rights does not seem to pose any fundamental problems with regard to 3D printed medical devices.

Key points

- **The lack of scientific knowledge on 3D printed medical devices does not make it impossible to inform the patient in order to obtain a valid informed consent. The healthcare professional must however be transparent on this scientific uncertainty. The greater the uncertainty, the more elaborate the provision of information on (known) relevant risks should be.**
- **Healthcare professionals who plan on using 3D printed medical devices should also inform the patient on reasonable alternatives, both traditionally manufactured and 3D printed ones, if any.**
- **It is not unlawful to ask the patient who withdraws his consent in the middle of the 3D printing procedure to compensate the actual costs of this procedure so far, unless the patient was insufficiently informed by the healthcare professional.**

5.8.3 Conclusion

There are no specific EU or national provisions on patients' rights with regard to 3D printing of medical devices. The general patients' rights will apply.

For every healthcare intervention involving a 3D printed medical device, the patient has the right to informed consent. It is clear that the Annex VIII Statement of custom-made 3D printed medical devices (Annex XIII Statement under the MDR) does not contain sufficient information for a duly informed consent. The healthcare professional must inform the patient on aspects such as the relevant risks of the use of 3D printed devices, the reasonable (traditionally manufactured or 3D printed) alternatives and the costs of using 3D printed devices. Although the lack of evidence on the effectiveness and results of 3D printed devices constitutes an obstacle for NIHD reimbursement, it does not necessarily prevent a duly informed consent. It is sufficient that the patient is made aware of the scientific uncertainty. The greater the uncertainty, the more elaborate the provision of information on the known risks should be. A similar view is taken in France, the Netherlands, the UK and the USA (see appendix 3). The concept of reference networks in EU Directive 2011/24/EU and evidence gathering on patient-and process outcomes via the exploitation of existing administrative databases (see 5.10.2) are interesting options to quickly increase the knowledge on 3D printed devices and improve patient information.

Whether the withdrawal of the patient's consent during the 3D printing/manufacturing process requires that the patient repays the costs made, remains a matter of speculation in most countries. In Belgium, there are arguments to accept that the patient should indeed pay these costs if he was duly informed on these financial aspects beforehand. It is therefore recommended that this 'financial risk' for the patient is taken into account when deciding on the reimbursement of 3D printed medical devices.

With regard to other patients' rights we have found no issues specifically relating to 3D printed medical devices.

²⁷⁰ Art. 5, 6, 9, 10 and 11 Patients' Rights Act.



5.9 Traceability issues associated with 3D printed medical devices

Traceability of medical devices can be defined as the ability to trace the history of those medical devices. Ideally, it should be made possible to trace a medical device throughout the entire supply chain, *i.e.* from the moment it is placed on the market until the moment it is used on a patient (or removed). This way, traceability would contribute to patient safety by facilitating market surveillance and materiovigilance (*e.g.* via incident reporting and corrective actions such as product recalls).²⁷¹

A prerequisite for traceability is the possibility of (unique and preferably uniform) identification of a medical device. Identification allows for the medical device to be linked to the relevant supply chain data (*e.g.* the name and address of the manufacturer, distributor, user and patient) and to other medical devices from the same model, series or batch. This can be achieved by a variety of tools (*e.g.* labelling, registers, coding systems, etc.).

There is no doubt that traceability is equally important for 3D printed medical devices as for traditionally manufactured medical devices. Imagine for example a 3D printed orthopaedic implant that has started to degenerate after being implanted in the patient. It is imperative to be able to backtrack the supply chain in order to locate the origin of the problem (implantation, design, input material, etc.) and to identify all other patients whose implant might be affected by the same problem.

In this section, we will therefore examine the current and future EU and national traceability requirements for medical devices with a specific focus on 3D printed medical devices.

5.9.1 EU

5.9.1.1 Current regime on traceability

A common traceability tool is the *labelling* of the medical device. The MDD, IVDD and AIMD require that **all medical devices** are accompanied by a label that contains *inter alia* the name of the manufacturer and the batch code or serial number.²⁷² This labelling information is considered a basic traceability requirement.²⁷³ It is however insufficient in itself for full traceability. This has been made clear by the 2012 PIP breast implant scandal, where it was very difficult to trace the potential victims of leaking breast implants. The label does not contain information on the distributors or the users and there is no requirement for the user to keep the label. Even if the labelling information is displayed on the medical device itself, it might still be impossible to check this information if the device is implanted into the patient's body. For this reason, the European Commission has recommended in 2013 a new way of identifying medical devices, called the "*unique device identification*" system (UDI-system) within the EU (see 5.9.1.2).²⁷⁴

EU guidance also foresees that economic operators are obliged to keep track of the economic operators they supplied their product to or from whom they bought products for a period of 10 years. Patients are not covered by this requirements as they are not considered as economic operators.²⁷⁵

For **custom-made devices** such as most 3D printed medical devices (see section 5.4.1.1), the MDD however already provides for a more efficient traceability tool. Next to the *labelling* requirement, it also required that every custom-made device is made according to a *written prescription* which gives the specific design characteristics for the particular patient and that every custom-made device is accompanied by a *statement* that contains amongst others the name of the manufacturer, data allowing the identification of the

²⁷¹ Cf. Commission Notice, The 'Blue Guide' on the implementation of EU products rules 2016, 2016/C 272/01), *Off. J.* 26 July 2016, C 272/52; Consideration 1 and article 3(d) Commission recommendation 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union, *Off. J.* 9 April 2013, L99/17.

²⁷² Annex I, art. 13.3. MDD; Annex I, art. 8.4. IVDD

²⁷³ The European Commission considers this a basic traceability requirement (Commission Notice, The 'Blue Guide' on the implementation of EU products rules 2016, 2016/C 272/01), *Off. J.* 26 July 2016, C 272/52-54.

²⁷⁴ Commission recommendation 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union, *Off. J.* 9 April 2013, L99/17.

²⁷⁵ 4.2.2.4. of the 'Blue Guide' on the implementation of EU products rules 2016.



device concerned, data that allows the identification of the patient, the name of the healthcare professional and health institution, as well as specific characteristics of the product. The Annex VIII statement requirement however only applies to class IIa, class IIb and class III devices.²⁷⁶ The information must only be kept by the manufacturer for 5 years or (in case of implants) for 15 years and must be made available to the patient. In case of an incident (e.g. defective raw material), national authorities can contact the manufacturer who can check the specificities in the batch record.

Key points

- **The traceability of 3D printed medical devices under the MDD will ultimately depend on the qualification of these devices.**
- **Under the MDD, 3D printed medical devices will usually qualify as custom-made devices. The traceability for such devices generally relies on the labelling, prescription and Annex VIII statement information. The Annex VIII statement must be kept by manufacturer.**
- **For 3D printed medical devices that qualify as standard medical devices, the labelling requirement applies and economic operators are obliged to keep track of the economic operators they supplied their product to or from whom they bought products for a period of 10 years. This is however insufficient to guarantee full traceability (on a patient level).**

5.9.1.2 Future regime on traceability

In response to the 2012 PIP breast implant scandal, the future MDR and IVDR contain several specific provisions to ensure a higher degree of traceability of medical devices. In general, the new regulations require that distributors and importers co-operate with manufacturers and their authorised representatives to achieve an adequate level of medical device

traceability. This must entail identification of the economic operator²⁷⁷ from whom they received the device, as well as the economic operator, health institution or healthcare professional to whom they have supplied the device.²⁷⁸

The MDR and IVDR also contain more specific provisions concerning the required traceability tools. There is only a full application of these specific traceability provisions for **standard medical devices**. The UDI requirements do not apply to custom-made devices. For hospital produced devices no *specific* traceability requirements are foreseen as they are only delivered within the same institution to a patient.

It must be noted that under the MDR and IVDR many 3D printed medical devices might no longer qualify as custom-made devices, but rather as (customizable) standard medical devices (see section 5.4.2.1). This would imply a change in traceability regime for those 3D printed medical devices. As custom-made devices, these 3D printed devices had to be accompanied by the Annex VIII statement, which can be considered an important traceability tool, as it contains information on the manufacturer, physician or health institution and patient. This Annex VIII statement is not required for standard medical devices. So when these 3D printed devices no longer qualify as custom-made devices, the new traceability provisions for standard medical devices will apply instead. It must therefore be examined whether these 'standard' traceability provisions are adequate for **3D printed medical devices**. Apart from the already existing labelling information,²⁷⁹ this new system will mainly rely on the following traceability tools²⁸⁰:

- a Unique Device Identification (UDI) system. The UDI is a unique (numeric or alphabetic) code that will act as a traceability tool by facilitating the identification of medical devices in a uniform way. As already mentioned, identification of the medical device is a prerequisite for the traceability of that device. Logically, the UDI system does not

²⁷⁶ Art. 4, sec. 2 Annex VIII, art. 2.1. and 4 MDD. For class I custom-made devices, the prescription of the health care professional for the manufacturing of the custom-made device could still play a role in the traceability of this device.

²⁷⁷ Under the MDR, an "economic operator" is defined as "a manufacturer, an authorised representative, an importer or a distributor or the person referred

to in Article 22(1) and 22(3)" (art. 2(35) MDR). The healthcare professional or lay person who uses the device is defined as the "user" (art. 2(37) MDR).

²⁷⁸ Art. 25 MDR; art. 22 IVDR.

²⁷⁹ Annex I, art. 23.2. MDR and Annex I, art. 20.2. IVDDR.

²⁸⁰ See Chapter III MDR and IVDR.



apply to custom-made devices because they are already uniquely produced and linked to a specific patient.

The UDI consists out of two parts: the device identifier (UDI-DI) and the product identifier (UDI-PI).²⁸¹ The UDI-DI is a unique (numeric or alphanumeric) code specific to the manufacturer and the device model. The UDI-PI is a (numeric or alphanumeric) code that identifies the unit of device production. Possible UDI-PI's include serial number, lot number, software identification and manufacturing and/or expiry date. Which type of UDI-PI is used, can thus vary according to the specifics of the device. This means that the UDI-PI does not necessarily require a serial or lot number if there is none. For implantable devices, the MDR however always requires a serial or lot number.²⁸² For class III implantable devices, the economic operators and health institutions must also store and keep the UDI (preferably by electronic means) of the devices which they have *supplied or with which they have been supplied*. Member states can expand this requirement for hospitals for other medical devices (than those of class III) with which they have been *supplied*. Furthermore, member states can require that healthcare professionals store and keep the UDI of the devices with which they have *been supplied*.²⁸³

- a registration of the UDI-DI and the core data elements referred to in part B of Annex VI related to the (3D printed) medical device by the manufacturer in the UDI database. The UDI-PI, which contains information on the medical devices itself, will not be registered.
- a registration of the manufacturers of (3D printed) medical devices, their authorised representatives and the importers in an electronic system that will be set up by the European Commission;

- integration of all above mentioned tools in EUDAMED (European Databank on Medical Devices); and
- in case of **an implanted device**, the manufacturer must provide together with the device information allowing identification of the devices (including the device name, serial number, lot number, UDI and the device model) as well as information allowing the identification of the manufacturer (name, address and website). The health institution will be required to make this information available to the patient who has been implanted with the device by a means that allows rapid access to that information (e.g. a website) and by means of an implant card, which is delivered with the device and which contains the identity of the patient.²⁸⁴ Neither the implant card, nor the UDI-PI will be registered in EUDAMED. For 3D printed medical devices that keep their qualification as **custom-made devices**, a different traceability regime is in place that does not include the UDI requirement. Only the traceability tools of the current EU regime apply (identification through labelling, prescription and the Annex XIII statement with traceability information)²⁸⁵ (see section 5.9.1.1.), as well as some of the new requirements, namely:
 - the requirement for implanted devices to provide the patient with an implant card; and
 - the general requirement for distributors and importers to co-operate with manufacturers to achieve an appropriate level of traceability, which applies for custom-made devices as well.²⁸⁶ It remains to be seen how this requirement will be filled in with regard to custom-made devices. The guidelines of supervisory authorities will be of importance here.

²⁸¹ Annex VI, part C MDR.

²⁸² Annex VI, part C, 6.1.2. MDR

²⁸³ Art. 27, sec. 8 and 9 MDR

²⁸⁴ Art. 18 MDR. This requirement does not apply to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates wires, pins, clips and connectors.

²⁸⁵ Art. 10, sec. 5, art. 21, sec. 2 and Annex XIII MDR. However, this information must now be kept for 10 years instead of 5 years (and still for 15 years in case of implants).

²⁸⁶ Art. 25 MDR.



- finally, member states could also require manufacturers of custom-made devices to submit to the competent authority a list of custom-made devices which have been made available in their territory.²⁸⁷

For 3D printed **hospital produced devices**, the MDR does not provide any specific traceability requirements. The MDR only states that the general labelling requirement (see already 5.9.1.1. above) applies to hospital produced devices and that the health institution is required to make publicly available *inter alia* the name and address of the manufacturing health institution and the details necessary to identify the devices produced by the health institution. This appears to be similar to the requirement of mentioning the “*details strictly necessary for a user to identify the device*” on the label,²⁸⁸ which is interpreted as a requirement to indicate the type of device (e.g. cardiac ablation catheter 10 French/20 cm).²⁸⁹ Such “*details*” would of course be insufficient for traceability. Member states may however require that such health institutions submit any further information to the competent authorities.²⁹⁰

- **The traceability of 3D printed medical devices under the MDR will ultimately depend on the qualification and classification of these devices.**
- **Under the MDR, 3D printed medical devices will most likely qualify as (customizable) standard medical devices. In addition to the labelling requirement, such medical devices are to be traced with the help to the new UDI system, the manufacturer and importer registration and the provision of implant cards (for implanted devices).**
- **3D printed devices that still qualify as custom-made devices, are to be traced in a similar way as under the MDD.**

- **3D printed devices that qualify as hospital produced devices, which is a new device category, traceability relies on the labelling and a publicly available statement.**
- **For class III implantable devices, the economic operators and health institutions must also store and keep the UDI of the devices which they have supplied or with which they have been supplied. Member states can expand this requirement for hospitals for other medical devices (than those of class III) with which they have been supplied. Furthermore, member states can require that healthcare professionals store and keep the UDI of the devices with which they have been supplied.**

5.9.2 Belgium

5.9.2.1 Current Belgian regime on traceability

The current Belgian regime on traceability for medical devices is contained in the RD Medical Devices, the RD Active Implantable Medical Devices and RD In-vitro Devices on the one hand and in the Law of 15 December 2013 relating to medical devices²⁹¹ on the other hand. This legal framework implements the traceability tools provided in the MDD, AIMDD and IVDD (see section 5.9.1.1) and provides for some important additional traceability tools as well:

- for **all medical devices (including all 3D printed devices), Belgian distributors or EU distributors that operate in Belgium must register themselves**, as well as the product characteristics (at the time of writing this is to be interpreted as the Belgian category²⁹²) of the medical devices which they distribute to the end user or retailer **with the FAMPH** before distributing these medical devices in Belgium.²⁹³

²⁸⁷ Art. 21, sec. 2 MDR.

²⁸⁸ Art. 13.3. Annex U MDD; art. 23.2 Annex I MDR

²⁸⁹ GHTF/SG1, Label and Instructions for Use for Medical Devices, 16 September 2011, www.imdrf.org.

²⁹⁰ Art. 5, sec. 5 MDR.

²⁹¹ B. Off. J. 20 December 2013

²⁹² Category as meant in Annex XIII of RD Medical Devices.

²⁹³ Art. 50 Law of 15 December 2013. This requirement has come into effect since 17 February 2015 (art. 3 Royal Decree of 3 February 2015 on the



The information that must be registered is to be determined by royal decree. According to the upcoming royal decree, distributors will only have to provide information on their activity and on the EU risk class of their devices. This way, the distributors' registration will aid the FAMPH to identify distributors within the Belgian market and to subsequently perform a risk analysis and plan inspections using a risk-based approach, but will not function as a traceability tool;

- for standard medical devices (which normally do not include 3D printed devices under the current regime) the labelling information can act as a traceability tool.²⁹⁴ As already mentioned, the labelling is insufficient to guarantee full traceability in itself as the label does not contain information on the distributors or users and the users are not required to keep the label. It remains therefore necessary to impose an equally strong traceability tool to the users in both hospitals as private practices. This hiatus is however somewhat compensated by the fact that the FAMPH has provided guidelines on good distribution practices for standard medical devices. These guidelines state that distributors should keep a register that ensures traceability. This register must enable to check the origin and destination of medical devices on the basis of lot numbers, especially for class IIa, class IIb and class III medical devices.²⁹⁵ This constitutes a strong tool for tracing standard medical devices up to the point where they are no longer in the hands of the manufacturer/distributor. Moreover, when distributing medical devices to professionals the distributor is legally obliged to keep record of lot/serial numbers of the distributed medical devices²⁹⁶

Additionally, it can also be mentioned that the Belgian notified bodies recognized for the conformity assessment of (standard) medical devices

must provide their competent authority with the data regarding all CE certificates for medical devices, with the data regarding all class IIa, class IIb and class III medical devices for which they have granted a CE marking and with the data that allows the identification of the manufacturer of these medical devices.²⁹⁷ This information is gathered in EUDAMED II and thus accessible for other competent authorities. This requirement is however also insufficient in itself for traceability throughout the entire supply chain.

- for **custom-made devices** (which includes most 3D printed devices under the current regime) both the labelling information and the Annex VIII statement containing certain traceability information can function as a traceability tool.²⁹⁸

Furthermore, every **manufacturer** that has its registered office in Belgium and places custom-made devices (or class I medical devices) on the market under its own name, is required to **notify the FAMHP** of its name and address, as well as a description of the custom-made devices that are placed on the market²⁹⁹. The text of the law states that this notification should be done for each custom-made device separately,³⁰⁰ which seems to suggest that a description of *each* patient specific (3D printed) device should be provided. The FAMHP however interprets this requirement in a flexible manner by only requesting the manufacturer to send one notification per GMDN code of the devices it puts onto the market (e.g. one notification for "orthopaedic knee devices", but not for each custom-made orthopaedic knee device separately).³⁰¹ Manufacturers with a registered office in another EU member state, must notify the competent authority of that other member state, whereas manufacturers with a registered office outside the EU

implementation of the Act of 15 December 2013 relating to medical devices, *B. Off. J.* 17 February 2015).

²⁹⁴ Annex I, art. 13.3. RD Medical Devices and Annex I, art. 8.4. RD In-vitro Devices.

²⁹⁵ FAMHP, *Guidelines regarding the good distribution practices for distributors of medical devices with a EC-marking*, version of 12 October 2010, <https://www.fagg-afmps.be>.

²⁹⁶ Art. 2, sec. 1 MD of 18 May 2005 on the implementation of article 10bis, §7 of the RD of 18 March 1999 on medical devices, *B. Off. J.* 1 June 2005.

²⁹⁷ Art. 16, §4 RD Medical Devices.

²⁹⁸ Art. 8 and Annex VIII, art. 2.1. and art. 4 RD Medical Devices.

²⁹⁹ https://www.afmps.be/sites/default/files/formulaire_notification_nl_20170105.pdf

³⁰⁰ Art. 10, §1, sec. 1 and 2 RD Medical Devices.

³⁰¹ Personal communication FAMHP



must designate an authorised representative in the EU which must notify the competent authority of the EU member state in which the EU representative is localised. The FAMHP can request the notified information from another member state and *vice versa*.³⁰²

This duty is however insufficient in itself for full traceability, as it does not require the manufacturer to notify the FAMHP of the distribution and use of that device. The FAMHP can nevertheless use the Annex VIII statement, which is not kept centrally on a national level by the FAMHP but only by the manufacturer,³⁰³ to trace each custom-made (3D printed) device individually. As already mentioned, this statement contains the necessary traceability information on the prescribing physician, the hospital and the patient.

- **certain types of (standard or custom-made) medical devices (including 3D printed devices) such as implants, sterile devices or invasive devices**, can under the current distribution regime only be sold or distributed by manufacturers or distributors to other distributors or pharmacists and they can only be received, stored and delivered to patients by pharmacists or (in case of 3D printed dental implants and protheses) by dentists (see section 5.5.2.1). For these types of medical devices, distributors and importers must, under the current regime, also notify to the minister of Public Health (via the FAMHP) *inter alia* their name and coordinates, as well as the categories of the medical devices they distribute/import and the manufacturer thereof.³⁰⁴ Because only the “categories” of devices must be notified it is not necessary to notify each 3D printed custom-made device individually. This requirement is however expected to be replaced by the royal decree which will implement the abovementioned general requirement for distributors to

register themselves, their activities and the risk class of their products with the FAMHP;

- for **implanted medical devices (including 3D printed implants)**, the Belgian legislator has provided a specific traceability regime in reaction to the 2012 PIP breast implant scandal. The healthcare professional who implants, removes or replaces such a device must:
 - o register certain data with the *implant database* of the FAMHP (the Central Implant Register).³⁰⁵ This data contains the information necessary to identify the patient, as well the specific medical device that was implanted in that particular patient. The access to this data is -under strict conditions- limited to healthcare professionals and the FAMHP because such access is a form of personal data processing (*cf.* section 5.7.2.1.). The FAMHP acts as the data controller for this processing.
 - o the healthcare professional must also provide the patient with an *implant card*³⁰⁶ that contains information on the medical device that was implanted in that patient.³⁰⁷ The implant card is intended to be a copy of the information registered in the Central Implant Register of the FAMHP.³⁰⁸ The further provisions on this information, its content and its conditions are to be determined by royal decree.

Although the Central Implant Register is already integrated in and accessible through the eHealth platform, the provisions regarding the implant database and implant card did not yet officially come into effect. It must still be determined by royal decree to which implantable medical devices these traceability requirements apply, taking into account the risk the medical device presents for patients and for public health (*e.g.* hip or knee protheses, cochlear implants).³⁰⁹ This database is not to be

³⁰² Art. 14 MDD and art. 10, §2 and §4 RD Medical Devices.

³⁰³ The FAMHP checks on the spot during inspections whether the manufacturer has kept the required statement.

³⁰⁴ Art. 10*bis*, § 1 RD Medical Devices. See Annex XIII, art. 1 RD Medical Devices for a full list of devices that require such a notification.

³⁰⁵ Art. 51 Law of 15 December 2013.

³⁰⁶ Explanatory memorandum on the bill concerning various provisions with regard to medical devices, *Doc. Parl.* Ch. 2013-2014, nr. 3057/001, p. 42

³⁰⁷ Art. 53 Law of 15 December 2013.

³⁰⁸ Source: <https://www.ehealth.fgov.be/nl/zorgverleners/online-diensten/centraal-traceringregister>

³⁰⁹ Art. 51, §1, sec. 2 Act of 15 December 2013; Explanatory memorandum on the bill concerning various provisions with regard to medical devices, *Doc. Parl.* Ch. 2013-2014, nr. 3057/001, p. 49.



confused with the implant registers that already exist for certain types of implants (e.g. coronary stents, endoprotheses, hip- and knee protheses) under the legal framework for the reimbursement of such implants (QERMID).³¹⁰

The current system for the registration of implants however requires that the implant has an “implant number”, which is the implant’s NIHDI notification number (see section 5.10.2).³¹¹ As custom-made devices (including 3D printed custom-made devices) do not have such a number, this would mean a lack of registration of custom-made implants and a lack of the corresponding implant card. This is problematic as current legislation does not exempt custom-made implants from the registration obligation nor from the obligation to provide an implant card. However, once the UDI system applies, the UDI will be used for the registration of implants. As the MDR does not foresee a UDI code for custom-made devices, custom-made implants will not be included in the traceability register.

The traceability provisions focus at the moment of the redaction of the report only on implants, but it could be considered to expand them to certain non-implantable medical devices by royal decree.³¹² This provides an opportunity to shape these traceability requirements in function of non-implantable (especially high-risk/high-risk) 3D printed medical devices as well.

5.9.2.2 *uture Belgian regime on traceability*

In the future, the MDR and the IVDDR will directly apply in Belgium. It is important to remind that under these future regulations most 3D printed medical devices will probably no longer be considered custom-made devices, but rather standard medical devices.

In order for Belgium to use the **UDI system** for standard medical devices as efficiently as possible, it is recommended that it becomes the only tool for medical device identification (e.g. in registers, such as the Central Implant Tracing register, QERMID, and for linking to patient- and process outcome data such as rehospitalisation, mortality, etc. in the existing administrative databases- see 5.10.2.3). For 3D printed devices that remain custom-made devices under the MDR, the question rises whether Belgium could impose a national UDI requirement as well in order to facilitate the registration of such devices. According to the principle of free movement of medical devices, a member state may not impose additional requirements for the marketing of custom-made devices if they comply with the requirements of the MDR.³¹³ This seems to be particularly true for the UDI requirement with regard to custom-made devices, as it has been explicitly decided in the MDR that the UDI requirement should not apply to custom-made devices.³¹⁴ However, member states are allowed to take any necessary and justified preventive measures regarding a specific category or group of devices (including subjecting them to particular requirements) after they have performed an evaluation which indicates that they present a potential health and safety risk.³¹⁵ So, if Belgium can show that the UDI requirement is necessary to prevent potential risk (e.g. by improving traceability and/or improving knowledge on the risks of custom-made devices through data collection), a national UDI requirement for custom-made devices would be possible. As data gathering on custom-made devices on a national level will

³¹⁰ Pact Medical Technologies (2016) of the current Minister for Social Affairs and Public Health, Mrs. Maggie De Block, p. 22; art. 2 Royal Decree of 25 June 2014 regarding the procedures, terms and conditions for the reimbursement by the mandatory insurance for health care and benefits of the costs of implants and invasive medical devices, *B. Off. J.* 1 July 2014.

³¹¹ Source: https://www.ehealth.fgov.be/sites/default/files/rct_manuel_nl_240414.pdf

³¹² Art. 51, §13, sec. 2 Law of 15 December 2013.

³¹³ Art. 21, sec. 1 and art. 24 MDR.

³¹⁴ Consideration 42 and art. 27 MDR.

³¹⁵ Art. 98 MDR, which also states that the member states must notify these measures to the European Commission, that can decide whether these measures are justified or not.



probably affect only few cases (based on which it is hard to draw conclusions), it will be hard to justify this option.

The MDR explicitly allows Belgium to require the manufacturer to submit to the FAMHP a list of all (types of) custom-made devices (including 3D printed devices) that they have made available in Belgium.³¹⁶

With regard to hospital produced 3D printed devices, the current regime the MDR allows Belgium to require hospitals to submit to the FAMHP any further relevant information on the hospital produced devices that have been manufactured and used on Belgian territory. Currently, the Belgian Law of 15 December 2013 already requires for all medical devices that the distributors of these devices register themselves and their product characteristics with the FAMHP. However, hospitals are not considered as distributors for in house produced medical devices since they do not make a device available on the market. Yet, in the future, hospitals will have to register their activity and the risk class of devices they produce in the portal of the FAMHP.³¹⁷

Apart from the MDR, the FAMHP is currently developing a system of self-surveillance for medical devices. This system requires that all parties involved (e.g. manufacturers, distributors, hospitals, healthcare professionals) provide the FAMHP with information regarding their activities and the risk class of the devices. This information will be used for a risk analysis which will allow the FAMHP to plan its inspections more efficiently using a risk-based approach.³¹⁸ As the information for the FAMHP will be limited to the activity of the distributor and the risk class, this information will be too general to function as a traceability tool. Nevertheless, the FAMHP also intends to accompany this system with (non-binding) guidelines which will go further than the legal information requirements. Economic operators that follow these guidelines will be considered to present a lower risk in light

of the FAMHP inspections. These guidelines will contain guidance regarding traceability.

Key points

- **The traceability of 3D printed medical devices under Belgian law will depend on the qualification and classification of these devices.**
- **Currently, 3D printed devices most likely qualify as custom-made devices. In conformity with the MDD, such devices mainly rely on the Annex VIII statement for traceability. The FAMHP does not require that each custom-made (3D printed) device is notified separately to the FAMHP, although the text of RD 18 March 1999 appears to suggest otherwise.**
- **Under the future MDR, 3D printed (customisable) devices will most likely qualify as standard medical devices. This means that the UDI system applies as the main traceability tool. For purposes of traceability and also outcome data collection, it is recommended that this becomes the sole tool for medical device identification.**

5.9.3 Conclusion

There are no specific EU or national provisions on the traceability of 3D printed medical devices. The general traceability regime applies. This means that the traceability requirements will largely depend on the qualification and classification of the 3D printed device as either a standard medical device or a custom-made device and whether they are class III implantable or on the list of the EC/national provisions or not.

Under the current regime based on the MDD, we concluded that customisable 3D printed devices will most likely qualify as **custom-made devices**. The traceability of customisable and unique custom-made devices

³¹⁶ Art. 21, sec 2 MDR. It appears from the wording of this article that the list of custom-made devices should be a list of each custom-made device separately (*"Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory."*). Seeing that this is however not a MDR requirement, it nevertheless falls within the decisional margin of the

Member States to either require a list of each custom-made device separately or to require a list of each type of custom-made device that has been made available by the manufacturer.

³¹⁷ Personal communication FAMHP.

³¹⁸ Pact Medical Technologies (2016) of the current Minister for Social Affairs and Public Health, Mrs. Maggie De Block, p. 7-8.



will therefore mainly rely on the corresponding Annex VIII Statement, as well as the device labelling and the registration of the manufacturer/distributors with the FAMHP, which supervises the Belgian market. The Annex VIII Statement is especially important because it identifies the manufacturer, hospital and healthcare professional, as well as the patient, and also contains product characteristics. The national Central Implant Register (that at the moment of writing is not implemented yet) is currently not suited for custom-made devices, since they lack a NIHDI notification number. In the future, the Central Implant Register will be based on the UDI number. As the MDR does not foresee a UDI number for custom-made devices, custom-made implants will not be included in the implant register. Either way, this register is currently limited to implants only.

For 3D printed devices that qualify as **standard medical devices** under the current regime, we found that the current regime mainly depends on the labelling requirement and the registration of distributors with the FAMHP and the identification of the economic operators, which is not sufficient for full traceability. There is also the Central Implant Register but this is limited to implants and is at the time of writing the report not operational yet. The current situation is however somewhat attenuated by the FAMHP guidelines, which require that distributors and pharmacists keep a register that contains the origin and destination of the device.

Under the future MDR regime, we concluded that 3D printed devices will likely qualify as (customizable) standard medical devices. This has important consequences for the traceability regime. It means that these 3D printed devices would no longer be able to rely on the Annex XIII Statement (= Annex VIII Statement under the MDD) for traceability purposes. The MDR does provide some new traceability tools for standard medical devices in addition to the existing Belgian regime to strengthen traceability, namely the UDI system and registration in the UDI database.

For 3D printed devices which still qualify as custom-made devices under the future regime, the Annex VIII Statement will still be required. For this, we refer to our conclusion regarding the current regime.

To further improve the traceability of 3D printed medical devices (regardless of their qualification as a standard or custom-made device), it is also advisable that in the future the FAMHP starts paying particular attention to 3D printed devices in its guidelines like the FDA already did in the USA by requiring additional labelling information (e.g. anatomical location and the final design version) for such devices (see appendix 3 section 5.4.2).

5.10 Reimbursement issues associated with 3D printed medical devices

5.10.1 EU

Reimbursement of medical devices (like reimbursement of drugs) is not regulated at EU level. The regulation concerning the **reimbursement of medical devices** is a competence of the **Member States**. The Member States could thus decide at national level which medical devices are reimbursed by the national health insurance and under which conditions.

Cross border healthcare is however regulated at European level. For **cross border health care** a specific European reimbursement system exists within the European Union:

5.10.1.1 Regulation 883/2004/EC319

This Regulation 883/2004/EC is applicable to “*to nationals of a Member State, stateless persons and refugees residing in a Member State who are or have been subject to the legislation of one or more Member States, as well as to the members of their families and to their survivors*”.³²⁰ This Regulation applies to a list of branches of social security.³²¹ Article 20.2 of Regulation 883/2004/EC contains an important principle: “*An insured person who is authorised by the competent institution to go to another Member State with the purpose of receiving the treatment appropriate to his condition shall receive the benefits in kind provided, on behalf of the competent institution, by the institution of the place of stay, in accordance with the provisions of the legislation it applies, as though he were insured under the*

³¹⁹ Regulation 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ.L. 5 July 1971 (“Regulation 883/2004/EC”).

³²⁰ Article 2 Regulation 883/2004/EC.

³²¹ Article 3 Regulation 883/2004/EC.



said legislation.”. This article 20.2 is thus applicable to an insured person travelling to another member state than the member state of residence in order to receive a treatment. Article 33 of Regulation 883/2004/EC stipulates the following concerning prostheses: “An insured person or a member of his family who has had a right to a prosthesis, a major appliance or other substantial benefits in kind recognised by the institution of a Member State, before he became insured under the legislation applied by the institution of another Member State, shall receive such benefits at the expense of the first institution, even if they are awarded after the said person has already become insured under the legislation applied by the second institution. The Administrative Commission shall draw up the list of benefits covered by paragraph 1.”

5.10.1.2 ECJ and Directive 2011/24/EU

Reference should also be made to the jurisprudence of the European Court of Justice³²², that on the basis of the free movement of (health care) services (article 56 TFEU³²³) under certain circumstances provides in a right on reimbursement (based on the rules of the homeland). Meanwhile this jurisprudence has been codified in **Directive 2011/24/EU**³²⁴. For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued. For the definition of a “medical device” Directive 2011/24/EU refers to “a medical

device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC”.³²⁵

Key points

- **Reimbursement is left to the Member States and is not regulated at EU level. Cross-border healthcare, however, is governed by Regulation 883/2004/EC and Directive 2011/24/EU**
- **Regulation 883/2004/EC can apply to an insured person travelling to another Member State other than the Member State of residence in order to receive treatment, and provides for the possibility of substantial benefits in kind to an insured person**
- **Directive 2011/24/EU can provide, under certain circumstances, a right to reimbursement.**

5.10.2 Belgium

5.10.2.1 Reimbursement of implants and medical devices

In the following sections the reimbursement rules for ‘standard’ medical devices and custom-made medical devices will be outlined and applied to 3D printed (custom-made) devices and related services such as the pre-operative planning (see also Figure 14). We use the term “medical device” to refer to the global category of medical devices. When specification is needed, the appropriate terms (implant, (non-)invasive, custom-made, standard (= >> custom-made) are used.

³²² See for example ECJ C-372/04, *Watts v. Bedford Primary Care Trust and Secretary of State for Health*, 2006. See for an overview of this jurisprudence: U. NEERGAARD, “EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of ‘Solidarity’, and ‘Social Europe’”, in J.W. VAN DE GRONDEN *et. al.* (eds.), *Health Care and EU Law*, Den Haag, Asser, 2011, (19), 25-36.

³²³ Treaty on the Functioning of the European Union.

³²⁴ Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, *OJ.L.* 4 April 2011 (“Directive 2011/24/EU”).

³²⁵ Article 3, j Directive 2011/24/EU.



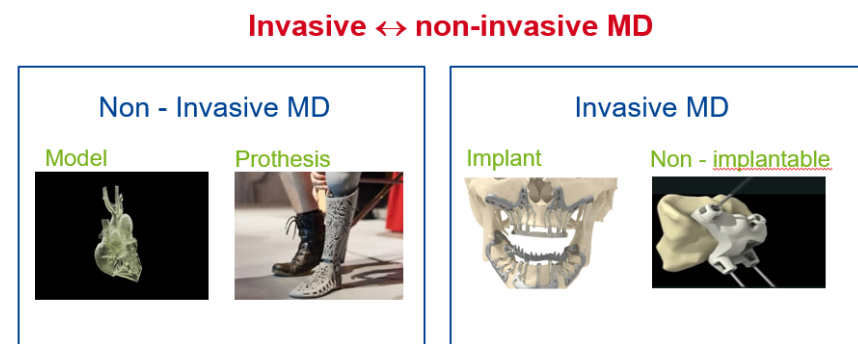
CE label and notification procedure

Before “standard” implantable and some invasive medical devices are eligible for reimbursement, they need to receive a CE label and be notified to the NIHDI.³²⁶ A notification number is assigned by NIHDI to every notified device. This notification does not make an evaluation of the quality of the devices that are available on the market, but offers the compulsory health insurance the possibility to have an overview of all devices that are on the market. This notification to the NIHDI does however not mean that the device is reimbursed by the Belgian health insurance. A device can thus be CE labelled and notified to the NIHDI, without being reimbursed. It is also important to point out that devices that are not notified to the NIHDI, whereas they do fall under the notification obligation, cannot be charged to the patient (see further).³²⁷ Custom-made devices, however, do not fall under the notification obligation (see 5.9.2.1).

Implants and invasive medical devices versus non-invasive medical devices

To give a clear overview of today’s reimbursement system for medical devices in Belgium, a distinction should be made between implants and invasive medical devices on the one hand and the non-invasive medical devices on the other hand (see Figure 10). This distinction is also generally made by the NIHDI.³²⁸

Figure 10 – Invasive medical devices versus non-invasive medical devices



Reimbursement modalities for implants and invasive medical devices (other than osteo-integrated dental implants and implants and invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible)

In the following section the reimbursement modalities for implants and invasive medical devices will be listed according to the (potential) payers of the cost for the respective product (see also Figure 13).

³²⁶ <http://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/verstrekke-van-implantaten/Paginas/implantaten-notificatieprocedure.aspx#.WV0l1E3oupo>; RD of 1 March 2009 related to the notification of implants and invasive medical devices for long term use, executing article 35septies, [...], of the Health Insurance Act coordinated on 14 July 1994, B. Off. J. 26 March 2009

³²⁷ Article 102, 4° of the Hospital Act.

³²⁸ Implants and invasive medical devices: see <http://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/verstrekke-van-implantaten/Paginas/terugbetaling->

<http://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/implantaten.aspx#.WKwEQTgzWpo> (in Dutch) or <http://www.riziv.fgov.be/fr/professionnels/sante/fournisseurs-implants/Pages/remboursement-implants-dispositifs.aspx#.WKxGVjgzWpo>; non-implantable devices (in French): see <http://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/medisch-hulpmiddel-materiaal/medisch-materiaal-apotheek/Paginas/default.aspx#.WKxGMTgzWpo> (in Dutch) or <http://www.inami.fgov.be/fr/themes/cout-remboursement/par-mutualite/dispositif-materiel-medical/materiel-medical-pharmacie/Pages/default.aspx#.WKxGfTgzWpo> (in French).



1. Cost borne by the NIHDI

The RD of 25 June 2014³²⁹ reformed the Belgian reimbursement system of **implants and invasive medical devices**. Since 1 July 2014 the RD of 25 June 2014 should be consulted to know whether a specific implant or invasive medical device is reimbursed by the Belgian health insurance.³³⁰ Osteo-integrated dental implants and implants and invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible do not fall in the scope of this RD (cfr. Infra). The following sections will thus not apply. The notion implants and invasive devices as referred to in the next sections thus exclude these devices.

The compulsory health insurance will only reimburse implants or invasive medical devices used in services that are included on the (nominative) list.

- **Annex I** to the RD of 25 June 2014³³¹ contains the **list** of provided services of reimbursed implants and invasive medical devices, including the applicable reimbursement conditions. The list contains 10 chapters with several subchapters.
- **Annex II** to the RD of 25 June 2014³³² contains the **nominative list** of implants or invasive medical devices that are reimbursed. These **nominative lists** of implants and invasive medical devices are coupled with a service from the **list**. Each device on the nominative list has an identification code. This nominative list of implants and invasive medical devices is divided into subcategories linked to the generic provided service, such as: toric lenses, implantable pumps with adjustable/constant flow rate, neurostimulators pain, cochlear implants, implantable bladder stimulators, pacemakers, etcetera.

There are several reimbursement categories for items on the list³³³:

- Category A: reimbursed based on an individual price when included in the nominative list
- Category B: no lump sum reimbursement, without nominative list
- Category C: no lump sum reimbursement, with nominative list
- Category D: lump sum reimbursement, without nominative list
- Category E: lump sum reimbursement, with nominative list
- Category F: reimbursement based on selling price incl. VAT
- Category G: the restricted clinical application (RCA)³³⁴: The Committee for the Reimbursement of Invasive Medical Devices and Implants (CTIIMH-CRIDMI, “*Commissie Tegemoetkoming Implantaten en Invasieve Medische Hulpmiddelen*”-“*Commission de Remboursements des Implants et des Dispositifs Médicaux Invasifs*”) may propose to reimburse under specific research conditions for a medical device that is part of a technological innovation for which there is uncertainty on the added value compared to existing alternatives.
- Categorie H: the possibility to close a contract³³⁵: the applicant may express his wish to the Minister to negotiate a contract with NIHDI if the CTIIMH-CRIDMI has not been able to formulate a final proposal for a temporary reimbursement in the context of a restricted clinical application.

2. Costs borne by the hospital budget

³²⁹ RD of 25 June 2014 establishing the procedures, terms and conditions of insurance for medical care and benefits in the costs of implants and invasive medical devices, *B. Off. J.* 1 July 2014.

³³⁰ A link to the list and nominative list is available under <http://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/verstrekke rs-van-implantaten/Paginas/terugbetalng-implantaten.aspx#.WV9G5IFLdrQ>

³³¹ Annex I to the RD of 25 June 2014 replaces the previous articles 35 and 35bis of the Nomenclature.

³³² Annex II to the RD of 25 June 2014 replaces the previous “limitative lists”.

³³³ https://www.inami.fgov.be/SiteCollectionDocuments/implants/1-implantaten_nieuwe_wetgeving.pdf

³³⁴ Articles 57 to 65 of the RD of 25 June 2014. See more in detail: KCE report 229, Chapter 8.2.

³³⁵ Articles 66 to 71 of the RD of 25 June 2014. See more in detail: KCE report 229, Chapter 8.2.



Article 102, 4 of the Hospital Act³³⁶ stipulates that the cost of **implants** is borne by the hospital budget (Budget of Financial Means (BFM)) in specific cases, such as³³⁷:

- implants that are subject to the obligation of notification and that have not fulfilled this obligation;
- implants free of obligation of notification that are not eligible for reimbursement (e.g. viscerosynthesis material)
- implants with a retail price (incl. VAT) higher than the ceiling price or the maximum price (= the reimbursement basis plus the safety margin) → total cost of the devices is charged to the BFM
- implants that received a negative decision of the Minister or the Insurance Committee (IC) after a negative evaluation of the CTIIMH-CRIDMI. A negative decision refers to an implant of inferior quality or with harmful side effects. If the reason for a negative decision was the lack of evidence or no available budget to finance the implant, the cost can (in principle) **not** be borne by the hospital but by the patient (cfr. Infra). According to the patient's rights act, patients need to be informed on a.o. the costs of the medical intervention, the lack of evidence and the existence of (reimbursed) alternatives so that an informed decision can be taken.³³⁸

For the 4 listed categories of **implants** the costs can thus not be charged to the patient. Furthermore no costs can be charged to the patient in case of a lump sum payment by the compulsory health insurance. The amount exceeding the lump sum will be charged to the BFM.

Non-reimbursed invasive devices are charged to the hospital.

3. Costs of **implants** borne by the patient

The costs of implants that are not on the list for one of the following reasons *can* be borne by the patient:

- no request for reimbursement is submitted;
- a request for reimbursement is submitted and positively evaluated, but the decision of reimbursement by the compulsory health insurance is not yet in force;
- a request for reimbursement is submitted, but a negative decision was given for the following reasons (cfr. supra):
 - o evidence is currently lacking
 - o there is no budget
 - o the requested price is considered to be too high (according to the added value)

Procedure for reimbursement of implants and invasive medical devices (Other than osteo-integrated dental implants and implants and invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible)

Title III of the RD of 25 June 2014 describes the procedure to be followed for a request to list, amend or remove an implant or invasive medical device for long-term use from the **list**.³³⁹ After receiving a CE-label and notification (not for custom-made devices, see 5.9.2.1), the applicant can submit an application for reimbursement to the CTIIMH-CRIDMI (see Figure 11).³⁴⁰ Not only the manufacturer but the Minister of Social Affairs or the CTIIMH-CRIDMI as well³⁴¹ can initiate the application for listing or amending or removing an implant or invasive medical device from the list³⁴². A request for reimbursement for an implant or invasive medical device of class 1 (medical devices with added value compared to existing alternatives) or subclass 2a (medical device without added value and equivalent to existing

³³⁶ Hospital Act of 10 July 2007, B. Off. J. 7 November 2008

³³⁷ The cost of tissue adhesives, anti-adhesives, hemostatic products, which are not the subject of reimbursement by the NIHD are also on charge of the hospital.

³³⁸ Article 8 §2 Patient's Rights Act of 22 August 2002, B.S./M.B. 26 September 2002

³³⁹ Title III of the RD of 25 June 2014.

³⁴⁰ For some implants registration in Qermid is required to be eligible for reimbursement.

³⁴¹ If a manufacturer omits to apply for reimbursement whereas the CTIIMH-CRIDMI is aware of the fact that evidence is available.

³⁴² Article 14 RD of 25 June 2014



alternatives) must e.g. include, amongst others, (the) notification number(s) (not for custom-made), CE certificate, a scientific justification for the reimbursement request, epidemiological data, clinical and health economic studies (only for class 1), as well as price information. The required type of study or study design is not specified in law. The evaluation of the reimbursement application is done by the CTIIMH-CRIDMI. The evaluation criteria are the therapeutic value of the medical device, the individual price and the reimbursement basis, the value of the medical device in the medical practice according to the therapeutic and social needs, the budgetary impact and the cost-effectiveness.³⁴³

The CTIIMH-CRIDMI is composed of³⁴⁴:

- Members (21) (+ replacing members (21)) with a voting right: experts from Belgian universities (7 (+7)), sickness funds (8 (+8)), hospital pharmacists (3 (+3)) and physicians (3 (+3)) representing the professional associations of physicians and pharmacists;
- members (+ replacing members) without a voting right: hospital administrators (2 (+2)), manufacturers/importers/distributors (BeMedTech) (1 (+1)), representatives from the Ministries social affairs, public health, and budget (3 (+3)) and a representative from the NIHDI Service for Medical Evaluation and Control (DGEC-SECM) (1 (+1)).³⁴⁵

If a firm submits a reimbursement request for an implant or a medical device for long term use of class 1 or 2a, the CTIIMH-CRIDMI drafts a proposal related to the class, the provided service and the reimbursement modalities within 180 days (taken into account possible suspension periods) following the eligibility of the request form (see Figure 12). If the proposal of the CTIIMH-CRIDMI does not diverge from the applicant's request, the motivated proposal gets a definitive character. If the proposal of the CTIIMH-CRIDMI deviates from the applicant's initial request, a temporary motivated proposal open for reaction of the applicant, is drafted before the final motivated proposal is drawn up. The Inspector of Finances advises on the budgetary impact. If the Minister of Budget approves this advice, then the Minister of Social Affairs and Public Health takes the final decision. If a request for submission on the list comes from the Minister or the CTIIMH-CRIDMI, no deadlines are defined in law.³⁴⁶ One or more internal or external experts evaluate the request for submission and draft a motivated proposal. If the definitive motivated proposal, including a proposal on the class, the provided service and the reimbursement modalities, is approved by the Commission, it is sent to the Minister of Social Affairs and Public Health. The Minister takes the final decision after advice of the inspector of Finances and approval of the Minister of Budget. For some implants or invasive devices that are included in the list, the CTIIMH-CRIDMI can request that reimbursement in individual dossiers can only take place after a case by case control/assessment of the reimbursement modalities by the College Physicians-Directors (CPD). This College is an organ of the NIHDI, composed of physicians of the sickness funds and physicians of the NIHDI.³⁴⁷ The same College is also the decision-making organ of the Special Solidarity Fund (cfr. *infra*). The procedures for the restricted clinical application and contracts are described in respectively art. 57-65 and 66-71 of the RD of 25 June 2014.

³⁴³ Art. 17 RD of 25 June 2014

³⁴⁴ Article 29^{ter} of the NIDHI-Law.

³⁴⁵ Article 122 sexdecies of the RD of 3 July 1996. For a more detailed overview of the reimbursement in Belgium of implants and invasive medical devices, we also refer to KCE report 229, Chapter 8.2. A.o., this chapter describes the procedure and terms for a reimbursement request, the restricted clinical

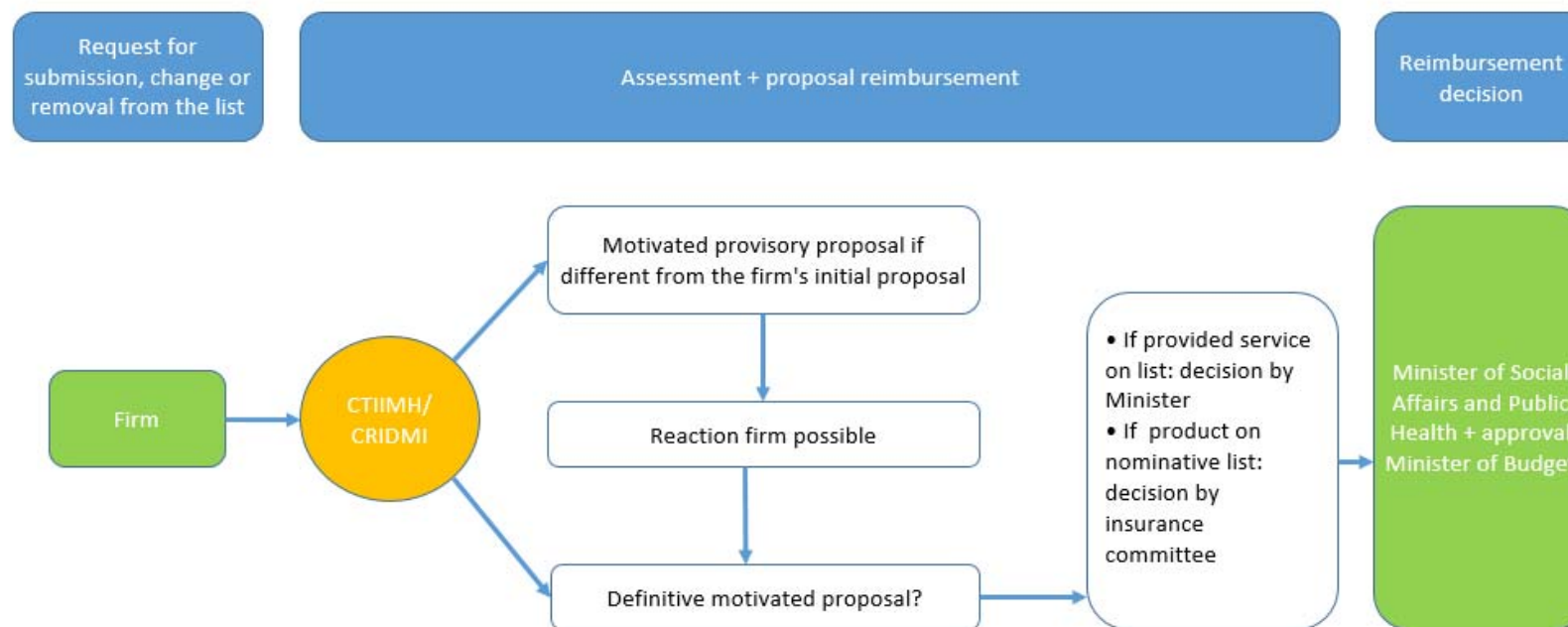
application and the possibility for the applicant to close a contract with RIZIV/INAMI. In the latter two cases, the reimbursement decision can be linked to specific research conditions.

³⁴⁶ Title III, Chapter III of the RD of 25 June 2014

³⁴⁷ Art. 107 RD executing the Health Insurance Act coordinated on 14 July 1994, B. Off. J. 31 July 1996.



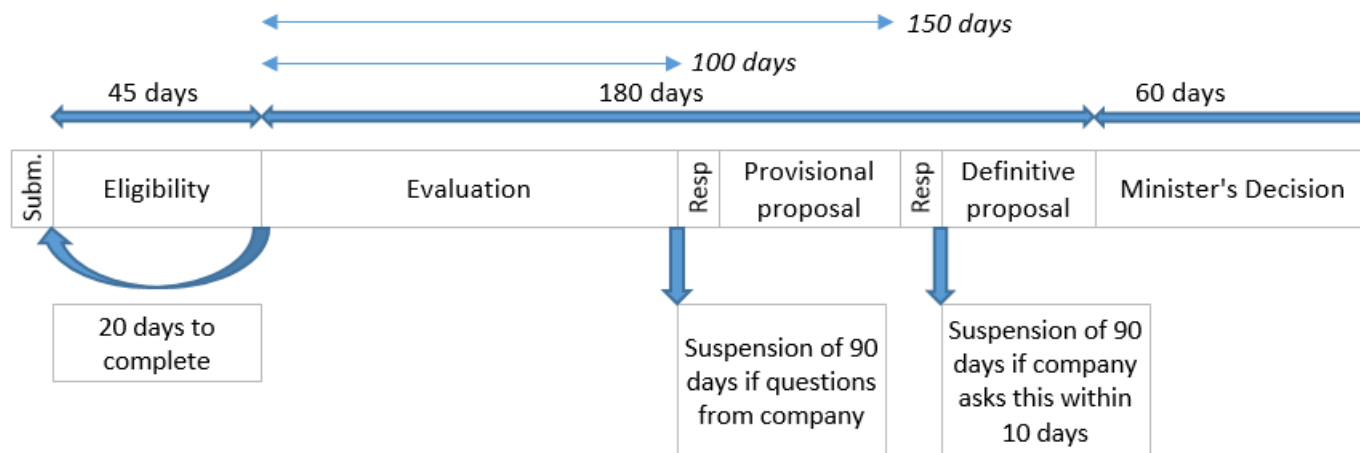
Figure 11 – Procedure for submission to (=reimbursement), amendment of- or removal from the list – request from the firm (*)



(*) The Minister of Social Affairs or the CTIIMH-CRIDMI as well can initiate the application for listing or amending or removing and implant or invasive medical device from the list



Figure 12 – Deadlines for the procedure for submission to- (=reimbursement), amendment of - or removal from the list



*The figure does not include the procedures for restricted clinical application or contracts. Subm. = submission; Resp. = response.

The RD of 25 June 2014 (Title IV) also describes the procedure to be followed for an application for listing, modification and deletion by the applicant concerning **the nominative lists** (see Figure 13).³⁴⁸ Such request form for the CTIIMH-CRIDMI has to include, amongst others, (the

notification number(s), conformity statement/CE certificate, a motivated declaration that the device is in conformity with the service mentioned in the list and that **sufficient data is available confirming the safety of the medical device**, information about the price, as well as the user manual.³⁴⁹

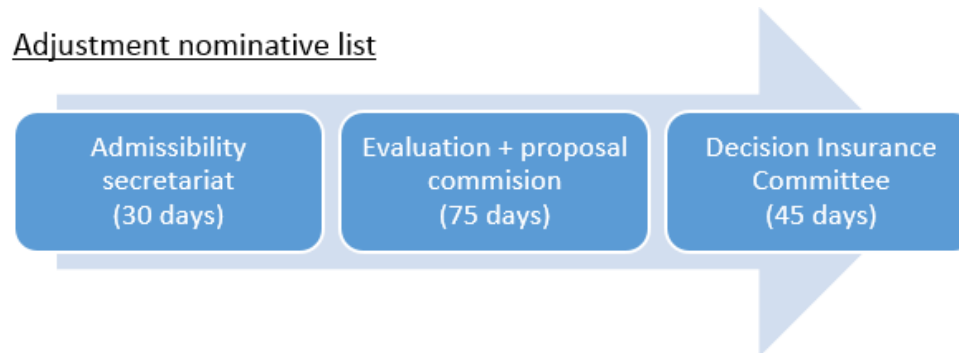
³⁴⁸ Title IV of the RD of 25 June 2014.

³⁴⁹ Article 145 of the RD of 25 June 2014.



Figure 13 – Deadlines for the procedure for submission to- (=reimbursement), amendment of - or removal from the nominative list

Adjustment nominative list



Reimbursement of osteo-integrated dental implants and implants and invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible

- Osteo-integrated dental implants.

Osteo-integrated dental implants and/or replacements of the bone in patients with a functional and psycho-social handicap due to a mutilation of the bone after a trauma, a resection of a tumour or hereditary malformation are eligible for reimbursement via the nomenclature code 312756-312760. Requests for reimbursement with a detailed justification and an evaluation of the costs of the implant need to be addressed to the CPD, via the patient's sickness fund. The reimbursement covers the surgical intervention and part of the costs of the material.

- Some dental implants in the lower jaw for persons older than 70.

Other dental implants are only eligible for reimbursement under very strict conditions for persons older than 70 years old (art. 5 of the nomenclature³⁵⁰). The respective dental implants can be reimbursed only once via the nomenclature codes 308512-308523 and 308534-308545 if the conditions of art. 6 §5bis of the nomenclature³⁵¹ are fulfilled.

- Invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible

Reimbursement for invasive facial or buccal medical devices which are at least partially intrabuccally or extrabuccally visible can be granted via the nomenclature code 317295- 317306 after approval of the Dental Technical Council approves based on a detailed justification and an evaluation of the costs of the device. At the time of writing the report, several reimbursement requests have been introduced for 3D study prints for obturators, but these have been refused by the Dental Technical Council.

³⁵⁰ http://www.inami.fgov.be/SiteCollectionDocuments/nomenclatuurart05_20161201_01.pdf

³⁵¹ http://www.inami.fgov.be/SiteCollectionDocuments/nomenclatuurart06_20161201_01.pdf



Reimbursement modalities for non-invasive medical devices

Depending on the category, non-invasive medical devices are submitted to different reimbursement arrangements. The Royal Decree of 24 October 2002³⁵² regulates the reimbursement of the following categories of non-invasive medical devices:

- solutions for bladder irrigation;
- care material: hairprostheses, oxygen concentrators, pumps and cassettes for medicines, plaster cast and other plaster material, etcetera;
- diagnostic devices: blood pressure monitors, blood glucose meters, etcetera;
- sterile insulin syringe;
- probes for “*autosondage*” at home.

The decision on the submission to-, the modification of- or removal of the list includes a decision on the reimbursement basis, the reimbursement conditions, and the reimbursement category. Hereto an evaluation of the following criteria is done by the Technical Council for diagnostic devices and care material:

1. the value of the device
2. the price of the device and the reimbursement basis proposed by the applicant
3. the importance of the device in medical practice
4. the budgetary impact for health insurance

5. the cost-effectiveness.

The device is included in the list after a positive evaluation by the Technical Council of the quality of the device. The Technical Council refers to existing national or international quality norms or drafts its own norm if there are no existing norms. Other norms can be accepted if the applicant can prove that the quality standards he uses, are equivalent to the quality standards set by the Technical Council. The procedure for reimbursement is described in article 8 et seq. of the Royal Decree of 24 October 2002.

If devices of the former listed categories of non-invasive medical devices are not reimbursed, they are charged to the hospital

Chapter IV of the Belgian Nomenclature³⁵³ (a coded list with medical services that are reimbursed by the compulsory health insurance) regulates the reimbursement of glasses and other ocular prostheses (art. 30 nomenclature), hearing aids (art. 31 nomenclature), mobility aids³⁵⁴ (art. 28 § 8 nomenclature), bandages (art. 27 of the nomenclature), orthoses (art. 29 nomenclature) and external prostheses. The reimbursement conditions differ according to the categories of devices and are managed by a Convention Commission of the respective sector (=organ negotiating reimbursement issues of the respective device category with the NIHDI). In general, the respective devices are eligible for reimbursement if delivered by a recognised provider and on prescription by a physician (general practitioner or in some cases specialist. Some devices (stoma and incontinence material, elastic compressions and other therapeutic stockings, breast prostheses, arm corselets for lymphedema, mobility aids, such as wheelchairs...) are included in limitative lists for reimbursement. Furthermore, the reimbursement of some devices necessitates the approval of the advising physician of the sickness fund (e.g. replacement of custom-

³⁵² Royal Decree of 24 October 2002 setting the procedures, terms and conditions for reimbursement by the health insurance of the services referred to in art. 34, 1st section, 20° of the health insurance act, coordinated on 14 July 1994, B. Off. J. 20 November 2002

³⁵³ http://www.riziv.fgov.be/nl/nomenclatuur/nomen/Paginas/default.aspx#Hoofdstuk_IX_-_Implantaten

³⁵⁴ The competence for mobility aids has been transferred to the defederated entities due to the 6th state reform but at the time of writing the Technical Council for Wheelchairs and the Convention Commission of bandagists are still managing this category.



made orthoses due to anatomic changes) or of the College physicians-directors of the NIHDI (e.g custom-made mobility aids).

Non reimbursed glasses and other ocular prostheses, hearing aids, orthoses and other prostheses are charged to the patient (art. 102, 2°, d) Hospital Act).

5.10.2.2 Current reimbursement of 3D printing/3D printed medical devices, difficulties and options for the future

General rules apply

There are no specific rules for the reimbursement of 3D printing/3D printed medical devices (see overview Figure 14). As explained above (see 5.4.1), the rule of thumb under the MDD is that 3D printed medical devices (= output) qualify as “*custom-made devices*”. Yet, this does not exclude that some 3D printed devices are classified by firms as standard devices, bear a CE mark and are billed under a reimbursement label of a “standard” device that does not specify the mode of fabrication. As such these 3D printed medical devices are not reimbursed differently than the alternatives fabricated via traditional ways. It is thus impossible for the NIHDI to trace the global categories of “standard” 3D printed products in the billing data as there is no differentiation according to the fabrication mode. However, just like other –non-3D printed– devices, individual “standard” 3D printed devices that are submitted to notification can be traced based via the notification number.³⁵⁵

In the following section we will focus on the reimbursement of medical devices that are (under the MDD) classified as 3D printed custom-made medical devices. As mentioned above 3D printed custom-made medical devices do not need to bear a CE label and they do not need to be notified at the NIHDI. This does, however, not prevent them from being reimbursed under the Belgian health insurance system. If the producers of the invasive

medical devices/implants used/generated in the framework of 3D printing follow the procedures as stipulated in the RD of 25 June 2014, and finally receive a positive decision from the CTIMH-CRIDMI, these devices can be reimbursed, just like all other non-3D printed invasive medical devices/implants. This also counts for the non-invasive medical devices (cfr. supra). The general principles and conditions for reimbursement of medical devices are thus also fully applicable to 3D printed custom-made medical devices. In the following sections, however, we will **focus on 3D printed custom-made implants and invasive medical devices** as at the time of writing the report, these are the categories for which reimbursement was regularly requested and several questions raise.

In theory, 3D printed custom-made *implants and invasive* medical devices can be reimbursed in any reimbursement category (category A-H: cfr. supra). There are not always clear decision criteria to decide in which reimbursement category invasive devices/implants should be included, but there are some general observations:

- Nominative list versus no nominative list

Nominative lists are used for a) all active implants, b) when there is a need for additional guarantees on the quality of the medical device or c) when there is a need for more control on the invoicing.³⁵⁶ Whereas the description of reimbursed services on the list is rather generic and it is (most of the time) to the hospital pharmacist to interpret whether the service can be billed under that particular category, items on the nominative list do not allow any interpretation. This allows a stricter follow-up by the NIHDI, for instance to control the correct invoicing of a device, particularly for more complex and expensive devices. For devices that are on a nominative list, a request for reimbursement needs to be introduced for each individual device.

- Lump sum versus maximum price

³⁵⁵ RD of 1 March 2009 implementing article 35septies, [...], of the Compulsory Health insurance law, coordinated on 14 July 1994, related to the notification of implants and invasive medical devices for longterm use, B. Off. J. 26 March 2009

³⁵⁶ Art. 11 Medical devices Act of 15 December 2013, B. Off. J. 20 December 2013



For categories where the reimbursement is fixed at a lump sum, it is up to the hospital to negotiate with the manufacturer to buy the product for (max.) the lump sum. If the price of the device exceeds, because the firm considers that the lump sum does not cover the real costs, the hospital will need to bear the amount exceeding the lump sum. In practice the lump sum will be negotiated by the sickness funds and the hospitals pharmacists (in the CTIIMH-CRIDMI). If a maximum price is set, manufacturers will be put under pressure to sell the product under or at the maximum price. If the price exceeds the maximum price, the total price of the product needs to be borne by the hospital budget. In practice, it is often difficult for hospitals to know whether different devices produced by different firms (at different prices) exist for the same indication, which may hamper negotiation or an informed choice for a particular product. There is a list of manufacturers' names and addresses and their products available at the FAMHP, but unfortunately this list is not publicly available. Moreover, the FAMPH only requests the manufacturer to provide a general description of the devices it puts onto the market (e.g. "orthopaedic devices") (see 5.9.2.1).

- Case-by-case assessment for individual dossiers

For some custom-made devices that are included in the list, the CTIIMH/CRIDMI can decide that reimbursement of a device can only take place after a case-by-case assessment by the College Physicians-Directors of the NIHDI (e.g. customized joint prostheses). The reimbursement decision is taken after the intervention has taken place. For custom-made prosthesis, however, the advice on the eligibility for reimbursement can be submitted before the intervention has taken place. A recurring condition for reimbursement of custom-made devices in the case-by-case assessment, is the proof that the use of a "standard" implant was not possible. In the example of the "customized joint replacing implant" (nomenclature number 167716-167720), the treating physician needs to demonstrate in a medical

report that in the particular case the implantation of a 'traditional' joint prosthesis was not the appropriate. There seems to be a lot of ill communication between physicians and the College on this point and there are no clear criteria that determine when standard implants are insufficient.³⁵⁷ According to a 2017 report of "Kom op tegen Kanker", this assessment should be a balanced evaluation based on, on the one hand general guidelines and on the other hand case-by-case analysis. Furthermore a fast, transparent procedure preceding the medical intervention, in presence of the physician (instead of a writing procedure), reinforcement of the College Physicians-Directors with experts in the particular domain is argued for.

It should be noted that in theory, in limited cases, (3D printed) custom-made devices for which no specific reimbursement is foreseen could also be billed under a "generic" reimbursement code that is used for a similar standard device. If a custom-made device is used for a service in category I. (=implantable) D. (=lump sum reimbursement, without nominative list) chapter I (= pneumatology and respiratory system³⁵⁸) or category II. (=invasive) D., all chapters, for which a notification code is obligatory (= services with value « 1 » or « 2 » in the zone "notificationZone55" of the reference file "LIST")³⁵⁹, the pseudo notification code needs to be filled out in that zone. However, this is not a very good commercial option for hospitals as the custom-made 3D printed device will probably be more expensive than the reimbursed amount for the standard alternative and the amount exceeding the lump sum needs to be borne by the hospital. Hospitals may thus opt not to apply this possibility and charge the respective devices to the patient (see 5.10.2.3).

³⁵⁷ Kom op tegen Kanker, De kosten van implantaten en medisch materiaal, artsenhonoraria, bijvoeding, verzorgingsmateriaal en thuiszorg, maart 2017, http://www.komoptegenkanker.be/sites/kotk/files/de_kosten_van_implantaten_def_pdf_0.pdf

³⁵⁸ See for instance: self-expandable metal bronchial stent (nomenclature number 162514 – 162525) <http://ondpanon.riziv.fgov.be/IRREQPublic/nl/>

³⁵⁹ See for instance: tracheostomy tube without distal or proximal extension (nomenclature number 153930)

**Table 9 – Overview of the currently reimbursed custom-made 3D printed medical devices**

152751-152762 / B.6. Cranioplasty/Reimbursement basis: 6.000,00 €; Reimbursement category: I.D a

Custom-made skull bone prosthesis to replace a part of the skull, due to an accident, a tumour, an infection or any other reason for bone shortage or for skull reconstruction in case of malformations or craniosynostoses by congenital diseases.

Firm(s): JnJ, Rembrandt Medical, Sophysa.

Based on the information provided by firms, 143 prostheses have been implanted in Belgium since its introduction.

167716-167720 / L.2.4. Custom-made joint prosthesis/Reimbursement basis: Decision College physicians-directors; Reimbursement category: I.F a

Custom-made prosthesis except for the cupula's for reconstruction (individually fabricated according to the different dimensions).

170796-170800 / L.2.4. Custom-made joint prosthesis/Reimbursement basis: 5000,00€; Reimbursement Category: I.E a

Outer part of a custom-made modular cupula for reconstruction, with 3 support points (triflanged)

Firm: ZimmerBiomed

172535-172546 / L.2.4. Custom-made joint prosthesis/Reimbursement basis: 8.500,00€, Reimbursement Category: I.E a

Outer part of a custom-made modular cupula for reconstruction, with 3 support points (triflanged), and with 1 or more fixed parts in porous metal for stuffing bone defects

Product: aMace® - custom-made implant + scaffold

Firm: Mobelife

171172-171183 / L.10. Guide for osteotomy/Reimbursement basis: 800,00€, Reimbursement Category: II.D a

Custom-made device for single use for osteotomy during the exeresis of a tumour.

Firm(s) : CenTIS – distributed by other firms , Materialise

171194-171205 / L.10. Guide for osteotomy/Reimbursement basis: 800,00€, Reimbursement Category: II.D

Custom-made device for single use for removal of the massive allograft according to the tumoural exaeresis.

Firm(s) : CenTIS – distributed by other firms, Materialise

<http://ondpanon.riziv.fgov.be/IRREQPublic/nl/>



Special Solidarity Fund

3D printed custom-made devices can be eligible for compensation by the Special Solidarity Fund ("SSF") under strict conditions. The Fund complements the compulsory health insurance coverage and serves as a social care net covering (expensive) interventions for treating rare diseases, excluded from the universal insurance system. One can make an appeal to the SSF if all other possible sources of reimbursement have been exhausted.³⁶⁰ Additionally, several criteria have to be met in order to be eligible for reimbursement through the SSF (Article 25 of the Law of 14 July 1994).

The cases in which medical costs are eligible to reimbursement by the SSF are stipulated in the law. The main categories are cost of medical treatment related to:

- rare indications (art. 25bis)
- rare diseases (art. 25ter §1) requiring a specific fysiopathological treatment
- rare diseases requiring a continuous and complex treatment (art. 25ter §2)
- innovative treatment techniques (art. 25quater)
- chronically ill children (art. 25quinquies)
- medical treatment abroad (art. 25sexies)

If the cost of 3D printed custom-made devices is eligible for reimbursement by the SSF, it is most likely that this would apply for the categories "rare diseases", "rare indications" or "innovative treatment techniques". For each of these categories several additional requirements need to be fulfilled.

Reimbursement of the treatment costs for **rare indications** has to meet the following additional requirements:

- The treatment is expensive;

- Medical treatment is prescribed by a medical doctor specialized in the treatment of the related disorder and authorized to practice medicine in Belgium;
- Medical treatment has a scientific value and effectiveness which is largely recognized by the medical profession. The medical treatment has to have outgrown the experimental phase;
- The compulsory health insurance system can't provide an alternative;
- Medical treatment is used for an indication threatening vital functions of the patient.

Additional requirements for reimbursement of medical costs for patients suffering from **rare diseases** are:

- The medical treatment is considered as expensive;
- The compulsory health insurance system does not provide a therapeutic alternative treatment;
- Medical treatment is used for a rare disease that threatens the vital functions of the patient;
- The medical treatment is prescribed by a medical doctor specialized in the treatment of the specific disease and authorized to practice medicine in Belgium;
- The medical profession recognizes the treatment as the specific approach for the rare disease.

For **innovative treatment techniques and medical devices** the SSF can specifically intervene if the following conditions are fulfilled: reimbursement is only allowed when the treatment techniques and medical devices are expensive and rare. Authoritative medical bodies (such as guidelines of professional associations, the FAMHP, publications in scientific articles) moreover need to recommend the treatment and medical device as the appropriate way to treat the disease that threatens vital functions of the patient. Additional requirements for reimbursement are³⁶¹:

³⁶⁰ Article 25 of the Law of 14 July 1994.

³⁶¹ Article 25quater of the Law of 14 July 1994.



- the medical treatment has outgrown the experimental phase;
- based on a cost benefit-analysis, it should be clear that the medical treatment has an important and proven added value;
- the medical treatment is prescribed by a doctor, specialized in the rare disease and authorized to practice medicine in Belgium;
- an application to assess the medical “added value” of the treatment and/or the request for inclusion for reimbursement within the compulsory insurance system has to be submitted to the authorized Technical Council, part of the compulsory insurance system;
- the medical treatment or medical devices need to be on a limitative list approved by the Insurance Committee of the NIHDI for which reimbursement can be granted for a period of maximum one year. This maximum period of one year can be renewed once if motivated by the Insurance Committee. At the time of writing the report there is no such a list.

In practice, requests for reimbursement of custom-made medical devices introduced at the SSF did not always relate to the category “innovative treatment and techniques and medical devices.

As the conditions for an intervention through the SSF are very strict, only very few of the 3D printed medical devices will however be eligible for such intervention. Up to date, at least one Belgian hospital already requested the SSF, multiple times, to intervene in the costs related to 3D printed surgical guides. According to this hospital the SSF systematically refused to intervene in these costs because the added value of the 3D printed guide was not sufficiently proven. The right argumentation, however, is that according to art. 102 of the Hospital law, these guides – being non-reimbursed invasive devices- cannot be charged to the patient, but need to be borne by the hospital (BFM). As the patient does not pay, the SSF cannot intervene.

Even if these SSF conditions for reimbursement would be fulfilled, the patient always will have to pay for the device upfront. Furthermore, the SSF has a closed budget per year, which implies that if the budget was exhausted, reimbursement is no longer possible. The SSF can also decide

to intervene only partially in the total cost, implying that patients still have to bear large amounts.

Key points

- **The general principles and conditions for reimbursement of medical devices are fully applicable to 3D printed (custom-made) medical devices.**
- **For some custom-made devices that are included in the list, the CTIIMH can decide that reimbursement of a device can only take place after a case-by-case assessment by the College Physicians-Directors of the NIHDI (e.g. customized joint prostheses). A recurring condition for reimbursement of custom-made devices in the case-by-case assessment, is the proof that the use of a “standard” device was not possible. There are, however, no clear criteria that determine when standard devices are insufficient.**

5.10.2.3 Difficulties and options related to the reimbursement of custom-made 3D printed medical devices/ 3D printing related services

In the following sections current difficulties and options for the future related to the reimbursement of custom-made 3D printed medical devices and services related to 3D printing are discussed.

Today the cost of the 3D printed custom-made **implants** can be charged to the patient when:

- no request for reimbursement is submitted;
- a request for reimbursement is submitted and positively evaluated, but the decision of reimbursement by the compulsory health insurance is not yet in force;
- a request for reimbursement is submitted, but a negative decision was given due to a negative evaluation of the CTIIMH-CRIDMI for the following reasons:
 - o evidence is currently lacking



- o there is no budget
- o the requested price is considered to be too high (according to the added value)
- a request for reimbursement is submitted but not for the reimbursed indication, e.g. the College physicians – directors judged that the reimbursement conditions of the list were not fulfilled (e.g. the respective custom-made invasive device is not necessary because there is an alternative)

The price of non-reimbursed invasive medical devices will be charged to the hospital.

The fact that a 3D printed device is not (yet) reimbursed (even due to a lack of evidence) does not hinder the unrestricted use of the device under the responsibility of the physician. This could lead to a large-scale distribution of high-risk devices throughout the market, and uncertainty for the patient. In turn, this could create indirect pressure to reimburse the device anyhow. Furthermore, this also implies that even if no reimbursement was requested for or if reimbursement was refused in the options mentioned before, manufacturers are free to determine themselves the price and the cost of the implant can (at least partially) be charged to the patient. Some hospitals have 'innovation' funds to cover the costs of this kind of devices. Yet, the question raises whether it can be justified that the patient or the hospital should bear the risk and the cost for (possible) innovation, even if there is an existing equivalent alternative. Furthermore, it is questionable if patients are always aware that they are treated with (possibly) innovative devices. Although surgeons have the duty to inform the patient on existing equivalent alternatives, the patients' rights legislation does not explicitly request that surgeons also justify why they prefer one product above the alternative.

The following options aim to come forward to the above mentioned problems. The decisive factor for the reimbursement modality is the **existence of an equivalent alternative**. The presence of an equivalent alternative should serve as a comparator for price and demonstration of added value. As a rule of thumb, no higher price than the comparator can be granted, if there is no evidence of added value. If no equivalent alternative is available however, it concerns a unique solution for the patient, which

makes – in absence of an appropriate comparator- price setting and proof of added value difficult.

Although we focus in this part on custom-made devices, the same reasoning goes for standard devices. Even if under the MDR 3D printed medical devices would qualify as (customisable) standard devices, the key principles can be applied. It should also be noted that the listed difficulties and proposed solutions not only apply to 3D printed custom-made medical devices but can be used as a generic framework for the assessment of custom-made medical devices, independent of their fabrication mode.

1. A request for submission to the list is introduced for a 3D printed device for which evidence of the added value is lacking and an "appropriate" alternative is available

Reimbursement up to the level of the appropriate alternative

If there is an **appropriate alternative available**, the 3D printed device for which evidence of the added value is currently lacking, but for which safety was established, should be eligible for reimbursement up to the level of the appropriate alternative. This approach is beneficial for all parties involved. As long as the safety of the 3D printed device is established, there is no risk for the health of the patient. Moreover, the patient does not pay for the (possible) innovation. Hereby, it needs to be stressed, however, that the patient should at least be informed of the fact that he/she is treated with a device/implant for which no evidence of the added value is demonstrated yet, whereas an appropriate reimbursed alternative exists. For the NIHDI, the budgetary risk is not higher than if the appropriate alternative was used, as the custom-made device will only be reimbursement up to the level of the alternative. Finally, this option does not block innovation for industry as the (possibly) innovative device/implant is reimbursed up to level of the alternative till evidence of added value is demonstrated. In that case a higher price can be justified (cfr. infra). Furthermore, firms can be (financially) supported by the government in the gathering of evidence of the added value by the set-up of a system exploiting the data on patient outcomes (e.g. 30-days mortality, rehospitalisation,...) in the existing administrative databases (cfr. infra).



In practice, the difficulty of this proposed solution will relate to the assessment whether an “appropriate” alternative is available. Sometimes several custom-made very comparable invasive devices/implants are available for the same indication (e.g. Temporo-mandibular joints (TMJ) are distributed by several firms at different prices, the guides for osteotomy distributed by Centis and Materialize: see Table 9). In most cases, however, this will not be the case and the 3D printed custom-made device will have to be compared to a custom-made device via traditional fabrication modes or even to a standard (non custom-made) procedure. As it often concerns highly specialised cases in small patient populations for which expertise in the specific domain is needed (but often scarce), it is important that clinical experts from the specific domains are involved in the assessment of the existing ‘appropriate’ alternatives. In an optimal scenario, international collaboration could enhance this process. In the procedure for submission of a new “provided service” on the list, peer group evaluation and intercollegial exchanges could be introduced. Furthermore, the assessment procedure should be a transparent process.

2. A reimbursement request is introduced for a 3D printed device where no appropriate alternative is available

Where no appropriate alternative is available, the fixation of the price and the level of evidence requested are difficult to set since there is no appropriate comparator. As mentioned above, the assessment on what is an appropriate alternative is primordial. If there is no appropriate custom-made comparator, comparison with “standard” options via conventional ways or the technique preceding the 3D technique may be an option. In some cases the alternative may be a non-custom-made device, ‘doing nothing’ or watchfully waiting.

Stakeholders raised the question whether an orphan status for medical devices, comparable to medicines would be a good option. The regulation for orphan drugs primarily aims at facilitating market access and does not focus on reimbursement³⁶². As the rules for market access are already

alleviated for custom-made devices (see 5.4.1), there is no need to grant a separate orphan status.³⁶³ Yet, as mentioned above, 3D printed medical devices may be qualified as standard devices according to the MDR. If this is the case, the “standard” requirements for market access (CE marking, assessment by a notified body,...) will apply. This stresses once more the importance of a clear guidance on when a 3D printed medical device is to be considered as a custom-made device under the MDR.

3. No reimbursement request was introduced, firm asks for removal of the list because the reimbursement is considered to be too low or negative reimbursement decision because too expensive

In some cases firms may have no incentive to introduce a request for reimbursement. Evidence may be too weak or they may have knowledge of results that will not support a positive reimbursement decision with the respective device or implant. In theory, firms can even remove their products from the list because they consider that reimbursement is too low (see example in box below). Even if no reimbursement request was introduced, if the reimbursement was refused because the price requested was too high or if the firm removed it from the list, the device may unrestrictedly be used by surgeons. The price for the non-reimbursed implant can be charged to the patient or the hospital can bear (part of) the costs on its own initiative. In order to allow patient to make an informed choice, surgeons should explicitly inform the patient on the fact that he/she pays for the implant and explain why a non-reimbursed implant (without proven added value) is proposed while reimbursed alternatives exist.

The price of non-reimbursed invasive medical devices will be charged to the hospital.

³⁶² The orphan drugs regulation provides incentives such as a form of scientific advice specifically for orphan medicines, called protocol assistance; http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000552.jsp&mid=WC0b01ac058061ecb7

³⁶³ For more information about the “regulation” for orphan medical devices in the USA, Canada, Australia, Japan and the EU see the Dutch RIVM Report 360020001/2007 IN “Medical devices for small target groups – Availability guaranteed?”.



Example

e.g. aMace has been removed from the nominative list on demand of the firm and a new dossier for revision of reimbursement was introduced. A lump sum, slightly higher than the previous reimbursement has been granted to avoid that the entire price would be charged to the patient. Yet, only 2 cases have been reimbursed since April 2016, whereas 6 products of another firm (that previously did not sell any) have been reimbursed. The reason could be that aMace is sold at a price much higher than the lump sum (in which case the hospital needs to bear the cost exceeding the lump sum) whereas the product from the other firm is sold at the price of the lump sum or to a lower price.

Separate reimbursement of the pre-operative planning phase?

It is typical for 3D printed devices that, contrary to medical devices produced via traditional processes, a lot of time, efforts and financial means goes to technical (mechanical) development of the 3D printed device and the pre-operative 3D image based fine-tuning of the positioning in the body. This is the so-called “pre-operative planning” phase. During this “pre-operative planning” phase, the physician (who will implant the 3D printed device) and the engineers (usually working for the 3D printing company) work closely together to develop the 3D printed device. This phase starts with the physician delivering the patient data and other relevant medical information. Based on this information the development process starts. During this process there is a permanent exchange of information between the physician and the engineers (usually multiple meetings and/or conference calls have to be organised). Some argue that the cost of this “pre-operative planning” phase should be separately reimbursed by the Belgian health insurance because this is one of the most time-consuming phases of the complete 3D printing process. Today, while in theory solely the 3D printed implant/device is eligible for reimbursement, it is possible to include these costs in the price of the implant/device since the cost structure is not

transparent. This implies, however, that the costs cannot be billed if the pre-operative planning ultimately did not result in the implanting or the use of the device.

In practice, the time spent on pre-operative planning by surgeons will usually be integrated in the honorarium of the surgeon. This is not different from classical pre-operative planning acts. In the domain of oral and maxillofacial surgery, however, an example can be found of a “pre-operative planning” that is reimbursed (see Nomenclature codes 258790 (ambulant) and 258801 (hospitalized) of the Nomenclature³⁶⁴). This “pre-operative planning” includes the 3D analysis. This 3D analysis is done before the actual 3D printing of the surgical guides, used during the oral and maxillofacial surgery. This example proves that in some cases the NIHDI is willing to reimburse the pre-operative phase. It should be noted, however, that in principle this only refers to the remuneration of the pre-operative planning work invested by the surgeon, whereas other parties are involved in this phase as well.

The sole argument for an additional reimbursement for the pre-operative planning phase is the proof of evidence of added value. Yet, as demonstrated in chapter 3, the claimed impact on patient outcomes (less risks of infections, improvement of the quality of the surgery (implantation, less damage to surrounding tissue,...), ...) seems to be very limited. Some stakeholders argue that the added value of the pre-operation phase can be found in process outcomes, such as a shorter operation time. This expensive “*pre-operative planning*” could (according to 3D medical device manufacturers) be compensated by a shorter operation time. Evidence shows, however, that if there are time gains in operation time, these are limited (see evidence chapter 0). Furthermore, even if there were significant gains in time, allowing savings in operation related activities (such as decrease in anesthesia related items) or to reinvest in other interventions, this would only be beneficial for the surgeon and for the hospital and not from a patient or payer’s point of view. Consequently, if the added value is not proven, there are no sound arguments to foresee an additional reimbursement for pre-operative planning or extra services related to 3D printing of medical devices. Stakeholders reported however that patients –

³⁶⁴ Nomenclature N° 258801: “Computer geassisteerde preoperatieve planning in geval van reconstructie van een uitgebreide resectie in het hoofd

halsgebied” or “Planning préopératoire assisté par ordinateur en cas de reconstruction d'une large résection dans la région de la tête et du cou”.



based on their approval in the informed consent form – are sometimes extra charged for costs related to planning, whereas this is forbidden by law.³⁶⁵

- **The decisive factor for the reimbursement modality of a 3D printed (custom-made) device is the existence of an appropriate alternative. The presence of an appropriate alternative should serve as a comparator for price and demonstration of added value. As a rule of thumb, no higher price than the comparator can be granted, if there is no evidence of added value. If no appropriate alternative is available however, it concerns a unique solution for the patient, which makes – in absence of an appropriate comparator - price setting and proof of added value difficult.**
- **It is important that clinical experts from the specific domains are involved in the assessment of the existing ‘appropriate’ alternatives.**

5.10.2.4 Evidence gathering via iterative process of safe introduction and use of innovative devices/implants (IDEAL – model)

Current practice shows that for (3D printed) custom-made devices an **extra cost**, compared to the non-custom-made alternative is often claimed by the applicant for reimbursement (e.g. custom-made versus non custom-made TMJ). Sometimes, significantly different prices are claimed for very comparable (3D printed) custom-made devices (e.g. guides for osteotomy were introduced by CenTis and Materialise but at a significantly different price. A lump sum reimbursement of 800 € was granted – see Table 9). As a rule of thumb, a higher price can only be granted if evidence on the added value was proven. However, as demonstrated in chapter 3, currently, evidence on the added value of 3D printed invasive medical devices/implants is scarce. Often heard arguments supporting the difficulty to gather evidence for innovative custom-made invasive devices/implants are the small patient groups, the unethical character of comparing interventions with high-risk medical devices/implants with traditional

methods. Yet, practice in the US, often demonstrates the opposite of the latter argument. Take transcatheter aortic valve implantations (TAVIs) for instance, which have been in use in the EU for years and in respect of which data of thousands of patients have been recorded. However, these could not be used to reliably demonstrate that the procedure had an added value for patients because of the lack of a control group. Yet, in the US, they did manage to conduct the relevant randomized trials.³⁶⁶

A good approach for the safe introduction and use of innovative (3D printed) medical device routinely used by doctors, is the *IDEAL framework*. The IDEAL framework describes the stages in the development and assessment of surgical innovations. IDEAL stands for: idea, development, exploration, assessment and long-term study (see Table 10).

- Idea/proof of concept: when (a) surgeon(s) try out a procedure for the first time.

*“At this stage, research ethics approval is not appropriate, although full and clear informed consent is an ethical obligation for competent patients. **All new procedures should be reported automatically, whether successful or not. It is perhaps even more important to report adverse events and failures than successes, to avoid their repetition in the future. Hospitals need to be informed; however, surgeons should also report the new procedures in an online register available to all surgeons. ... These reports should contain clear anonymous details of the patient, their condition, the rationale and background for use of the procedure, exactly what was done, and adequate details of relevant outcomes.**”*

- Development: if early reports suggest benefits → early adopters may take up the innovation.

*“Involves the planned use of a procedure in an initial small group of patients (rarely more than 30 and sometimes less than ten) **to support experience with its first use and often to refine or modify the precise technique. ... we recommend that protocols for***

³⁶⁵ Art. 35 § 4 Act of 14 July 1994 on the mandatory insurance for healthcare and benefits, *B. Off. J.* 27 August 1994.

³⁶⁶ <https://kce.fgov.be/nl/publication/report/transcatheter-aortakunstklep-implantatie-tavi-een-health-technology-assessment-ac>



prospective development studies are registered before patient recruitment begins, describing patient selection principles, operative methods, and outcomes to be measured. Protocols should be registered beyond the surgeon's institution and should undergo some form of ethical approval. ... Learning curves are also an important issue in this phase, and clear sequential outcome reporting of all cases should be done, without omissions. Ethical considerations require that all reasonable precautions are taken to avoid harm to patients during the learning curve, including, when possible, mentoring."

- Exploration/learning: understanding potential benefits and harms .

*"Exploration occurs **once the procedure has been described and the main technical aspects worked out.**" In this phase, "prospective research databases are valuable. These carefully planned, **prospective but uncontrolled clinical studies** could run as parallel additions to smaller feasibility or explanatory randomised clinical trials that might be appropriate at this stage. These uncontrolled studies could also be an integral preparatory stage for a major randomised trial".*

- Assessment: Is this technique better than established methods in terms of clinical efficacy and cost-effectiveness?

*"this stage aims to **assess effectiveness against current standards.** ... The key issue is to decide which is the best feasible comparator for the new procedure. **Randomised trials should be the default option in this stage,** but trials of surgical techniques are sometimes unnecessary,⁴⁰ sometimes not feasible, and sometimes might need adaptations or additional features. ... Most operations, however, are smaller advances prone to overoptimistic assessment by their*

developers and, therefore, need controlled randomised studies, when possible. ... randomised trials may not be feasible for ethical or pragmatic reasons, such as recruitment difficulties. In these cases, alternative designs are necessary."

- Long-term study/surveillance:

*"In this stage, established procedures are assessed for **rare and long-term outcomes**, and for variations in outcome. ... differences in selection criteria or in the quality of surgery or aftercare may become apparent through unexpected outcome variation between study centres. The **typical study design is a registry.** ... The value of this type of study depends on its representativeness; therefore, only key outcomes and relevant information should be obtained to encourage complete data entry."*

*"The main focus of outcome evaluation will change with the stages, from the possibility of the intervention to the refinement and standardisation of technical details, to the potential for benefit and harm, to comparison with current practice, and finally to quality control, with outcomes focusing on long-term benefit and harms."⁴¹ There is no precise timepoint to indicate when an 'innovation' goes from one phase to another. However, before being widely used, a formal scientific evaluation of an innovation in comparison to existing alternatives in an appropriate research design is recommended. The IDEAL framework also stresses the **importance of "transparent reporting** of research protocol and context, and of ethical approvals to register research initiatives before patient enrolment, and to report outcomes in peer-reviewed publications. ... A lot of data for innovation (especially unsuccessful innovation) are simply not recorded at present, condemning failed innovations to be repeated by others."⁴¹*



Table 10 – IDEAL

	1 Idea	2a Development	2b Exploration	3 Assessment	4 Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Single digit; highly selected	Few; selected	Many; may expand to mixed; broadening indication	Many; expanded indications (well defined)	All eligible
Number and types of surgeons	Very few; innovators	Few; innovators and some early adopters	Many; innovators, early adopters, early majority	Many; early majority	All eligible
Output	Description	Description	Measurement; comparison	Comparison; complete information for non-RCT participants	Description; audit, regional variation; quality assurance; risk adjustment
Intervention	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method	Structured case reports	Prospective development studies	Research database; explanatory or feasibility RCT (efficacy trial); diseased based (diagnostic)	RCT with or without additions/modifications; alternative designs	Registry; routine database (eg, SCOAP, STS, NSQIP); rare-case reports
Outcomes	Proof of concept; technical achievement; disasters; dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes	Clinical outcomes (specific and graded); middle-term and long-term outcomes; patient-centred (reported) outcomes; cost-effectiveness	Rare events; long-term outcomes; quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No
Examples	NOTES video ⁶	Tissue engineered vessels ⁷	Italian D2 gastrectomy study ⁸	Swedish obese patients study ⁹	UK national adult cardiac surgical database ¹⁰

RCT= randomised controlled trial. SCOAP= Surgical Clinical Outcomes Assessment Programme. STS= Society of Thoracic Surgeons. NSQIP= National Surgical Quality Improvement Program. NOTES= natural orifice transluminal endoscopic surgery.



What actions should be taken to make the IDEAL approach possible in Belgium?

- Guiding principle: safety and added value compared to existing alternatives

An efficient system should not only be able to (retroactively, e.g. reaction if several events occur) demonstrate the safety of 3D printed high-risk medical devices but also the comparative safety (e.g. adverse events for the patients) and added value. Today, European legislation does not require any proof of comparative safety and added value for high-risk medical devices. Therefore, national governments should invest in the set-up of such a system.

In the following sections, several possibilities for the safe introduction of (3D printed) high-risk medical devices and the joint (by the NIHDI, FAMPS, healthdata.be) set-up of a system that enables the systematic evaluation of safety and added value of high-risk (3D printed) medical devices are listed.

Most options show that currently practical and legal uncertainties and barriers exist. Further reflection and collaboration of the parties involved will thus be necessary.

- Action 1: In the development phase: limit use of 3D printing/3D printed devices in selection of centres of expertise

In the development phase, the use of 3D printing/3D printed devices should be limited to a **selection of centres of expertise**. Such limitations become increasingly common with regard to the treatment of rare diseases, and in particular of some rare cancers. There might be different reasons to work with centres of excellence. First, this might lead to better outcomes by minimizing the learning curve effect and promoting the concentration of expertise. Next, for devices where evidence on efficacy/effectiveness is lacking, the limitation to a number of centres of excellence might be linked to limiting the number of procedures and gathering further evidence in a research setting before widely spreading the device. Some stakeholders reported that custom-made 3D printed devices might be used by surgeons in low volume centres to correct their lack of experience because they are easier in use than the prefabricated alternatives. This can lead to the unjustified diffusion of practice (in particular in the rare indications), whereas

the patient or the payer bears the extra cost. The limitation to a selection of centres could come forward to this practice.

Criteria to select such centres could be: the experience of the doctors and medical teams, involvement of the team in research, the obligation to train other specialists, etcetera.

- Action 2: Improve the use of existing registries + impose registry of patient- and process outcomes

As demonstrated in chapter 3, data on patient- and process outcomes related to 3D printing/3D printed devices are often lacking. Yet, registers can be very useful in the development, exploration and long-term study stages of the IDEAL model.

There are opportunities to use existing administrative databases (containing data such as e.g. 30 days mortality, rehospitalisation,...) as scientific knowledge development tools,⁴² as a condition for reimbursement as well as an opportunity to gather important observational data for devices that are not (yet) reimbursed. Coupling data from already existing databases to a unique device can help to improve the knowledge on the use and specific outcomes (e.g. length of stay, rehospitalisations,...) of certain devices. In this regard, it is important to provide records which include both devices used for research purposes (the first three phases in the IDEAL framework, see Table 10) and those used for strictly therapeutic purposes (the long-term follow-up in the IDEAL framework). Registries are not only useful during the initial phases of the IDEAL process but also in the **long-term surveillance and post-marketing surveillance phase**. For the latter, one of the advantages is that registry data reflects the use of devices in the real-world setting and can contain data on large numbers of patients. On the other hand, the main disadvantage of a registry is that there is no control group. Such studies will usually have problems to demonstrate the benefit for the patient in comparison to other alternative interventions (the assessment phase).

Anyhow, it should be checked whether the existing registries can answer the open research questions. In the **assessment phase**, the outcomes available in the existing databases may be insufficient to demonstrate added value. The added value of 3D printed (custom-made) devices may lie in an increased patient satisfaction, better comfort for the patient, aesthetic



benefits... These are outcomes that are typically not included in the existing administrative databases. Whereas the government can co-finance the set-up of the system of exploitation of existing databases, the financing of a study including the evaluation of outcomes that are not included in the existing databases should usually be financed by the firm. Co-financing at the level of existing alternatives can be considered since this bears no additional financial risks for the government and can support conducting research.

The registered data can only be efficiently used when linked to a unique (patient-specific) device identifier. In Belgium, it is in theory currently possible to identify devices/implants used in hospitals based on the nomenclature number and to extract the existing patient- and process outcomes. Yet, it is not possible to exploit patient- and process outcomes of non-reimbursed implants. Furthermore, it is not always possible to deduce from the nomenclature number if the device has been fabricated via 3D printing.

- Possibilities to utilise traceability data linked to (existing) patient- and process outcomes

In the idea of using registries for traceability as well as for research purposes, an ideal option would be to link the UDI code to process- and patient outcomes registered by physicians and available in the existing administrative databases (via a common patient identifier³⁶⁷). At the same time the UDI code could also be used for identification of the device in the other registers, such as those of the NIHDI.

Most of the 3D printed medical devices will have a UDI in the future (see 5.9.1.2). Based on the Belgian Central Implant Registry, that will include the UDI-DI of the respective implants (at the moment of writing the report it is still to be defined which implants will be in it), it will be possible to trace which implants have been used in which patient. Linking data from the Implant register to existing patient- and process outcomes of the administrative databases would thus be a good option to start from.

Depending on the content of the UDI-DI several approaches are possible to allow the identification of devices with different fabrication modes (e.g. 3D printed or other fabrication mode) or constructed with different materials.

1. Explicitly including material and fabrication specifications in the UDI-DI.

The UDI consists of a unique code specific to the manufacturer and the device model (UDI-DI) and a code that identifies the unit of device production (UDI-PI). Possible UDI-PI's include serial number, lot number, software identification and manufacturing and/or expiry date. Solely the UDI-DI will be included in the central database. The UDI-PI, which includes more detailed product information will only be available with the manufacturer. The mode of fabrication (e.g. 3D versus other method) or the type of material (e.g. metal – on – metal hip prosthesis versus ceramic) is information that will not be included in the UDI-DI. Possibly this information will be inserted on the manufacturer's initiative in the UDI database (see Annex VI part B, 13° MDR). For high-risk medical devices, the inclusion of the material specifications and the fabrication method in the UDI-DI would be an optimal solution to allow the set-up of the proposed system. Thereto, the extension of the UDI-DI with extra fields would enable the direct identification of the type of device (e.g. 3D versus other or metal versus ceramic), without any intervention of the manufacturer. The feasibility and the necessity that justifies the extra fields in the UDI-DI needs to be studied.

2. Different UDI-DI for medical devices with different fabrication modes or fabricated with different materials.

Another option to allow the distinction between medical devices with different fabrication processes or constructed with different materials, is to grant a different UDI-DI.

- For medical devices produced by **different manufacturers** this is already the case (e.g. a 3D printed surgical guide of manufacturer X will have a different UDI-DI than a similar 3D printed guide of manufacturer Y). Yet, even if medical devices have a different UDI-DI, collaboration of the manufacturer or the implanting physicians will be necessary to identify the medical devices behind the UDI code.

³⁶⁷ In Belgium this will probably be the National Registry Number



- If medical devices with a different fabrication mode or constructed with different materials are produced by the **same manufacturer**, it is in principle possible that they have the same UDI-DI if they are considered to be of the same model. An ideal solution would be that the notified bodies grant different UDI-DIs for each essential difference in fabrication mode or material. Manufacturers can, however, legally introduce one technical file for a group of medical devices with “similar properties”. It is thus likely that notified bodies will not be able to impose separate technical files for products made of the same material but via a different fabrication mode (e.g. 3D versus other fabrication mode).
- 3. New UDI-DI when essential modifications or if other essential components are used.

The MDR already imposes a new UDI-DI if a modification to a medical device can lead to misidentification or difficulties in traceability (3.9 annex VI). A limitative list defines situations where a new UDI-DI is necessary, e.g. a new version or model of a medical device. It is unlikely that a modification of the fabrication process (e.g. 3D printed version of a medical devices that was previously fabricated with the same materials but via another production process) or the replacement of a component (e.g. a new battery with a longer lifecycle in a pacemaker) will be considered as a new version.

4. Additional restrictions for implementation

Even though the use of the UDI code offers a lot of possibilities, there are several additional barriers. First of all, the UDI code is not applicable for in hospital produced medical devices (that fall within the scope of art. 5(5) MDR) and for custom-made devices. The impact, however, will be minor, as most of the 3D printed medical devices will (under the MDR) no longer qualify as custom-made medical devices, but as standard devices for which the UDI code applies. Furthermore, as 3D printed custom-made devices are typically one off prints for one particular patient, it will be difficult to gather data in large patient groups, especially on a national level. Likewise, the number of hospital- produced 3D printed medical devices will probably also be limited as one of the conditions of art. 5 (5) MDR requires that it does not concern mass production on an industrial scale. Finally, the proposed system can only be implemented in Belgium a stepwise approach. In a first phase, solely the implants included in the Central Implant Register could be linked to the data of the administrative databases. At the time of redaction

of the report the Central Implant Register is not operational yet and it is to be determined which medical devices will be included. Probably it will concern high-risk implants. This implies that invasive non-implantable medical devices and lower risk implants initially will not be included. A stepwise approach with a priority on high-risk implants is thus the most feasible option. Collaboration between the FAMHP, the NIHDI and Healthdata.be is primordial for a successful elaboration of the proposed system.

Key points

- **A good approach for the safe introduction and use of innovative (3D printed) medical device routinely used by doctors, is the IDEAL framework**
- **In the development phase, the use of 3D printing/3D printed devices should be limited to a selection of centres of expertise.**
- **Before being widely used, a formal scientific evaluation of an innovation in comparison to existing alternatives in an appropriate research design is recommended .**
- **Existing administrative databases can be used as scientific knowledge development tools as a condition for reimbursement as well as an opportunity to gather important observational data for devices that are not (yet) reimbursed. Coupling data from already existing databases to a unique device identifier can help to improve the knowledge on the use and specific outcomes (e.g. length of stay, rehospitalisations,...) of certain devices. Traceability registries are an excellent basis to link with outcome data of the existing administrative databases.**
- **The UDI code could serve to link with process- and patient outcomes registered by physicians and available in the existing administrative databases. There are, however several barriers to the use of the UDI-DI for the identification of a 3D printed medical device (and the ultimate goal of linking it to process-and patient outcomes). Therefore, a working group with the main stakeholders (FAMHP, NIHDI, Healthdata.be) should further reflect on the suggested options.**



- **A stepwise approach, starting with the high-risk implants that will be included in the Central Implant Register is the most feasible option. Furthermore the UDI code does not apply to custom-made devices, nor to in hospital produced devices (that fall within the scope of art. 5 (5) MDR).**

5.10.3 Conclusion

There are no specific rules for the reimbursement of 3D printing/3D printed medical devices. As such, they are reimbursed as other devices that are fabricated in a traditional way. Current practice shows that for 3D printed custom-made devices an extra cost, compared to the non-custom-made or non 3D printed alternative(s) is often claimed by the applicant for reimbursement. Current regulation allows that in some cases patients bear the cost for (possible) innovative 3D printed devices, even if a reimbursed appropriate alternative exists. As a rule of thumb, no higher price than the comparator should be granted, if there is no evidence of added value. If no appropriate alternative is available however, it concerns a unique solution for the patient, which makes – in absence of an appropriate comparator-price setting and proof of added value more difficult. Therefore it is of an utmost importance that evaluation of the possible alternatives is performed by clinical experts in the respective domain.

A higher price than the alternative can be justified if added value was demonstrated. However, currently, evidence on the added value of 3D printed medical devices is scarce (see chapter 3). Often heard arguments supporting the difficulty to gather evidence for innovative custom-made invasive devices/implants are the small patient groups, the unethical character of comparing interventions with high-risk medical devices/implants with traditional methods. In some cases, the argument of small patient groups is justified. Yet, to date some 3D printed devices are used in very large patient groups³⁶⁸, but systematic data gathering is often lacking. A

good approach for the safe introduction and use of innovative (3D printed) medical device routinely used by doctors, is the IDEAL framework. The IDEAL framework describes the stages in the development and assessment of surgical innovations. One of the key ideas is that before being widely used, a formal scientific evaluation of an innovation in comparison to existing alternatives in an appropriate research design should take place. In the development phase, the use of 3D printing/3D printed devices should be limited to a selection of centres of expertise. Furthermore existing administrative databases containing patients' outcome data (e.g. length of stay, rehospitalisations,...) can be used as scientific knowledge development tools as a condition for reimbursement as well as an opportunity to gather important observational data for devices that are not (yet) reimbursed. Coupling data from already existing databases to a unique device identifier can help to improve the knowledge on the use and specific outcomes of certain devices. Traceability registries are therefore an excellent source to link with outcome data of the existing administrative databases. The financing of the practical set-up of the exploitation of the administrative data may be considered as a governmental support of firms in the data gathering. It has to be kept in mind however, that the existing administrative databases do not always contain the desired outcomes (e.g. quality of life,...) to justify the claimed extra cost. Evidence on these specific outcomes needs to be gathered (and financed) by the firm.

A 3D printed device is the ultimate output of a chain of actions in a process where many parties intervene. In the “pre-operative planning” phase the physician (who will implant the 3D printed device) and the engineers (usually working for the 3D printing company) work closely together to develop the 3D printed device. Today the time and money invested in this pre-operative phase is not taken into account for reimbursement. As solely the device is eligible for reimbursement, and the price structure is not transparent, the cost for the pre-operative actions may implicitly be included. Some parties argue that the cost of this “pre-operative planning” phase should be

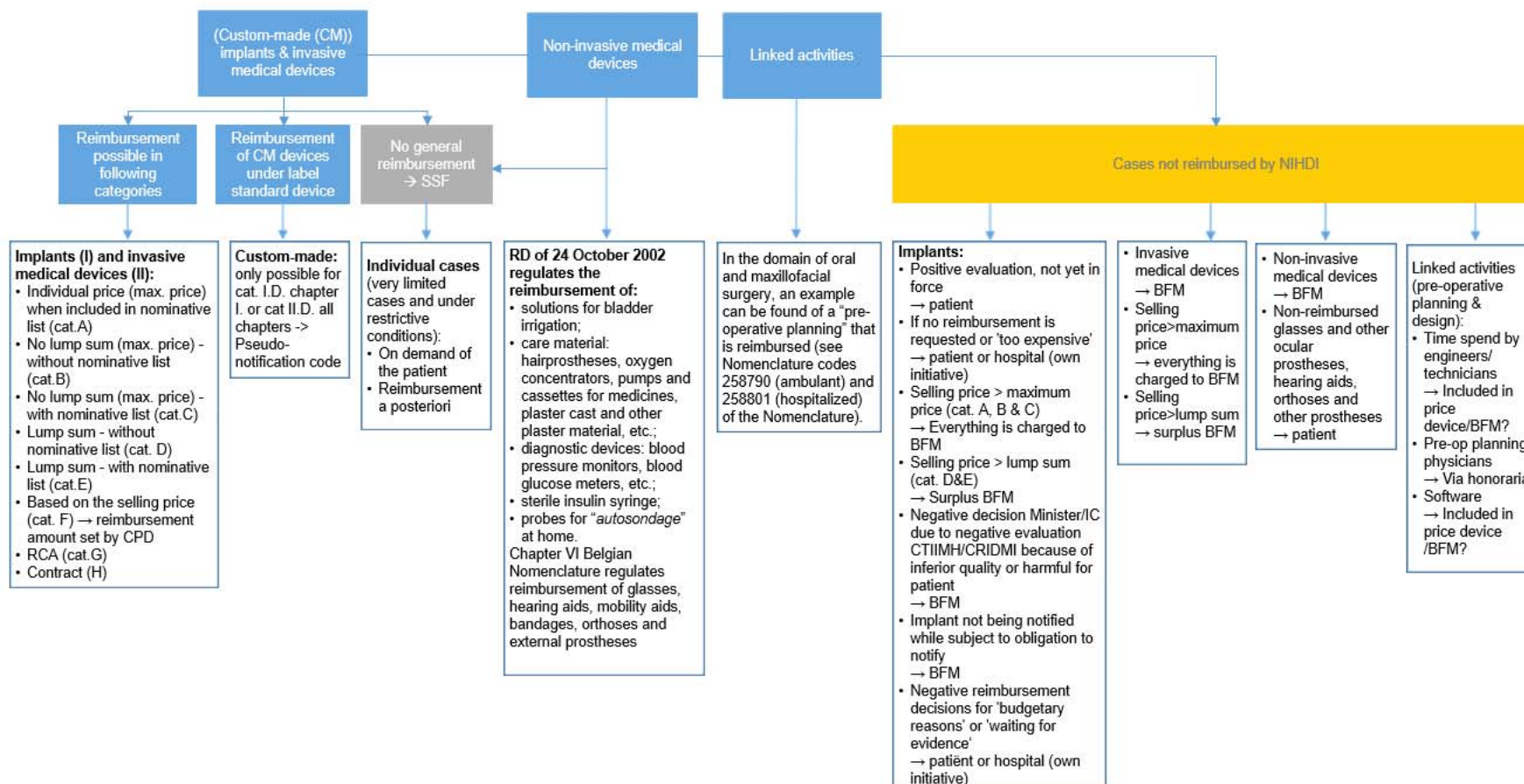
³⁶⁸ E.g. Custom-made hydroxyapatite ceramic implant for cranioplasty manufactured were (since its introduction) implanted in 143 patients in Belgium and 5.407 worldwide, patient-matched instrumentation for the knee of the firm was used for 500 patients in Belgium and 40.000 patients worldwide,...The figures were reported by the respective manufacturing firms.



separately reimbursed by the Belgian health insurance because this is one of the most time-consuming phases of the complete 3D printing process. Evidence of the added value of the pre-operative planning phase however, is scarce (see chapter 3). Even if there was evidence that there are time gains in operation time, allowing to reinvest in other interventions, this would in the first be beneficial for the surgeon or the hospital, not necessarily for the patient or the payer. Consequently, there is no sound justification to reimburse the interventions linked to the pre-operative phase separately. An evaluation of the added value of the entire process (inclusive the pre-operative phase) is recommended.



Figure 14 – Reimbursement options for 3D printed custom-made medical devices and linked activities





5.11 Intellectual Property Rights issues associated with 3D printed medical devices

3D printing, a revolution *per se* which has the potential to cause tectonic movements in the industry and in the world as we know it today in general, clearly has many implications in the sphere of intellectual property rights. Some authors argue that 3D printing is the trifecta of intellectual property infringement.³⁶⁹ Therefore, it is important to determine and to discuss the Intellectual Property (IP) issues with regard to 3D printed medical devices.

IP is the area of law which has played the most prominent role in discussions related to 3D printing and what makes 3D printing technology so interesting to discuss about, is the fact that it involves all main categories of IP: **copyright, patents, trademarks and design rights**.³⁷⁰ As 3D printing of medical devices becomes more commercially viable, its IP implications will increase for medical devices manufacturers. For example, counterfeiting may become a major concern because 3D printing will simplify and decentralize the manufacture of counterfeit goods, including medical devices. It is rather unlikely that health care providers or even patients themselves will start 3D printing of complex medical devices and other medical equipment, but they might use 3D printing technology to generate replacement parts for such equipment to replicate simpler devices.

The medical and dental sectors together correspond to around 13,1% usage of Additive Manufacturing, according to the Wohlers report 2015, and as such are the third largest 3D printing market.³⁷¹ This sector is particularly driven by personalisation or mass customisation. At present, it remains difficult to assess the nature and the speed of the 3D printing's impact on product manufacture and related activities. However, currently this technology is better for making customised products rather than mass-

produced, generic products. This is the key argument which explains why is it important to pay special attention to the intellectual property aspects when discussing about 3D printed medical devices, main characteristic and advantage of which is that they are made exactly according to the patient's needs and measures. However, one could argue that the intellectual legal principles apply to 3D printing no differently than they apply to any other technology. Yet, there is 'an elephant in the 3D printed room' because the difference is really an order of magnitude: 3D printing may involve all types of intellectual property rights and most of the 3D printed objects, so the range and scope of potential infringement and the pool of potential infringers is much larger.³⁷² It has been predicted by the Gartner research firm that by 2018, 3D printing will result in the loss of at least \$100 billion per year in intellectual property globally.³⁷³ Hornick gives three explanatory reasons what would lead to the above stated great loss. The first is so-called 'democratisation of manufacturing', meaning that almost anyone may be able to make almost anything. The second is that the increasing trend of lack of respect for the intellectual property and the third one is the "away from control" syndrome, i.e. the ability to make almost anything without anyone knowing about it or being able to control it.³⁷⁴ When anyone can print 3D objects with virtually any functionality, away from control, intellectual property rights will suffer the "Five Is": 1. Infringement; 2. Identification - meaning that it will be extremely difficult to identify an infringement away from control; 3. Impractical or 4. Impossible enforcement; 5. Irrelevant (or Impotent), i.e. intellectual property rights will become increasingly irrelevant.³⁷⁵

Firstly, it is important to notice that intellectual property rights at stake may go from copyright and design rights (which can be either registered or unregistered) to trademarks and patents. All these rights are subject to infringement by the end-user or intermediaries in the process of 3D printing,

³⁶⁹ Thierer, Adam; Marcus, Adam. Guns, Limbs, and Toys: What Future for 3D Printing. Minnesota Journal of Law, Science & Technology, Spring, 2016, Vol.17(2); 805 – 854.

³⁷⁰ Daly, A., 'You Wouldn't Download a Car': 3D Printing and Intellectual Property in Socio-Legal Aspects of the 3D Printing Revolution, 19 – 47.

³⁷¹ Wohlers Report 2015: 3D Printing and Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, 2015.

³⁷² Hornick, John. 3D Printing and IP Rights: The Elephant In the Room. Santa Clara Law Review, 2015, Vol. 55; 801 – 819.

³⁷³ Idem.

³⁷⁴ Idem.

³⁷⁵ Idem.



but also later on in the dissemination process. And what is different in comparison to the traditional counterfeit goods is that 3D printing technology allows end-users to obtain counterfeit goods with no intervention nor assistance of commercial counterfeiters, thus making piracy more **decentralised**.³⁷⁶ Traditionally, manufacturers would be able to go after the large-scale counterfeiting manufacturers, but this part of the counterfeiting chain is likely to disappear in the context of 3D printing which is changing that traditional chain as we know it today.³⁷⁷

Different types of IP rights offer different type of protection. For example, copyright, if applicable, offers the best intellectual property protection against large-scale piracy by individual end-users, since end-users who use the 3D printed object for private and non-commercial purposes could be held liable for copyright infringement and could easily end up in court³⁷⁸. On the other hand, this is not the case with design rights and trademarks where private and non-commercial use will not be considered infringing.³⁷⁹ Furthermore, trademarks must be registered prior to the act of invoking their protection. However, pursuing individual end-users that make or order 3D printed medical devices may be costly, cumbersome and time consuming. Moreover, the decentralised character of 3D intellectual property infringements certainly does not facilitate enforcement. For right holders, it may be difficult to know which protection strategy to adopt and how to pursue infringers and hence courts' reaction to the legal challenges of 3D printing will play the crucial role.³⁸⁰ **So far, the jurisprudence across the EU**

regarding the infringement claims of IP rights via 3D printing is non-existing.

A good understanding of the different actions and actors involved from the making of the 3D model to the actual printing of the 3D replica is important to assess potential infringements of intellectual property rights. The whole process of 3D printing begins with the making of the 3D model, which can be done either from a scratch or with the help of 3D scanners that allow for the preparation of the 3D model in a Computer Aided Design (CAD) file – an accurate digital image of the object that will be printed by the printer. Hence, in this initial stage of the process there are three actors involved: designer, manufacturer, and supplier of the 3D scanner and the person scanning the object. However, if the 3D object design CAD file is written from scratch, then the designer of the 3D model/blueprint is the only actor involved, either by first scanning the object or by directly writing a digital CAD file.³⁸¹

In the stage of the subsequent dissemination of the 3D model, people who would like to print 3D replica will first need access to the 3D model. Here, a website platform offering links to the 3D model will be the most common disseminator of the 3D model.^{382 383}

The actual printing of the 3D replica is an action that cannot go without 3D printer, and here many players are involved, not only the designer, but also manufacturer, retailer, or the seller of the 3D printer, supplier of the raw materials and the person making the copy. That can be either the end-user or a third party making the copy on behalf of the end-user.³⁸⁴ However, it is expected that the role of intermediaries will decrease when high-quality 3D

³⁷⁶ European Commission. Growth: Internal Market, Industry, Entrepreneurship and SMEs: Legal review on industrial design protection in Europe. 2016. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8845 (Accessed 2017-03-21)

³⁷⁷ Idem.

³⁷⁸ Overview of 3D printing & intellectual property law Under the contract with the Directorate General Internal Market, Industry, Entrepreneurship and SMEs (MARKT2014/083/D), page 6

³⁷⁹ Idem.

³⁸⁰ Idem.

³⁸¹ European Commission. Growth: Internal Market, Industry, Entrepreneurship and SMEs: Legal review on industrial design protection in Europe, op.cit., 3

³⁸² Overview of 3D printing & intellectual property law Under the contract with the Directorate General Internal Market, Industry, Entrepreneurship and SMEs (MARKT2014/083/D), page 6.

³⁸³ Some of the most prominent websites of this kind are: 123D, GrabCad, i.Materialise, Thingiverse, Youimage, etc.

³⁸⁴ Overview of 3D printing & intellectual property law Under the contract with the Directorate General Internal Market, Industry, Entrepreneurship and SMEs (MARKT2014/083/D), page 6.



scanners and 3D printers become easily accessible for end-users in their domestic environment.³⁸⁵ This will consequently result in more decentralised 3D printing. People who print the 3D replica can keep it for private and non-commercial purposes or disseminate it for free or against payment. In this subsequent dissemination, the holder of 3D replica can be the end-user or a professional printing company.³⁸⁶ All above mentioned and explained players are potential infringers of the intellectual property rights in this process before and after 3D printing.

In practice, **right holders may prefer to go after intermediaries for indirect liability rather than starting a legal battle against the end-users for direct liability, since the latter will often be exempted because there is no commercial purpose.** The most obvious intermediaries in the supply chain are those website platforms that allow users to make available CAD files for 3D printing. This means that they host or communicate the related files, either with or without the consent of the original intellectual property right holder. Probably the most popular website of such a kind is Thingiverse, a CAD file hosting website utilising the open source model. Users must select two licences: a primary licence that users grant to Thingiverse, and a secondary licence which determines what third parties can do with their uploaded CAD file. Apart from the hosting website platforms, other intermediaries may be third parties taking care of printing jobs on behalf of the end-user as well as the producer of the actual printers, under certain circumstances.

It is true that the challenges presented by 3D printing and intermediaries are to great extend similar to those challenges previously arisen in the context of the digitisation of books or music and the sharing of digital files between end-users (peer-to-peer sharing).³⁸⁷ Just like it is the case already with regard to the file sharing of digital audio-visual content, the likelihood of

liability for committing or facilitating intellectual property infringement will be higher when the intermediary plays the active role in the 3D infringement process. Regarding the distribution of files and software via Internet, the same blocking and content removal obligations as for audio-video content will be applicable. In practice, **it will be most efficient for right holders to send a notice and take down request to online platforms to prevent them from relying on the safe harbour benefit contained in the e-commerce legal framework.**^{388 389}

Industry is one of the key players in the world of 3D printing and therefore it will be interesting to see which approach will be taken by this stakeholder. But, at this moment in time we can only try to predict what will be the possible voluntary initiatives. Some suggest establishing possible digital rights management (DRM) protections on software files with instructions for 3D printing of the object or building customer relationship management strategies, e.g. for the supply of authentic, authorised CAD files and raw materials needed for 3D printing. Also, introduction of trade secrets for keeping certain information confidential is one of the options as well. In addition, right holders could create collective rights management and enforcement organisations. Notice and takedown mechanism, a system already known, could be also implemented by websites hosting 3D medical device's design files (online depositories of CAD files).³⁹⁰ In this respect it is also interesting to see how some companies decided to offer open source licensing agreements allowing the users of their products to improve the products whereas other companies do not. Online depositories of CAD files also seem to encourage open licence to promote actions such as customisation and remixing by end-users as part of a collaborative community.³⁹¹ To have open-source hardware actually means that the design is made publicly available so anyone can study, modify, distribute, make and sell the design or the hardware based on that design. The open-

³⁸⁵ Idem.

³⁸⁶ Idem.

³⁸⁷ Idem.

³⁸⁸ Idem.

³⁸⁹ Section 4: Liability of intermediary service providers in Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce)

³⁹⁰ European Commission. Growth: Internal Market, Industry, Entrepreneurship and SMEs: Legal review on industrial design protection in Europe, op.cit., 3

³⁹¹ European Commission. Growth: Internal Market, Industry, Entrepreneurship and SMEs: Legal review on industrial design protection in Europe, op.cit., 3



source approach offers a unique combination of advantages, including reducing costs and faster innovation.³⁹² Some authors argue that having open-source hardware is a good idea for medical devices, since making the hardware design available under an open-source license allows anyone to improve and contribute to the device design can lead to very rapid innovation compared to traditional methods. It also enables the design to be modified for very specific uses, and makes the devices easy to repair; factors which also reduce the impact these devices have on the environment.³⁹³ They also hold the opinion that an open-source medical device increases safety, security and robustness by allowing more people to inspect and improve its designs. However, question of intellectual property here arises again, but they argue that being open rather than protecting their designs (e.g., with patents) has vastly increased their sales and lowered prices through stimulating a worldwide marketplace.³⁹⁴

Key points

- 3D printing is often regarded as the trifecta of intellectual property infringement.
- 3D printing will simplify and decentralize the manufacture of counterfeit goods, including medical devices.
- Health care providers or patients probably will not start 3D printing of complex medical devices and other medical equipment, but they might use 3D printing technology to generate replacement parts for such equipment to replicate simpler devices.
- 3D printing may involve all types of intellectual property rights and most of the 3D printed objects.
- The range and scope of potential infringement and the pool of potential infringers is much larger.

- The jurisprudence across the EU regarding the infringement claims of IP rights via 3D printing is non-existing.
- Right holders may prefer to go after intermediaries for indirect liability rather than starting a legal battle against the end-users for direct liability.
- possible solutions for preserving IP rights in the times of 3D printing are: establishing possible digital rights management (DRM) protections on software files with instructions for 3D printing of the object or building customer relationship management strategies, introduction of trade secrets for keeping certain information confidential, creating collective rights management and enforcement organisations, notice and takedown mechanism implemented by websites hosting 3D medical device's design files (online depositories of CAD files).
- having open-source hardware is considered to be a good idea for medical devices, since it allows anyone to improve and contribute to the device design which can lead to very rapid innovation compared to traditional methods

³⁹² Niezen, Gerrit, Eslambolchilar, Parisa, Thimbleby, Harold. Open-source hardware for medical devices. PubMed Central. 2016. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853539/> (Accessed 2017-03-15)

³⁹³ Idem.

³⁹⁴ Idem.



5.11.1 EU

The European patent system is a complex multi-level system, consisting of national and regional patent entities.³⁹⁵ One of the major European patent frameworks is based on the European Patent Convention (EPC)³⁹⁶ which established the European Patent Organization, as well as significantly impacted the harmonization of the European patent law.³⁹⁷ The main limitation of the EPC is the lack of harmonization at the post-grant litigation-related phase, which is still at the domain of national patent law.³⁹⁸ Ever since 1950s, there have been attempts to unify the patent systems across Europe. At the time when the EPC was discussed, there was also another agreement on the agenda: the Convention for the European patent for the Common Market, also referred to as the Community Patent Convention (CPC).³⁹⁹ However, although the CPC was signed by all the EEC states, not all ratified it and hence it did not enter into force. Nevertheless, the CPC provided some concrete tools for approximating European patent laws and, as a result, national rules on patent infringement in Europe are very much alike.⁴⁰⁰ In addition, these harmonisation efforts contributed to what is called as 'EU patent package' – a deal agreed upon and signed by 25 EU Member States in February 2013.⁴⁰¹ If it takes effect⁴⁰², the Unitary Patent Package

will establish the necessary legal framework for the creation and enforcement of unitary patent protection in the territories of 13 or more participating EU Member States.⁴⁰³

A patent gives the owner an exclusive and absolute right to exploit the invention covered by the patent. It gives the owner 20 years of protection. In order for a patent to be valid, there must be an invention which is new and inventive (not obvious to a person skilled in the art). It must be capable of industrial application and not within a list of excluded inventions. Those are the requirements of patentability, the basic rule of which is contained in Article 52(1) EPC.⁴⁰⁴ According to Article 57 EPC, an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. This rule is supplemented by Article 53 EPC⁴⁰⁵, which excludes three categories of subject matter from protection regardless of whether they satisfy the requirements of patentability. The third category which excludes the methods of surgical, therapeutic and diagnostic treatment from the patentability is particularly interesting for the 3D printed medical devices. To this extend it is important to keep in mind that the term 'human body and its elements' was defined in

³⁹⁵ Ballardini, Rosa Maria, Norrgård, Marcus, Minssen, Timo. Enforcing patent sin the era of 3D printing. *Journal of Intellectual Property Law & Practice*, 2015, Vol. 10, No. 11, 850 – 866.

³⁹⁶ Convention on the Grant of European Patents of 5 October 1973, in force as from 7 October 1977.

³⁹⁷ Ballardini, Norrgård, Minssen. Op. cit. 406

³⁹⁸ Idem.

³⁹⁹ Idem.

⁴⁰⁰ Idem.

⁴⁰¹ Idem.

⁴⁰² It will take effect when 13 states, including France, Germany and the UK, ratify the UPC Agreement. It remains yet to see the impact of UK leaving the EU on the above mentioned condition.

⁴⁰³ Pila, Justine, Torremans, Paul L.C, Introduction to European Patent Law in *European Intellectual Property Law*. Oxford University Press, 2016. 113 – 133.

⁴⁰⁴ Patentable inventions, Article 52(1) of the European Patent Convention: *'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'*

⁴⁰⁵ Exceptions to Patentability, Article 53 of the European Patent Convention: *'European patents shall not be granted in respect of:*

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.'



the Article 29 of the Implementing Regulations to EPC⁴⁰⁶. A diagnostic method has been defined as any method that includes four steps: a) examination; b) data gathering; c) comparison; and d) deduction, all performed directly on the human or animal body. However, it does not include any diagnostic method which includes technical steps carried out by a device, consistent with the limited purpose of the exclusions. Regarding the exception on surgical methods, there are two possible subject matters. The first are physical interventions requiring professional medical skills to be performed and involving health risks even when carried out with the requisite medical care and skills; and the second are uncritical methods involving only a minor intervention and no substantial health risks when carried out with the required care and skill. Only subject matter of the first type are to be excluded from patentability by Article 53(c) EPC.⁴⁰⁷ Such subject matter includes interventions that represent the core of the medical profession's activities, being interventions of a type for which members of that profession are specifically trained and assume a particular responsibility.⁴⁰⁸ By contrast are such subject matters as methods of tattooing, piercing, hair removal by optical radiation etc., which are consequently patentable.⁴⁰⁹ There are two types of liability recognized both by the CPC and in the UPC agreements: direct and indirect infringement, giving rise to 'strict' liability under patent law and giving rise to what is usually called 'secondary' liability, respectively.⁴¹⁰

According to Article 25, a Community patent granted under the CPC would have conferred the right on its owner to prevent a third party from making, using, putting on the market or using the patent invention.⁴¹¹ That would be direct infringement, which is doctrinally structured to something like 'strict' liability and concerns the entirety of the patented invention, including equivalents. Another element of strict liability is the fact that it includes little subjectivity on the 'quality' of the infringement, i.e. infringing activities are found independently of whether the alleged infringer had actual or constructive knowledge on the existence of a patent.

Article 26 provides when the patent holder could prevent a third party from the indirect uses of the protected invention. Namely in the cases of supplying or offering to supply a third party with means, relating to an essential element of that invention, for putting it into effect on the national territory, when the third party knows, or it is obvious in the circumstances, that these are suitable and intended for putting that invention into effect. Historically, indirect patent infringement was contemplated in order to facilitate the enforcement of patent rights by enabling patentees to start legal action already before their patent had been infringed directly.⁴¹² What is important is that in most of the European jurisdictions indirect infringement can be committed even where no direct infringement has occurred.

Although the CPC was never ratified and hence Articles 25 and 29 have never taken effect, the definition of patent rights that they contain has been widely adopted at the national, European and international levels, as we will further see. Thus, it can be said that the abovementioned articles formed the

⁴⁰⁶ Human body and its elements, Article 29 REPC: (1)

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

⁴⁰⁷ Pila, Justine, Torremans, Paul L.C, Introduction to European Patent Law in European Intellectual Property Law. Oxford University Press, 2016., pg. 170.

⁴⁰⁸ Idem.

⁴⁰⁹ Idem.

⁴¹⁰ Pila, Justine, Torremans, Paul L.C, Introduction to European Patent Law in European Intellectual Property Law. Oxford University Press, 2016.

⁴¹¹ Idem.

⁴¹² Ballardini, op.cit. 406



basis for the large harmonization of statutory definitions of patent rights throughout Europe.

The question worth of discussing is whether providing access to a CAD file representing a patented invention would qualify in patent law as providing the required 'means' to an essential element of the invention. Furthermore, can digital items that are not necessarily computer programs, like CAD files, qualify as 'means', and are digital blueprints like CAD files either merely a set of instructions on how to make the invention or something more than that? CAD files are purely digital entities and a software has to be used in order to make one file of such a kind. So far, the only potential digital means for indirect infringement relates to software and it is yet to see whether the courts will extend the scope to other digital works. However, the recent case law from the ECJ in the case C-519/13 *Art & Allposters* provided that digital exhaustion of sold copyright-protected works can take place in the case of software but not other types of digital works. Despite the fact that the decision concerns the copyright law, it is worth of noting that the Court's logic was based on the fact that the software, in contrast to other digital works, is a general purpose technology that carries certain types of special characteristics which are distinguishable from other digital works. The decisive step for the interpretation of indirect infringement theory, in particular in the area of 3D printing will be the courts' interpretation of the digital works in the light of the qualifications needed to fall under the category of 'means'. Hence, the ultimate and the most relevant question remains whether CAD files are 'means', rather than whether they are software.⁴¹³

Arguably the majority of IP rights qualify as **copyright**. At first sight, it may seem like our society already got used to constant technological development and that we are all able to embrace the novelties and changes that technology is bringing to us, nearly on the daily basis. However, this step into the future may be postponed by copyright law.⁴¹⁴ Should we learn

a lesson from the past and should we follow the footsteps of the printing press, the Xerox machine, and the DVR, the 3D printer could potentially cause more copyright complications than all the previous advances in technology combined.⁴¹⁵

The EU's regulatory framework for copyright and neighbouring rights (*acquis*) is a set of ten directives, addressed to the EU Member States, the most prominent of which is the so-called 'InfoSoc Directive'⁴¹⁶. Despite the so far done effort and endeavour coming from the European streams, there is still no harmonized European copyright law, and hence there are some differences between the national laws. However, many of the EU directives reflect Member States' obligations under the Berne Convention and the Rome Convention, as well as the obligations of the EU and its Member States under the World Trade Organisation 'TRIPS' Agreement and the two 1996 World Intellectual Property Organisation (WIPO) Internet Treaties (the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty).⁴¹⁷

Copyright requires no registration under the EU law and grants protection for the period of 70 years after the author's death⁴¹⁸. To be granted with this right, prerequisite that has to be fulfilled is 'originality', interpretation of which varies according to the applicable law⁴¹⁹. The actual scope will vary depending on the relevant jurisdiction. Original, creative objects are protected, and 3D CAD file written from scratch could potentially be protected as well, due to its technical drawings, diagrams and models. Also, derivative works are copyrightable as well. In contrast, specific materials used for the production cannot be protected under copyright law, as well as shapes with purely technical function, since they are considered to be lacking requirement of originality.⁴²⁰ However, it is important to stress out that medical devices are typically utilitarian, rather than original artistic

⁴¹³ Ballardini, op.cit. 406

⁴¹⁴ Swanson, Sarah. 3D Printing: A lesson in history. How to Mold the World of Copyright. *Southwestern Law Review*; Vol. 43 Issue 3 (2014): 483 – 515.

⁴¹⁵ Idem.

⁴¹⁶ Directive on the harmonisation of certain aspects of copyright and related rights in the information society, 22 May 2001

⁴¹⁷ The EU Copyright Legislation: <https://ec.europa.eu/digital-single-market/en/eu-copyright-legislation> (last visited on 12 March 2017)

⁴¹⁸ Pila, Justine, Torremans, Paul L.C. *European Intellectual Property Law*. Oxford: Oxford University Press, 2016

⁴¹⁹ Idem.

⁴²⁰ Idem.



objects and thus do not often qualify for copyright protection.⁴²¹ Nevertheless, copyright implications may still be relevant for replication of medical devices through 3D printing.

An important question to be clarified by courts and in particular by the European Court of Justice would be if and to what extent a CAD file is capable of copyright protection. Arguments in favour of giving a CAD file a copyright protection are because of its technical drawings, diagrams and models. On the other hand, courts need to be aware that no copyright is granted to technological solutions and progress.

The reproduction right according to Article 2(1) of the InfoSoc Directive has a very wide scope, since reproduction by any means and in any form – even indirect and temporary reproduction – will not be deemed as lawful, if it lacks a rightsholder's authorization. The same provision also forbids reproducing a part of a copyright protected work, providing that even including a small piece of previously manufactured 3D printed medical device into producing a new 3D printed medical device, would be considered as infringement of the first produced 3D medical device's rights.

The Software Directive⁴²² as well as the Database Directive⁴²³ provide copyright protection for computer programs and databases. Article 1(1) of the Software Directive makes it clear that computer programs shall be protected by copyright, 'as literary works within the meaning of the Berne Convention for the Protection of Literary and Artistic Works.'⁴²⁴ According to Article 1(2) of the Software Directive, protection 'shall apply to the expression in any form of a computer program.'⁴²⁵ A computer program is protected when 'it is original in the sense that it is the author's own intellectual creation. No other criteria shall be applied to determine its

eligibility for protection.'⁴²⁶ In the similar manner the Database Directive determines that 'databases, which, by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation shall be protected as such by copyright. No other criteria shall be applied to determine its eligibility for protection.'⁴²⁷ The Software Directive and the Database Directive are the only two legislative pieces of the EU copyright law that contain harmonized definition of the copyright⁴²⁸. They both specifically refer to the Berne Convention. This means that the definition of copyright is not harmonised when it comes to the application of the other directives on copyright, and that the national law decides for the other directives what works are copyright protected and may be covered by those directives.⁴²⁹ Computer software therefore requires no registration under the EU law and grants protection for the period of 70 years. A form of expression of computer code is the object of protection, not the CAD file which is not meant to be executed by the computer, but, instead, read by the computer. The functionality of software is, on contrary, not protected because it is not considered to represent a form of expression⁴³⁰.

Trademark as an intellectual property right aims at establishing the identification of particular products or services in a way which distinguishes them from similar products and services coming from other sources. Registration here is obligatory and it can be renewed for unlimited period of time, as long as the mark is kept in use. In limited cases registration is accepted for the shape of products. In order to register a mark as a trademark, mark has to be legitimate, distinctive and has to be graphically represented. The private use in non-commercial purposes cannot be considered as trademark infringement, since the trademark law gives the owner the monopoly over the usage of the sign as a trademark – which

⁴²¹ Davies, Colleen, Jacobson Matthew, Tabibkhpei (editors), 3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles. Reed Smith, White Paper. September 2015. https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf (last visited 1 April 2017)

⁴²² Directive on the legal protection of computer programs, 23 April 2009

⁴²³ Directive on the legal protection of databases, 11 March 1996

⁴²⁴ Article 1(1) of the Software Directive

⁴²⁵ Article 1(2) of the Software Directive

⁴²⁶ Article 1(3) of the Software Directive

⁴²⁷ Article 3(1) of the Database Directive

⁴²⁸ Mazziotti, Giuseppe, EU Digital Copyright Law and the End-User, Springer, Berlin, 2008, page 53.

⁴²⁹ Idem.

⁴³⁰ Pila, Torremans, 414



means as an indicator of source or badge of origin in the course of trade. If there is no trade, no infringement can occur. Trademarks hence help a device manufacturer guard against counterfeiting of its products. For products that bear a manufacturer's trademark, a 3D printer who includes the manufacturer's mark on its 3D printed products will run afoul of trademark law and anti-counterfeiting laws.⁴³¹ On the other hand, 3D printed products that do not include the manufacturer's trademarks, may be easier to notice as unauthorized copies.⁴³² In 2015 European Trademark law significantly improved by adopting the so-called 'Trademark Package': 'Trademark Directive'^{433 434} and 'Trademark Regulation'⁴³⁵. Within EU member states, national law implements Directives so that the law governing national registrations in each jurisdiction is more or less equivalent. The Benelux countries have introduced a common trade mark applying in their countries, abolishing their national trade marks. There are two main ways to register a trade mark in the EU. They can either be registered at national level at the industrial property offices of EU countries, or at EU level as a 'European Union trade mark' (EUTM) at the European Union Intellectual Property Office (EUIPO).

National and EUTMs coexist and are complementary to each other. The same trade mark can be registered at EU and/or national level. The EUTM system consists of one single registration procedure that grants the owner an exclusive right in all 28 EU countries. This dual system meets the requirements of companies of different sizes, markets and geographical presence. National trade marks may be better for small and medium-sized enterprises (SMEs) or local firms who don't need EU-wide protection.

In the 3D printing context, trademarks are likely to figure in three scenarios: objects being printed which incorporate a graphical 2D trade mark on their surface, 3D representations of 2D trademarks being printed, and 3D items which themselves constitute or replicate a 3D shape mark.⁴³⁶ When addressing and assessing the relevant issues with regard to intellectual property aspects, two different processes must be analysed, namely the creation process and dissemination process, both of which can relate to the 3D model (object design file) and the 3D replica.

The area of **design rights** is another area where there has been a directive harmonizing national laws on designs⁴³⁷. Design protection is harmonised rather extensively through Directive 98/71/EC on the legal protection of designs, hereafter called DD. DD was adopted in order to make an approximation of the Member States' national laws.⁴³⁸ One of the objectives of the directive is to 'give a unitary definition of the notion of design and of

⁴³¹ Davies, Colleen, Jacobson Matthew, Tabibkhpei (editors), 3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles. Reed Smith, White Paper. September 2015. https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf (last visited 1 April 2017)

⁴³² Ibid.

⁴³³ [Directive \(EU\) 2015/2436 to approximate the laws of the Members States relating to trade marks](#), 16 December 2015

⁴³⁴ Harmonisation Directive 2008/95/EC to approximate the laws of the Member States relating to trade mark will be repealed as from 15 January 2019, but currently is still in force.

⁴³⁵ Regulation (EU) 2015/2424 amending Council Regulation (EC) No 207/2009 on the Community trade mark and Commission Regulation No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community trade mark, and repealing Commission Regulation (EC) No 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trade Marks and Designs), 16 December 2015

⁴³⁶ Socio-Legal Aspects of the 3D Printing Revolution, pg 37

⁴³⁷ European Parliament and Council Directive 98/71/EC on the legal protection of designs [1998] OJ L 289/28, that runs in parallel with a regulation creating a community design – Community Regulation (EC) No. 6/2002 of 12 December 2001 on community designs [2002] OJ L 3/1, as amended by Council Regulation 1891/2006 [2006] OJ L 386/14

⁴³⁸ Directive 98/71/EC of the European Parliament and of the Council on the legal protection of designs, [1998] OJ L 289/28, hereafter referred to as the DD, recitals 5-6 in the preamble.



the requirements as to novelty and individual character with which registered design rights must comply.⁴³⁹ However, the Member States have their own national procedural provisions on registration, renewal and invalidation.⁴⁴⁰ The Council Regulation 6/2002 on Community designs⁴⁴¹, regulates Community designs, i.e. designs that are uniformly protected in the entire EU when they are registered⁴⁴². A Community design is directly applicable in each Member State through one application made to EUIPO⁴⁴³ after going through one single procedure⁴⁴⁴. According to recital 15, the Community designs 'should, as far as possible, serve the needs of all sectors of industry' in the EU.

Design is the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.⁴⁴⁵ If the object's appearance is determined exclusively by their technical function, no design protection will be granted.⁴⁴⁶ Design right holder has no remedy against those who print his model 'for their private use and not for commercial purposes'.⁴⁴⁷ In addition, holders of design rights also have no remedy against the printing of certain 'spare parts' or 'repair parts'.⁴⁴⁸ In principle, any party is allowed to make a 3D printout of such a repair part for an object under the design right's protection, provided that the manufacturer of the repair part imitates the original object, 'so as to restore to its original appearance'.⁴⁴⁹ A commercial party printing upon request would be entitled

to invoke the spare parts exception as well. However, a spare part created by a 3D printer would have to look the same as the original part. The question is whether a contractor is always in the position to determine whether this requirement has been met.⁴⁵⁰ Here again it is very important for the contractor to shift the liability for possible infringement to its assignor by means of waivers and disclaimers specifically targeted at this particular situation.⁴⁵¹ Design rights can be registered or unregistered. Registration is required for long-term protection, which is renewable every 5 years, with the maximum of 25 years of protection. For unregistered design right, no registration is required and protection that cannot be renewed is granted during 3 years from the date of disclosure. Conditions that must be met in order to be granted with the design right protection are new appearance and individual character of the whole or part of an object towards the informed user, i.e. overall impression of dissimilarity to previously existing designs. Design rights cover the external shape and features of the whole or part of the product, as well as the appearance of the materials, but do not cover raw materials, internal parts not visible during normal usage, computer programs, features determined by technical function only, an object that is commonplace in the relevant technical field nor the design features configured for mechanical connection to another product.⁴⁵²

Design right could potentially be the most useful intellectual property right for larger manufacturers to challenge commercial 3D printing. Whether they

⁴³⁹ DD, recital 9 of the preamble.

⁴⁴⁰ DD, recital 6 of the preamble.

⁴⁴¹ Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs, hereafter referred to as the CDR.

⁴⁴² Recital 1 of the preamble of CDR.

⁴⁴³ EUIPO stands for European Union Intellectual Property Office. However, the recital refers to the 'the Office for Harmonisation in the Internal Market (Trade Marks and Design)', which is how the office was called back in that time.

⁴⁴⁴ Recital 5 of the preamble of CDR.

⁴⁴⁵ COUNCIL REGULATION (EC) No 6/2002 of 12 December 2001 on Community designs, Article 3

⁴⁴⁶ COUNCIL REGULATION (EC) No 6/2002 of 12 December 2001 on Community designs, Preamble (10), Article 10.

⁴⁴⁷ COUNCIL REGULATION (EC) No 6/2002 of 12 December 2001 on Community designs, Article 20, par. 1

⁴⁴⁸ COUNCIL REGULATION (EC) No 6/2002 of 12 December 2001 on Community designs, Article 20, par. 2

⁴⁴⁹ COUNCIL REGULATION (EC) No 6/2002 of 12 December 2001 on Community designs, Article 110

⁴⁵⁰ De Clercq Advocaten, White Paper: The Legal Aspects of 3D Printing from a European Perspective. Leiden/Den Haag, November 2015 <https://www.declercq.com/assets/uploads/old/images/stories/pdf/white%20paper%20legal%20aspect%20of%203d%20printing%20-%20de%20clercq.pdf> (last visited 26 February 2017)

⁴⁵¹ Idem.

⁴⁵² Pila, Torremans, 414



are registered or unregistered, and valid, the manufacturing of a product incorporating the protected design will be illegal, if done by third party for commercial purposes, even without intention and knowledge of the infringing behaviour.

Table 11 – Overview IP rights

IP right	Definition	Requirements	Formalities for obtaining the right	Term
Patent	Limited-term monopoly rights granted in respect of new, inventive, and industrially applicable inventions.	Article 52(1) EPC: - Novelty - Inventive step - Susceptibility of industrial application Excluded (Article 53 EPC): - The <i>ordre public</i>/morality exclusions - The varieties and exclusively biological process exclusions - The medical methods exclusion	YES: application 3 possible routes: - National route – application to the patent office of the state in which protection is sought - European route: application to the EPO or other EPC receiving office - International route: application to the WIPO or other PCT receiving office	20 years from the filing date, the filing date being the actual date of filing an application for a European patent or the date of filing of an international application under the PCT designating the EPO.
Copyright	Limited-term exclusionary rights that subsist automatically in authorial works.	In the continental law system (<i>droit d'auteur</i> system), notion “work” is an open list. Copyright protects expression in an original form and does not extend to ideas, procedures, methods of operation or mathematical concepts as such.	NO – forbidden under Berne Convention (Article 5(1)).	70 years (EU)
Trademark	Signs used in trade to identify the origin of products, also being indicative of the quality of the associated product. They can also be referred to as “brands”.	3 essential requirements: - a sign - capable of being represented graphically - distinctiveness as to origin	YES: registration needed 4 options: National level, via national EU IP offices; Regional level registration in Belgium, the Netherlands and/or Luxembourg, via BOIP;	The effect of registration is to confer exclusive rights in the mark and the right to bring actions for infringement of the right for a period of 10 years , which is renewable for further



Design rights		• EU-wide protection (all EU Member States) via EUIPO; • International registration via WIPO.	period of 10 years (Community TM).
	Protect the appearance of a product, which results from attributes such as its shape, colours or materials. According to the Regulation on community design, design rights can be registered (RCD) or unregistered (UCD).	• Novelty • Individual character YES – for registered community rights NO – for unregistered community rights	A <i>registered</i> Community design is initially valid for five years from the date of filing and can be renewed in blocks of five years up to a maximum of 25 years. An <i>unregistered</i> Community design is given protection for a period of three years from the date on which the design was first made available to the public within the territory of the European Union. After three years, the protection cannot be extended.



Key points

- Patent owner has the right to prevent a third party from direct infringements by making, using, putting on the market or using the patent invention, but can also prevent a third party from the indirect uses of the protected invention.
- The question with regard to patent law is whether providing access to a CAD file representing a patented invention would qualify as providing the required 'means' to an essential element of the invention.
- There is still no harmonized European copyright law.
- To be granted with copyright, prerequisite that has to be fulfilled is 'originality', interpretation of which varies according to the applicable national law.
- Medical devices are typically utilitarian, rather than original artistic objects, and thus do not often qualify for copyright protection.
- Private use in non-commercial purposes cannot be considered as trademark infringement.
- Trademarks can help a device manufacturer guard against counterfeiting of its products.
- Design right could potentially be the most useful intellectual property right for larger manufacturers to challenge commercial 3D printing.

5.11.1.1 Infringements in the different phases of the 3D printing process and enforcement of the IP rights

Infringements

- Possible infringements in the technology's creation process with regard to the 3D models (CAD files).

Copyrightable object itself, 3D scanning software, including the graphic user interface or programming language and a CAD file (written from scratch or as a derivative work) may be infringed by different actions, either by digitising an object with a 3D scanner, or by copying the software or the CAD file. It is important to stress out that the private use will not be considered as infringing, if such a use is excepted under applicable copyright law. Examples of such valid exceptions are given in the Article 5 of the InfoSoc Directive: private copying (Article 5, 2 (b), provided the source of the 3D copy was legal) or repair (Article 2, 3 (I)). In addition, reverse engineering is possible. Software (computer code) could be infringed by the action of temporary or permanent copying of the program, by distributing it to the public or by translating, adapting or performing other alteration to the program. Reverse engineering is again possible, and the actual functionality of the software is not protected. Design right in this creation phase covers the shape and configuration of the object. Digitisation of the object may constitute an infringement and in contrast private and non/commercial use will not be considered as infringing. Patent right protects the innovation or the technology contained in the object. Patent right could be infringed by reversed engineering or by using or producing the invention. There are no exceptions for independent creations. Trademark right protects the trademark as it has been officially registered.

- Possible infringements in the technology creation process with regard to the 3D printed object itself.

Copyrightable 3D printed object may be infringed by actual reproduction. Patented 3D printed objects may be infringed by making the object, although printing for personal use is not infringing. 3D printed objects protected by trademark may be infringed by commercial 3D printing using the trademark in a way that consumers would think the object is produced by the trademark owner. Private printing at home would not constitute an infringement.



- Possible infringements in the technology's dissemination process.

With regard to the 3D models/CAD files, copyright infringement would be caused by sharing the CAD file, whereas patent rights would be infringed by the act of uploading the CAD file. Using the trademark when commercially disseminating the CAD file would constitute infringement of the trademark.

With regard to the 3D printed object itself, copyrightable 3D printed object may be infringed by the actual reproduction by the maker of the 3D printed object and here private use would be considered as infringing. If someone would put a product incorporating a protected design on the market, or would offer it for sale, perform marketing activities, import or export such a product, design rights of the 3D printed object in question would be infringed. To this extend, selling or trading the 3D object copying the invention would certainly constitute infringement of the patent rights. Also, using the trademark when commercially disseminating the 3D printed object would constitute infringement of the trademark rights.

3D Printing and enforcement of intellectual property rights

Right holders have two possibilities: they can either go after the end-user or after intermediaries involved in the creation and dissemination process.

If the first option is chosen – enforcement against the end-user, one must keep in mind that, with exception of the copyright, other intellectual property rights require a commercial use and therefore are not useful against the end-user. However, it may be difficult in practice to go after the end-user and prove that the object is counterfeit.

Enforcement against the intermediary may involve multiple players: the maker of the CAD files, the platform hosting the CAD files (if such hosting is done without his consent), the maker of the 3D printer or the printer operator.

Some of these intermediaries could be held liable together with the end-user, imposing this way a joint liability; or another option is that a right-holder

claims indirect liability for materially contributing to, facilitating, including infringing acts directly carried out by end-user.

Hosting platforms that disseminate digital files of protected objects will often be an interesting target since they present the real source problem, especially if they are actively encouraging the infringement. However, there are several critical points to this extend. Firstly, it seems that none of the known online platforms for 3D CAD files actively encourage counterfeit. Secondly, all liability in any case is put on the end-users, as it is stated in the most of the terms and conditions of the online platforms. Thus, end-users are made responsible for the content they design, edit, modify, customise, remix and share. In addition, most of these platforms appear to be based outside the EU and governed by the laws of these foreign countries. Therefore, it is not possible to invoke the European e-commerce hosting provisions towards them. Also, it is important to emphasize that only in case when a platform hosting the CAD file plays an active role in the infringement and consciously allows infringements while not expeditiously removing the infringing content upon receipt of a motivated notice thereof, secondary liability will raise in relation to such a platform. For example, Thingiverse is extremely vigilant regarding potential copyright claims and the website makes it very clear that any CAD files that breach the rights of third parties are strictly prohibited.⁴⁵³

⁴⁵³ Thingiverse. Terms of Use. 2016.
<http://www.thingiverse.com/legal/terms> (Accessed 2017-15-02)



Key points

- **Copyrights can be infringed by digitising an object with a 3D scanner, or by copying the software or the CAD file, by actual reproduction of the copyrighted 3D object and later by sharing the CAD file.**
- **Copyrights on the software (computer code) could be infringed by the action of temporary or permanent copying of the program, by distributing it to the public or by translating, adapting or performing other alteration to the program.**
- **Patent right could be infringed by reversed engineering or by using or producing the invention; patented 3D printed objects may be infringed by making the object and the act of uploading the CAD file would also be regarded as the patent infringement.**
- **3D printed objects protected by trademark may be infringed by commercial 3D printing using the trademark in a way that consumers would think the object is produced by the trademark owner.**
- **Right holders can go after the end-user or after intermediaries involved in the creation and dissemination process to enforce their rights.**

5.11.2 Belgium

Unlike trade mark and design protection, which are obtained according to two unitary Benelux laws, patent protection is still regulated by national provisions in Belgium, the Netherlands and Luxemburg.⁴⁵⁴ Patent protection must therefore be sought separately in each country using the national procedure or the European patent system.⁴⁵⁵ Patent law is regulated by 28 mars 1984 - Loi sur les brevets d'invention (mise jour le 22 décembre 2008). According to the Belgian Patent Register, 97.7% of Belgian patents issued in 2004 followed the so-called 'European route', for obtaining the regional European protection.⁴⁵⁶ Belgium offers a very powerful enforcement tool to patent owners: the descriptive seizure aimed at gathering evidence of a suspected infringement. Under Article 1369bis of the Belgian Judicial Code, the holder of intellectual property rights (including patents) can file an *ex parte* petition with the president of the competent commercial court, without having to make a showing of urgency, seeking the appointment of an independent expert in order to gather all relevant information about the alleged infringement (including its origin and scope) at the alleged infringer's premises. The petitioner can also request seizure measures. These "descriptive seizure proceedings" are widely used and quite successful in patent cases. Presumption of infringement is already sufficient to convince a Belgian judge to grant a patent owner a unilateral right to perform a descriptive seizure without prior notice at the requested location(s).⁴⁵⁷ The Belgian Parliament recently adopted a new regulation (Law of 29th June 2016, containing various provisions regarding the economy, articles 22, 48, 60) impacting patent validations in Belgium.⁴⁵⁸

Copyright law is governed by Code de droit économique - Livre XI. On 22 May 2005 the Law on the implementation of the Directive on the harmonisation of certain aspects of copyright and related rights in the information society was adopted in Belgium. It is interesting that Belgium is

⁴⁵⁴ Gevers, François, Quintelier, Claude, How to deal with patent protection in Belgium. [Managing Intellectual Property](#). Apr2005, Issue 148, p67-69. 3p.

⁴⁵⁵ Idem.

⁴⁵⁶ Idem.

⁴⁵⁷ Idem.

⁴⁵⁸ Namely, the new Belgian Regulation grants a waiver of European patent translation requirements in Belgium as from 2017. More on: <https://www.valipat.com/news/2016/10/17/new-belgian-regulation.html> (last visited 26 March 2017)



one of the few member states, if not the only one, that provides that all exceptions⁴⁵⁹ are of a mandatory nature.⁴⁶⁰

Trademark law relevant regulations are Benelux Convention on Intellectual Property (BCIP) (version 1 October 2013) and Regulation N° 207/2009 on the Community trade mark (codified version). For a Benelux trade mark, there is a mandatory deposit in Brussels or at the BOIP in The Hague. According to where you wish to register trademark protection, you must use the procedure for a Benelux trademark or a Community trademark.⁴⁶¹

The protection of a design or model in Belgium may be obtained through a Benelux design right (covering the territory of the three Benelux countries: Belgium, the Netherlands and Luxembourg), from the Benelux Office for Intellectual Property (BOIP). This protection is organised by the Benelux Convention of 25 February 2005 on intellectual property.⁴⁶²

Key points

- **Descriptive seizure as a very powerful enforcement tool for patent owners.**
- **For a Benelux trade mark, there is a mandatory deposit in Brussels or at the BOIP in The Hague.**

⁴⁵⁹ The previous list of exceptions already included uses for purposes of (1) citation, (2) the making of anthologies, (3) reporting of current events, (4) use of works located in public places, (5) communications taking place in domestic premises, (6) reprography for private use, (7) reproductions for teaching and research, (8) private copying of audiovisual works, (9) caricature, parody and pastiche, (10) communications for public exams, zur Fussnote 16 (11) reproductions by the Royal Film Archive and (12) the public lending right.

The 2005 Act has extended the list with six new exceptions including (13) temporary copying, (14) communications by dedicated terminals on the premises of certain establishments, (15) ephemeral recording by broadcasting organizations, (16) use for the benefit of people with a disability, (17) use for public exhibitions and sales and (18) reproduction of broadcasts by social institutions.

- **The protection of a design or model in Belgium may be obtained through a Benelux design right from BOIP.**

5.11.3 Conclusion

IP law in its current form appears sufficient to effectively protect both 3D files and those using 3D printing technologies for non-commercial purposes. However, there are many questions yet to be discussed relating to the specificities of the 3D printing process. For example, who would be considered as an owner of the 3D object in case when it was first conceived by one individual, digitally modelled by another, and printed by a third? Can a person who designed the work and the person who digitally modelled it be considered as co-authors of a collaborative work under copyright law? And if the object qualifies for patent protection, would abovementioned actors be considered as co-inventors?

3D printing although still in infancy, as on-going technological development, has been viewed as a disruptive and revolutionary technology for IP law. However, in practice the picture is rather different. The DMCA takedown notice regime has been used with regard to the online sharing website platforms and it resulted in removing certain files uploaded by users alleged to infringe IP, even if there was no copyright infringement from a practical point of view. Technological protective measures (TPMs) are also being considered in 3D printing as limitation of users' possibilities regarding design

⁴⁶⁰ Janssens, Marie-Christine, Implementation of the 2001 Copyright Directive in Belgium, International Review on Intellectual Property and Competition Law, (IIC): 2006, Volume: 37, Issue: 1, Pages: 50-62

⁴⁶¹ Trademarks. http://economie.fgov.be/en/entreprises/Intellectual_property/Trademarks/#.WOziJUangsp (last visited on 3 March 2017).

⁴⁶² Designs: https://www.boip.int/wps/portal/site/designs/action-register/tut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOKdg5w8HZ0MHQ0szFwMDTxdLQLMg919LZyDzIAKlpEVGPg6mRt4-jp6efv5-BibWBoT0h-uH4WqBM0EU3MCCkBWgBUY4ACOBvoFuREGmZ6OigCApnl/dl5/d5/L2dBISEvZ0FBIS9nQSEh/ (last visited on 3 March 2017).



files and their machines. Furthermore, unlike some assumed that 3D printing would be disruptive to many current industries, the reality is that many companies from these sectors are investigating how to use 3D printing technology themselves. To this extend, many of them do not see consumer-oriented 3D printing as a major threat to their activity and IP now. Arguments that can be often heard that the EU is lacking behind the USA when it comes to taking appropriate legislative measures with regard to the 3D printing technologies and IP area seems to be invalid, since there have been many differences between the European and American systems since long time ago. Each of the approaches has its own philosophy behind, but it can be said that European legislator is making a lot of effort to adapt its legislation to the technological development, and accordingly that have a huge influence on the national laws of the Member States. It is then only yet to see how this will change as the time passes, 3D printing technology advances and the availability of better-quality machines rises. However, it can be argued that for the moment, the potential for 3D printing to disrupt IP laws is not really being realised in practical way.



■ REFERENCES

1. Tack P, Annemans L. Preliminary cost-effectiveness assessment of 3D printed anatomic models for congenital heart diseases. *Value in Health*. 2016;19(7):A692.
2. Huijbregts HJ, Khan RJ, Fick DP, Hall MJ, Punwar SA, Sorensen E, et al. Component alignment and clinical outcome following total knee arthroplasty: a randomised controlled trial comparing an intramedullary alignment system with patient-specific instrumentation. *Bone Joint J*. 2016;98-B(8):1043-9.
3. Shea BJ, Bouter LM, Peterson J, Boers M, Andersson N, Ortiz Z, et al. External validation of a measurement tool to assess systematic reviews (AMSTAR). *PLoS One*. 2007;2(12):e1350.
4. Higgins JPTA, D.G.; Sterne, J.A.C.; (editors), . Chapter 8: Assessing risk of bias in included studies. . In: *Cochrane Handbook for Systematic Reviews of Interventions 5.1.0* (updated March 2011) ed: The Cochrane Collaboration; 2011.
5. Deeks J, Bossuyt P, Gatsonis C, editors. *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy Version 1.0: The Cochrane Collaboration*; 2010.
6. Bilgin MS, Baytaroglu EN, Erdem A, Dilber E. A review of computer-aided design/computer-aided manufacture techniques for removable denture fabrication. *Eur J Dent*. 2016;10(2):286-91.
7. Cavaignac E, Pailhé R, Laumond G, Murgier J, Reina N, Laffosse JM, et al. Evaluation of the accuracy of patient-specific cutting blocks for total knee arthroplasty: a meta-analysis. *Int. Orthop*. 2015;39(8):1541-52.
8. Chao I, Young J, Coles-Black J, Chuen J, Weinberg L, Rachbuch C. The application of three-dimensional printing technology in anaesthesia: a systematic review. *Anaesthesia*. 2017.
9. Malik HH, Darwood ARJ, Shaunak S, Kulatilake P, El-Hilly AA, Mulki O, et al. Three-dimensional printing in surgery: a review of current surgical applications. *J Surg Res*. 2015;199(2):512-22.



10. Mannan A, Akinyooye D, Hossain F. A Meta-analysis of Functional Outcomes in Patient-Specific Instrumented Knee Arthroplasty. *J. Knee Surg.* 2016.
11. Martelli N, Serrano C, Van Den Brink H, Pineau J, Prognon P, Borget I, et al. Advantages and disadvantages of 3-dimensional printing in surgery: A systematic review. *Surgery.* 2016;159(6):1485-500.
12. Popescu D, Laptoiu D. Rapid prototyping for patient-specific surgical orthopaedics guides: A systematic literature review. *Proc Inst Mech Eng H.* 2016;230(6):495-515.
13. Randazzo M, Pisapia JM, Singh N, Thawani JP. 3D printing in neurosurgery: A systematic review. *Surg Neurol Int.* 2016;7(Suppl 33):S801-S9.
14. Soon DSC, Chae MP, Pilgrim CHC, Rozen WM, Spychal RT, Hunter-Smith DJ. 3D haptic modelling for preoperative planning of hepatic resection: A systematic review. *Ann Med Surg (Lond).* 2016;10:1-7.
15. Tack P, Victor J, Gemmel P, Annemans L. 3D-printing techniques in a medical setting: a systematic literature review. *Biomedical Engineering Online.* 2016;15(1):21.
16. Thienpont E, Schwab P-E, Fennema P. Efficacy of Patient-Specific Instruments in Total Knee Arthroplasty: A Systematic Review and Meta-Analysis. *J Bone Joint Surg Am.* 2017;99(6):521-30.
17. Hendel MD, Bryan JA, Barsoum WK, Rodriguez EJ, Brems JJ, Evans PJ, et al. Comparison of patient-specific instruments with standard surgical instruments in determining glenoid component position: A randomized prospective clinical trial. *J. Bone Jt. Surg. Ser. A.* 2012;94(23):2167-75.
18. Qiu B, Tang B, Deng B, Liu F, Zhu W, Zhen D, et al. Clinical Study of 3D Imaging and 3D Printing Technique for Patient-Specific Instrumentation in Total Knee Arthroplasty. *Journal of knee surgery.* 2017;(no pagination).
19. Shuang F, Hu W, Shao Y, Li H, Zou H. Treatment of Intercondylar Humeral Fractures With 3D-Printed Osteosynthesis Plates. *Medicine (Baltimore).* 2016;95(3):e2461.
20. Yang L, Shang XW, Fan JN, He ZX, Wang JJ, Liu M, et al. Application of 3D Printing in the Surgical Planning of Trimalleolar Fracture and Doctor-Patient Communication. *BioMed Research International.* 2016;2482086.
21. Gan Y, Ding J, Xu Y, Hou C. Accuracy and efficacy of osteotomy in total knee arthroplasty with patient-specific navigational template. *Int J Clin Exp Med.* 2015;8(8):12192-201.
22. Pfitzner T, Abdel MP, von Roth P, Perka C, Hommel H. Small improvements in mechanical axis alignment achieved with MRI versus CT-based patient-specific instruments in TKA: a randomized clinical trial. *Clin Orthop Relat Res.* 2014;472(10):2913-22.
23. Mannan A, Smith TO. Favourable rotational alignment outcomes in PSI knee arthroplasty: A Level 1 systematic review and meta-analysis. *Knee.* 2016;23(2):186-90.
24. Small T, Krebs V, Molloy R, Bryan J, Klika AK, Barsoum WK. Comparison of acetabular shell position using patient specific instruments vs. standard surgical instruments: a randomized clinical trial. *J Arthroplasty.* 2014;29(5):1030-7.
25. Zhang YZ, Chen B, Lu S, Yang Y, Zhao JM, Liu R, et al. Preliminary application of computer-assisted patient-specific acetabular navigational template for total hip arthroplasty in adult single development dysplasia of the hip. *The International Journal Of Medical Robotics + Computer Assisted Surgery: MRCAS.* 2011;7(4):469-74.
26. Ayoub N, Ghassemi A, Rana M, Gerressen M, Riediger D, Hölzle F, et al. Evaluation of computer-assisted mandibular reconstruction with vascularized iliac crest bone graft compared to conventional surgery: A randomized prospective clinical trial. *Trials.* 2014;15(1).
27. Modabber A, Legros C, Rana M, Gerressen M, Riediger D, Ghassemi A. Evaluation of computer-assisted jaw reconstruction



- with free vascularized fibular flap compared to conventional surgery: a clinical pilot study. *Int J Med Robot*. 2012;8(2):215-20.
28. de Farias TP, Dias FL, Galvao MS, Boasquevisque E, Pastl AC, Albuquerque Sousa B. Use of prototyping in preoperative planning for patients with head and neck tumors. *Head & Neck*. 2014;36(12):1773-82.
29. Iannotti JP, Weiner S, Rodriguez E, Subhas N, Patterson TE, Jun BJ, et al. Three-dimensional imaging and templating improve glenoid implant positioning. *J Bone Joint Surg Am*. 2015;97(8):651-8.
30. Kozakiewicz M, Szymor P. Comparison of pre-bent titanium mesh versus polyethylene implants in patient specific orbital reconstructions. *Head & Face Medicine*. 2013;9(32):29.
31. Chrzan R, Urbanik A, Karbowski K, Moskala M, Polak J, Pyrich M. Cranioplasty prosthesis manufacturing based on reverse engineering technology. *Med Sci Monit*. 2012;18(1):MT1-6.
32. Baj A, Bolzoni AR, Gianni AB. Virtual planning and patient-specific implants in mandibular reconstruction surgery: A micro-costing analysis. *Value in Health*. 2016;19(7):A723.
33. Resnick CM, Inverso G, Wrzosek M, Padwa BL, Kaban LB, Peacock ZS. Is There a Difference in Cost Between Standard and Virtual Surgical Planning for Orthognathic Surgery? *Journal of Oral and Maxillofacial Surgery*. 2016;74(9):1827-33.
34. Rogers-Vizena CR, Sporn SF, Daniels KM, Padwa BL, Weinstock P. Cost-Benefit Analysis of Three-Dimensional Craniofacial Models for Midfacial Distraction: A Pilot Study. *Cleft Palate Craniofacial Journal*. 2016;3:3.
35. Romero L, Jiménez M, Espinosa MDM, Domínguez M. New design for rapid prototyping of digital master casts for multiple dental implant restorations. *PLoS ONE*. 2015;10(12):e0145253.
36. Yang M, Li C, Li Y, Zhao Y, Wei X, Zhang G, et al. Application of 3D rapid prototyping technology in posterior corrective surgery for Lenke 1 adolescent idiopathic scoliosis patients. *Medicine (Baltimore)*. 2015;94(8):e582.
37. Lethaus B, Bloebaum M, Koper D, Poort-Ter Laak M, Kessler P. Interval cranioplasty with patient-specific implants and autogenous bone grafts--success and cost analysis. *J Craniomaxillofac Surg*. 2014;42(8):1948-51.
38. Prisman E, Haerle SK, Irish JC, Daly M, Miles B, Chan H. Value of preoperative mandibular plating in reconstruction of the mandible.[Erratum appears in *Head Neck*. 2016 Jun;38(6):939; PMID: 27166754]. *Head Neck*. 2014;36(6):828-33.
39. Choonara YE, du Toit LC, Kumar P, Kondiah PP, Pillay V. 3D-printing and the effect on medical costs: a new era? *Expert Rev Pharmacoecon Outcomes Res*. 2016;16(1):23-32.
40. Glasziou P, Chalmers I, Rawlins M, McCulloch P. When are randomised trials unnecessary? Picking signal from noise. *BMJ*. 2007;334(7589):349-51.
41. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet*. 2009;374(9695):1105-12.
42. Ibrahim AM, Dimick JB. Monitoring Medical Devices: Missed Warning Signs Within Existing Data. *JAMA*. 2017;318(4):327-8.