

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

## APPENDIX 3





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## COLOPHON

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# 1. LEGAL QUALIFICATION OF 3D PRINTING/3D PRINTED MEDICAL DEVICES UNDER VARIOUS NATIONAL REGIMES

In the next sections an overview of the country-specific elements in France, the Netherlands, the UK and the USA related to the qualification and the requirements for placing 3D printed medical devices on the market is presented.

## 1.1. United Kingdom

### 1.1.1. Legal qualification

The MDD, IVDD and Directive 90/385/EEC regarding active implantable medical devices (see section 5.4.1 report)) are implemented in the UK by the Medical Devices Regulation 2002 (“UKMDR”). Despite the UK’s impending departure from the EU, the UK’s regulator, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) is gearing up to following the new EU Regulations on medical devices and IVDs. Whether UK law then develops its own jurisprudence, or whether it follows the *acquis* of EU law is an open question. For the foreseeable future, we anticipate that UK law on medical devices of all varieties will exactly mirror EU law.

#### 1.1.1.1. Qualification of 3D printer

See section **Error! Reference source not found.** of the report.

#### 1.1.1.2. Qualification of design software

See section **Error! Reference source not found.** of the report. The MHRA has produced guidance on the position of software as a medical device. This make it clear that, while the MHRA does not generally regulate data, databases or analytical services, software used for analysing or processing data for a medical purpose may fall within the UKMDR. It gives the example of image analysis to determine treatment; an example which might reasonably be extended to include software used for model production for a medical purpose.

#### Qualification of printing

See section **Error! Reference source not found.** of the report on the provisions concerning “*printing at a distance*” and “*hospital produced devices*” under the future MDR, which the law of a post-Brexit UK position is expected to approximate as closely to this as possible, possibly via the a mutual recognition agreement.

#### 1.1.1.3. Qualification of input material

See section **Error! Reference source not found.** of the report.

#### 1.1.1.4. Qualification of 3D printed medical device (= output)

See section **Error! Reference source not found.** of the report.

### 1.1.2. Applicable requirements for the placing on the market

See section **Error! Reference source not found.** of the report.

There are no additional requirements related to the marketing of medical devices like the mandatory intervention of a pharmacist under Belgian law. The advertising of medical devices in the UK is subject to provisions of the non-statutory British Code of Advertising Practice, as well as industry codes of practice and misleading advertising laws, which would apply to any 3D printed medical devices or accessories in the UK.



## Key points

- The legal qualification of 3D printed medical devices in the UK law is based on EU law.
- We expect the UK to adopt legislation that matches, as exactly as possible, the MDR and IVDR

## 1.2. France

No specific regulation on 3D printed medical devices exists in France. As a consequence, medical devices, whether they are 3D printed or not, are regulated **the same way**, i.e., by the French provisions which transposed the European Directives on medical devices.

However, having said that there is no specific regulation does not imply that there are no specific legal or regulatory issues of course, and as a matter of fact, l'Agence nationale de sécurité du médicament et des produits de santé (ANSM) initiated, in 2014, the creation of a working group on 3D printed medical devices with a view to publishing guidelines on the topic.

The reason for the creation of this working group was that ANSM discovered that some French healthcare institutions had started to either use or manufacture themselves some 3D printed products. At that time ANSM was wondering whether these products, should they qualify as medical devices, were manufactured in conformity with the French regulations on medical devices. The attention of ANSM focused particularly on the raw materials used for the manufacturing of such products, and their biocompatibility, notably taking into consideration the fact that the 3D printing process could modify the structure of the final product – being a medical device.

ANSM has not, as of today's date, published any official guidelines on the subject, presumably because of the imminent publication of the MDR.

To our best knowledge, there is also no French case-law involving a 3D printed medical device.

### 1.2.1. Legal qualification

#### 1.2.1.1. Qualification of 3D printer

Under French law, the qualification of the 3D printer is the **same as under the EU regime**, where it is qualified as a "*machine*" rather than a medical device. This qualification is based on the EU Machinery Directive 2006/42/EC (see section **Error! Reference source not found.** of the report), which has been implemented in France through the Decree No. 2008-1156 dated November 7, 2008<sup>1</sup> relating to work equipment and personal protective equipment (the "*Machinery Decree*"), which defines machineries as:

1. "An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;
2. An assembly mentioned in the first indent, missing only the components to connect it on site or to sources of energy and motion;
3. An assembly mentioned in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;
4. An assembly of machinery mentioned in the first, second and third indents or an assembly of partly completed machinery defined in Article R. 4311-6 which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;
5. An assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort."

<sup>1</sup> Codified in Articles R. 4311-4 and seq. of the French Labour Code



In practice, 3D printers could meet the definition above mentioned, rather than the definition of medical device, and could, therefore, be regulated under the Machinery Decree.

Pursuant to Articles R. 4312-1 and R.4313-1 et. Seq. of the Labour Code, before placing on the French market and putting into service the 3D printer, the manufacturer, the importer or any other person responsible for the placing on the market must notably:

- ensure that the 3D printer satisfies the relevant essential health and safety requirements set out in Annex I of Article R.4312-1 of the Labour Code;
- create the technical file and ensure that such technical file is available (Article R. 4313-6 of the Labour Code);
- draw up the EC declaration of conformity (Articles R.4313-1 and R.4313-2 of the Labour Code);
- affix the CE marking (Articles R.4313-3 and R.4313-5 of the Labour Code).

#### 1.2.1.2. Qualification of design software

Software may be qualified as medical devices, depending on their intended use as assigned by their manufacturers/developers.

As indicated by ANSM<sup>2</sup>, software may be qualified as a medical device if:

- it has a medical purpose, such as diagnosis, prevention, monitoring, treatment or alleviation of a disease / diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap / investigation, replacement or modification of the anatomy or of a physiological process / control of conception, and;

- it gives an individual result for a specific patient.

A software which would analyse the physiological signs of a patient, and which would allow the patient and/or any other third persons (such as healthcare professional) to receive alerts, when such alerts have a medical purpose, would qualify as a medical device.

In case a software has several modules, one should consider whether each module has a medical purpose and, as a consequence, some of the modules of a software may qualify as medical device, whereas others no.

As for all medical devices, the risk relating to the use of the software is not a criterion for the qualification. As above mentioned, software which intervene in the functioning of a medical device, by managing it or by acting on its use, would qualify as accessories and would be classified in the same way as that device.

**In practice**, the fact that the software is used to create a 3D printed medical device does not necessarily mean that such software is a medical device.

In order to determine whether a software is qualified as a medical device, ANSM refers to the Meddev Guide on the "*Qualification and Classification of stand-alone software*"<sup>3</sup> and its decision diagram to assist qualification of software as medical device.

Based on the assumption that the software used for printing the 3D medical devices:

- does not perform any action on data of a patient;
- is not intended to be used for the evaluation of patient data to support or influence the medical care provided to one patient;
- is not to be used for any of the purposes listed in Article 1(2)a of Directive 93/42/EEC,

<sup>2</sup> "Mise sur le marché des dispositifs médicaux et dispositifs médicaux de diagnostic in vitro (DM/DMIA/DMDIV)" on ANSM's website

<sup>3</sup> MEDDEV 2.1/6, July 2016 " Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices"



The software would, therefore, not qualify as medical device.

**As far as 3D printed custom-made devices are concerned, the qualification may be more problematic since the software obviously processes the data of an individualized patient, in a view to manufacture a medical device specifically adapted to such patient. Depending on the functionalities of the software, it may be considered that it "supports or influences the medical care provided to one patient", and would, therefore, qualify as medical devices.**

**As a matter of fact, all of the guidelines published by ANSM, on the subject of software qualifying as medical devices, do not refer, at all, to software used for 3D printers. We should, however, point out, as above explained that ANSM did eventually not issue any guidelines on 3D printed medical devices, so that no official position was issued on the subject.**

One should also bear in mind that the medical devices regulations may apply to some of the modules of the software, and not to others, so that the developer of software used for 3D printing activities should closely examine the functions and intent purpose of all of the modules, before determining that the software does not, as a whole, qualify as a medical device. Some of its modules may eventually qualify as medical devices.

In this connection, ANSM has, on 12 January 2015, issued a decision to ban the placing on the market (as well as putting into services, exportation and distribution) of a software on the ground that one of its module qualified as medical device of Class IIa, whereas the software (as a whole) had been placed on the market with a CE marking of Class I. The software in question allowed the saving and hosting of data collected from the medical exams of patients, and the module in question allowed the saving and the compression of medical images (under the Waaves format) and their visualization by the healthcare professionals. Under various documents (whether technical (IFU) or promotional), the manufacturer indicated that the Waaves format is a "format of images with a diagnostic purpose", that such format allows the "visualization of diagnostic images" and that it "reinforces the action of the healthcare professional who proceeds to a medical exam". Based on these elements, ANSM considered that the module in question

qualified as a medical device of Class IIa, and that, being integrated into a software, the software itself should be ban from the market until it complies with the regulations applicable to such classification.

#### 1.2.1.3. Qualification of input material

The "General guide for the placing on the market of custom-made device" from ANSM provides that "Components and intermediate products of custom-made medical device are considered as medical devices [...], if such components or products are specifically intended for manufacture of custom-made device (see Meddev 2.1/1 "definition of medical device, accessory and manufacturer"). This applies to dental alloys, dental ceramics and modular components for prosthesis. [...]"

Pursuant to this guide, components and intermediate products must be CE marked if their intended purpose is to manufacture a custom-made device.

However, manufacturers may use raw materials which are not CE marked if they ensure that such materials comply with the essential requirements regarding the security and the health pursuant to Articles R. 5211-21 *et. seq.* of PHC, which are those of the MDD.

This guideline is informative and does not have legal authority, but, being published by ANSM, having authority to regulate medical devices, one should obviously and preferably comply with it. ANSM has not, however, to our best knowledge, initiated any action in this field.

**In practice**, input material used to manufacture a 3D printed medical device may:

- either be specifically intended for manufacturing custom-made device in which case, they must hold a CE mark;
- or, are used to manufacture a medical device, without having that specific and sole intent, in which case the manufacturer of the final product must ensure that the material complies with the essential requirements regarding the security and the health.



#### 1.2.1.4. Qualification of 3D printed medical device (= output)

For qualifying the 3D printed final product, one should first determine whether it is manufactured for a medical purpose.

3D printed medical devices, with no medical intent, such as those used for training HCPs or students, or those used for patient education, are not considered medical devices. Obviously, should they be used for medical purposes, after the training, they would qualify as medical devices (there is no case law on the subject).

3D printed devices manufactured for a medical purpose, and to be used for a human being, may qualify either as medical devices or as custom-made devices.

More precisely, the 3D final product will qualify as a **medical device** if it complies with the EU definition of medical device.

As far as a **custom-made** device is concerned, French law provides:

*"Any medical device specifically manufactured in accordance with a duly qualified medical practitioner's written prescription, or any other person authorized by virtue of his/her professional qualifications to do so, and is intended for the sole use of a particular patient. The prescription mentioned in the previous subparagraph indicates, under the responsibility of the prescribing person, the specific design characteristics of the device.*

*The devices manufactured in accordance with continuous or mass manufacturing methods which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered as custom-made device."*

The decisive criterion to determine whether a 3D printed medical device is a standard medical device or a custom-made device is whether or not the final product was manufactured for only one patient, according to a medical prescription:

- if the device is intended for the sole use of a particular patient, the 3D printed medical device should be considered as a custom-made device
- This typically applies to dental implants and ANSM published some specific guidelines for dental custom-made devices<sup>4</sup>;
- if the device is not intended for the sole use of a particular patient, the 3D printed medical device should be considered a "standard" medical device.

The method of manufacturing of the device does not interfere in the first part of Article R. 5211-6 of PHC (defining custom-made devices), so that one could first argue that custom-made devices may be 3D printed or not.

However, before reaching such conclusion, one should examine closely the last paragraph of such article, which states that "*devices manufactured in accordance with continuous or mass manufacturing methods which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered custom-made devices*".

ANSM published some general guidelines on custom-made devices<sup>5</sup>, pursuant to which one should take into account the following criteria in order to qualify a device as custom-made (these guidelines are mostly the French translation of the European "Guidance note for manufacturers of custom-made medical devices"):

- the device is designed and manufactured for the exclusive use of a specific patient;

<sup>4</sup> *Ibid* b.

<sup>5</sup> [http://ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Dispositifs-medicaux-sur-mesure/\(offset\)/12](http://ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Dispositifs-medicaux-sur-mesure/(offset)/12)



- the design features of the device are specific to the point that it may not be used by another patient;
- the device is prescribed by a HCP who indicates, under his/her responsibility, the specific design features;
- the manufacturing is a non-standard process.

ANSM also indicates that the simple geometric declination of initial dimensional characteristics is not necessarily a criterion for defining a custom-made device: a product qualifies as a custom-made device if a standard product or its simple adaptation does not exist with regard to the specific characteristics of an individual patient.

We consider that the 4 criteria, as listed above by ANSM, should not be used as indicated. They obviously come from a combination of the two paragraphs of Article R. 5211-6 of PHC, and concur to a wrong application of the legal text: the non-standard process is not a criterion required under the first paragraph.

As to the “*duly qualified medical practitioner*” who establishes the specific design characteristics of the device to be customized: in France, only physicians have the right to prescribe all health products without exceptions (medicines, medical devices...).

Certain healthcare professionals have the right to prescribe, however, their right to prescribe is subject to some specific conditions, profession by profession, and also limited to certain medicines or medical devices listed by Ministerial Acts:

- for example, pursuant to Article L. 4311-1 and a Ministerial Act dated March 12, 2012, nurses may prescribe certain medical devices, unless directed otherwise by the physician, such as plasters, medical devices for home infusion, medical devices for treatment of incontinence and urogenital system;
- pursuant to Article L. 4151-4 of PHC and a Ministerial Act dated June 27, 2006, except for products and materials used during the visit, the midwives may prescribe certain medical devices in the field of his/her

competence such as: serial pregnancy belt, compressive elastic orthosis of lower limbs, intrauterine devices, diaphragm, cervical cap;

As above mentioned, the last paragraph of Article R. 5211-6 of PHC (devices manufactured in accordance with continuous or mass manufacturing methods which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered as custom-made device) raises in our opinion, some issues in the field of 3D printed devices.

In order to explicit this last paragraph, ANSM indicates that the fact that the product is manufactured on a per unit basis is not a criterion for the qualification of custom-made device: a device manufactured under a standard process, that is to say according to usual methods of manufacturing, as used for mass production, but which would require an adaptation in order to create, on a unit basis, a medical device meeting the specific demands from a HCP or a healthcare institution, is “*assimilated to a mass production and, therefore, does not qualify as custom-made device*”.

ANSM gives the following example: “*contact lenses individually manufactured in order to meet the specific demand from the prescribing HCP are not custom-made devices if such devices are not so specific to a particular patient and that other patients can use such contact lenses*”.

As far as 3D printed medical devices are concerned, the debate about their manufacturing, as to using mass-production methods or not, is obviously crucial: one may argue that a 3D printed device is manufactured with mass-production methods, and that, even if it is adapted to meet the specific demands from a HCP or a healthcare institution, it should (following a broad interpretation of ANSM’s position) be “*assimilated to a mass production and, therefore, does not qualify as custom-made device*”.

The legal exclusion from the qualification of custom-made devices concerns:

- devices manufactured in accordance with continuous or mass manufacturing methods;
- which need to be adapted;



- to meet the specific requirements of the medical practitioner or any other professional user.

We should examine these three elements to determine whether 3D printed devices, adapted to specific patients, should be considered medical devices or custom-made devices.

- devices manufactured in accordance with continuous or mass manufacturing methods;

*"Continuous or mass-manufacturing methods"* are neither defined by any legal or regulatory texts, nor interpreted by ANSM. We understand, however, that the process of manufacturing should include some standard manufacturing processes. This would be typically the case, at least up to the point of the customization, for 3D printed devices.

Also, the text does not indicate that the all manufacturing processes must be that of a mass-production, but that the manufacturing must be made in accordance with *"methods"* of mass-production. Those methods are not defined as well, however, one could argue that the manufacturing may be partially *"mass-produced"* and as far as the customization is concerned, *"non-mass-produced"*.

Following such argumentation, the first criterion could potentially be considered as fulfilled by a court.

- ... which need to be adapted to a patient;

The *"adaptation"* is not defined.

In this connection, ANSM indicates that the adaptation to the patient is not part of the manufacturing activities, when made by a HCP (as more detailed above - see definition of manufacturers). This interpretation is correct, but only as far as it is made about article R. 5211-4-3° of PHC (defining manufacturers) which concerns the adaptation of medical devices already placed on the market. This does not concern our issue since the 3D printed devices are placed on the market once they are already customized to one single patient.

Since, the legal text about custom-made devices does not contain any precision about the author of the adaptation, the issue which remains, is: what if the adaptation is made by the manufacturer itself (which is the case for 3D printed devices for which the manufacturer is not an HCP)?

As a general principle of law, when the law does not make any distinction, one should not make any either.

Following this, we consider that a court could rule that the last paragraph of Article R. 5211-6 of PHC does not prevent the adaptation to be made by the manufacturer itself, so that the second criterion could be considered by a French court as being fulfilled.

However, one could also counter-argue that the last paragraph of Article R. 5211-6 of PHC only refers to products which are first mass-produced and then adapted to the demands of the HCP.

This interpretation would exclude 3D printed devices which are, in a way, mass-produced and adapted to the patient, in the same time. However, we consider this argument as weak.

Following this, the second criterion could be considered by a French court as not being fulfilled.

- ... to meet the specific requirements of the medical practitioner or any other professional user.

The question is then to determine what are the *"specific demands of a HCP or of a healthcare institution"* referred to under the legal text.

The legal text (whether French law or the European directive on medical devices) does not specify that the demands from the HCP or the healthcare institution must, or may be, those meant to meet the needs of a specific patient.

We understand that the intent was to refer to the needs of the HCPs, as opposed to the needs of the patients, since only the first paragraph, defining custom-made devices, refers to a medical prescription for a specific patient.



In this connection, it is worth noting that the European “*Guidance note for manufacturers of custom-made medical devices*” provides for the following examples: adaptation of surgical instruments or patient support systems used for examination. One may consider that such devices are adapted to meet more the specific needs of a HCP or a healthcare institution, rather than those of a specific patient, not to mention that some of these devices could well be re-used for other patients.

However, since the text does not make any distinction, one could argue that the purpose of the demands from the HCP or the healthcare institution (whether for their own needs, or for the needs of a specific patient) is irrelevant.

The last criterion could then be considered by a French court as being fulfilled.

The criteria are cumulative so that a French court could consider that 3D printed devices cannot be custom-made devices, pursuant to this last paragraph of Article R. 5211-6 of PHC since they are:

- o manufactured in accordance with continuous or mass manufacturing methods;
- o and adapted;
- o to meet the specific requirements of the medical practitioner or any other professional user.
- o even though they are specifically manufactured and designed for a specific patient.

However, we understand that this interpretation is presumably not retained by ANSM, which, to our best knowledge, has not initiated any action against a manufacturer of 3D printed devices, specifically printed for the needs of a patient, on the basis that the product should qualify as a medical device and not as a custom-made device.

We should, however, point out that, as above mentioned, ANSM was questioning itself in 2014, about the qualification of such 3D printed devices. No official positioning has eventually been published as of today's date.

Due to the different argumentations and interpretations which may be made on the legal definition of custom-made devices, as above developed, we consider that the legal frontier between medical devices and custom-made device, in the field of 3D printed devices, is, currently, rather thin, which gives uncertainties as to the legal qualification of such devices.

Whether one should consider that 3D printed medical devices should be either “*standard*” medical devices (because they are mass-produced and even if they are customized to a single patient) or custom-made devices (precisely because they are customized for a single patient, even if they are mass-produced) could have been resolved by the creation of another type of devices: those manufactured by mass-production methods, but in accordance with a medical prescription, for the use of a single patient, which could then be, depending on the decision made about the applicable regulations, either standard medical devices or custom-made devices.

This wording does not exist so far under French law (nor does it under the European Directives).

However, one should note that the coming European Regulations should solve that issue since “*devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorized person*” should not be considered as custom-made medical devices. This definition should, therefore, clarify the debate about the qualification of 3D printed medical devices (and will obviously raise some others, such as those relating to the use of the Unique Device Identification and those relating to batches...).



### 1.2.2. Applicable requirements for the placing on the market

French regulations relating to the placing on the market only differ depending on whether the medical device is a custom-made or not. The fact that the medical device is 3D printed does not interfere in the application of such regulations (except for the raw material as above mentioned).

#### 1.2.2.1. Placing on the market of medical devices

Except for devices which are subject to clinical investigations, medical devices cannot be imported, placed on the market<sup>6</sup>, put into use<sup>7</sup> or used before holding a CE marking (Articles L. 5211-3 and R.5211-12 of PHC), as per the EU regulations.

There are no specific requirements on 3D printed medical devices under French Law, as far as CE marking is concerned.

Non-compliance with the above-mentioned requirements may be subject to criminal sentences and/or financial penalties from ANSM (of up to 30% of the turnover made during the last fiscal year for the product or the group of products concerned, within the limit of € 1,000,000 for legal entities).

The total amount of the fine and the financial penalty may not exceed the highest legal threshold of the two (L. 5471-2 of PHC).

Without prejudice to any criminal proceedings which may be implemented, ANSM may also pronounce administrative sanctions (such as the suspension of placing on the market) in case medical devices pose or is likely to pose a risk to the human health under normal condition of use or is put on the market, put on use or used in contravention of the legislative or regulatory provisions which may be applicable to them (Articles L. 5312-1 et. seq. of PHC).

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6 "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 or use in a member state of the EU or party to the Economic European, regardless of whether it is new or fully refurbished' (Article R. 5211-4 of PHC)

#### 1.2.2.2. Placing on the market of custom-made devices

##### Procedure

There is no relevant difference between the EU regime and the French regime regarding the placing on the market of custom-made devices.

Also, as above mentioned, ANSM requires some specific conditions as to input material used to manufacture custom-made devices: either they must be CE marked if they are intended to be used for medical purpose, or, if not CE marked, the manufacturer of the custom-made device must be in position to evidence their compliance with the "essential requirements regarding the security and the health".

The manufacturer must allow the evaluation or, as the case may be, the verification of these measures (Article R. 5211-51 of PHC).

The importation, the putting on the market, the putting into use or the use of a medical device which does not notably comply with the "essential requirements regarding the security and the health" is punished by criminal sanctions and by financial penalties pronounced by ANSM.

The French regime however also imposes the same kind of additional requirements than the Belgium ones, regarding the marketing of custom-made devices as far as the advertising and the prohibition of the offer of advantages to HCPs are concerned.

7 "Putting into use" means the making available to the final user of a medical device being ready for use on the Community market for its intended purpose (Article R. 5211-4 of PHC)



### Key points

- 3D printed medical devices may qualify either as “standard” medical devices or as custom-made devices.
- The position of ANSM on the qualification of medical devices which are mass produced, for a single patient, is ambiguous, and, therefore, gives some uncertainties for the qualification of 3D printed devices.
- The requirements for placing 3D printed medical devices on the market are the same as the European requirements, depending on whether the 3D printed medical device may qualify as “standard” medical device or as custom-made device.
- On top of the European requirements for placing custom-made devices on the market, the French law imposes some additional ones regarding the marketing of custom-made devices as far as the advertising and the prohibition of the offer of advantages to HCPs are concerned.

## 1.3. The Netherlands

### 1.3.1. Legal qualification

#### 1.3.1.1. Qualification of 3D printer

There is no relevant difference between the EU regime and the Dutch regime regarding the qualification of the 3D printer. We have not come across any contrary views upheld in literature or case law.

#### 1.3.1.2. Qualification of design software

There is no relevant difference between the EU regime and the Dutch regime regarding the qualification of the design software. However, it has been argued in the Netherlands that the CAD (Computer Aided Design) file, *i.e.* the end product made by the design software from which the medical device is printed, qualifies as an “(information)product” rather than software. This will be discussed in more detail in section 2.3.1. concerning liability and insurance of 3D printed products under the Dutch regime where this distinction is most relevant.

#### 1.3.1.3. Qualification of input material

There is no relevant difference between the EU regime and the Dutch regime regarding the qualification of the input material. We have not come across any contrary views upheld in literature or case law.

#### 1.3.1.4. Qualification of 3D printed medical device (= output)

There is no relevant difference between the EU regime and the Dutch regime regarding the qualification of the 3D printed medical device. We have not come across any contrary views upheld in literature or case law.

### 1.3.2. Applicable requirements for the placing on the market

There is no relevant difference between the EU regime and the Dutch regime regarding the requirements for placing on the market. We have not come across any contrary views upheld in literature or case law.

The restrictions on advertising of medical devices in the Netherlands are slightly different than in Belgium. The advertising of medical devices is only permitted for medical devices that meet the requirements of the Medical Appliances Act and the Medical Appliances Decree, and that have market authorization.

In addition, advertising aimed at the general public is permitted only if the medical device is considered a 3D printed self-help device that does not require intervention from a physician in order to acquire/use the device (non-



prescription medical devices). Also, in cases where a 3D printed medical device is used as additional (self)care for indications which must be primarily determined by a physician, advertising to the general public is permitted as long as the advert explicitly mentions that the indication must be determined by a physician and that the medical device is a self-help device used as additional care.

In all other cases, advertising aimed at the general public is prohibited.

The rules and regulations governing the advertising of medical devices can be found in the Self-regulatory code of conduct for the advertisement of medical devices (Code reclame voor Medische zelfzorg Hulpmiddelen<sup>8</sup>)

As regards other business to business promotional activities, the Netherlands has strict rules governing any interactions between suppliers and health care professionals as set out in the Code of Conduct Medical Devices (Gedragscode Medische Hulpmiddelen – “GMH Code”<sup>9</sup>). Among other things, bonuses and discounts are permitted provided they are related to business transactions and satisfy additional requirements. Furthermore, the GMH Code strictly regulates gifts (only gifts of little value and related to the business, etc.) and financial contributions and sponsorship. Also, a recent amendment to article 13 of the Medical Appliances Act, which will come into force in the near future, gives the Dutch Healthcare Inspectorate a legal basis for enforcement of similar rules concerning these interactions. Like in Belgium, regulators have tried to ensure that interactions between suppliers and health care professionals are transparent and responsible, avoiding any undue influence through undesirable financial incentives.

## Key points

- **The qualifications of the 3D printer, input material and the 3D printed medical device are similar to the EU regime**
- **The qualification of design software is similar to the EU regime. However, the CAD (Computer Aided Design) file may qualify as an ‘(information) product’ rather than software.**
- **There are no differences in the applicable requirements for the placing on the market between the Dutch regime and the EU regime.**

## 1.4. USA

### 1.4.1. Legal qualification

#### 1.4.1.1. Qualification of 3D printer

As the 3D printer has potential to qualify as a medical device under the definition of the FDA where a medical device is “*an instrument, apparatus, implement, machine [or] contrivance ... which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease*” and as the 3D printer could potentially impact the final output, being the medical device, it could be argued that the 3D printer itself should also be qualified as a medical device in its own right.<sup>10</sup>

However, the FDA has shown no sign of taking up this interpretation, and seems to be moving forward with the consideration that the “*intended purpose*” of the **3D printer itself is not that of a medical device but rather**

<sup>8</sup> <http://www.koagkag.nl/Nieuws-en-Downloads>

<sup>9</sup> <http://www.gmh.nu/>

<sup>10</sup> C.T. Davies et al, ‘3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles’, (1st ed. 2015), [http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf)

[5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf) [https://perma.cc/WS2V-K8C5], at 18 in A. Nissan, ‘NOTE – Regulating the three-dimensional future: how the FDA should structure a regulatory mechanism for additive manufacturing (3D printing).



that of a non-medical manufacturing tool, and, therefore, will be regulated as such.<sup>11</sup>

Manufacturing tools, when used as a component of the manufacturing process, are covered and regulated by the Quality System (QSR) and Good Manufacturing Practice (GMP) regulations.<sup>12</sup>

#### 1.4.1.2. Qualification of design software

The FDA does not qualify 3D printed medical devices any differently from non 3D printed medical devices. As such the design software used in 3D printing is qualified and evaluated in the same way as the software used in other medical device manufacturing.<sup>13</sup> However, the FDA notes in its most recent guidance that “any software or procedure used to make modifications to the device design based on clinical input should include **internal checks that prevent the user from exceeding the pre-established device specifications documented in the device master record**. [The FDA] recommend[s] that the design manipulation software identify the iteration of the design the user is making changes to. [Producers] should also identify all medical devices and accessories that the design manipulation software is validated to work with”.<sup>14</sup> The FDA has also highlighted several other recommendations to bear in mind and which correspond with existing

standards, for example the Additive Manufacturing File format (AMF) as described in the SIO/ASTM 52915 *Standards specification for additive manufacturing file format (AMF)*.<sup>15</sup> This, however, does not have any bearing on the qualification of the software.

3D preoperative or planning software is qualified as software as a medical device (SaMD). Software as a medical device is “defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”, where “without being part of” means software not necessary for a hardware medical device to achieve its intended medical purpose.<sup>16</sup> The software can work together with other medical devices but will still be considered a medical device in its own right.<sup>17</sup>

#### 1.4.1.3. Qualification of input material

Typically the FDA clears and/or approves finished medical devices rather than specific materials used in the manufacturing of medical devices.<sup>18</sup> For example, “the FDA has approved spinal implants made from titanium alloy, but the FDA does not review or provide blanket approval for the use of titanium in medical devices”.<sup>19</sup> Input material is qualified and evaluated in the same way as the input material of any other manufacturing process

<sup>11</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016.

<sup>12</sup> For more information regarding these regulations and the corresponding requirements see: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/>.

<sup>13</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p. 9.

<sup>14</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.9-10.

<sup>15</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.9-10.

<sup>16</sup> FDA Draft Guidance Software as a Medical Device (SaMD): Clinical Evaluation, based on IMDRF Proposed Document, IMDRF/SaMD WG (PD1)/N41R3, 5 August 2016, p. 8.

<sup>17</sup> FDA Draft Guidance Software as a Medical Device (SaMD): Clinical Evaluation, based on IMDRF Proposed Document, IMDRF/SaMD WG (PD1)/N41R3, 5 August 2016, p. 8.

<sup>18</sup> FDA, 'Medical Devices: Prices of 3D Printing Medical Devices', at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500544.htm> and for examples <https://webstore.ansi.org/additive-manufacturing/default.aspx>.

<sup>19</sup> FDA, 'Medical Devices: Prices of 3D Printing Medical Devices', at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500544.htm>.



using appropriate quality control systems ensuring “homogenous and traceable manufacturing substrate”.<sup>20</sup> More specifically:

*“the FDA evaluates a material as part of the finished device and its intended use, and determines if the device’s intended use and technological characteristics (including the materials) are reasonably safe and effective or substantially equivalent to the safety and effectiveness of a legally marketed device”*<sup>21</sup>

Like medical devices, any speciality materials used for implantation will have to undergo FDA approval. Because input material can change significantly both physically and /or chemically while undergoing the 3D printing, in order to gain approval a full review of the materials from the beginning of the process to the end product should be done in order to meet requirements.<sup>22</sup> The FDA advises clear documentation of the input materials (and their traceability) as well as specifications for commonly used input materials.<sup>23</sup>

This is not the case for dental laboratories, where some input materials with a specific intended use, and not the end product, is approved as the FDA does not consider the finished dental products medical devices.<sup>24</sup> “These specific materials are considered finished devices that are suitable for use

*by health care professionals and are patient-matched or fitted at the point of care”*.<sup>25</sup>

While appropriate quality control systems applicable to both conventionally manufactured and 3D printed medical devices have been applied successfully, the FDA and the industry have recognized that there is a unique manufacturing process available to 3D printing that falls outside of these control systems.<sup>26</sup> 3D printing allows for the recycling of “manufacturing substrate from one build to the next”<sup>27</sup>. While this recycling can even result in superior quality of the end product, the FDA has expressed **concern for potential “material contamination, diminishing performance of recycled materials over time, and additional complexities with material traceability. Several methods have been proposed to mitigate these issues”**.<sup>28</sup>

<sup>20</sup> Morrison et al, 'Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices', 8 Clinical & Translational Science 5, p.597.

<sup>21</sup> FDA, 'Medical Devices: Prices of 3D Printing Medical Devices', at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPri ntingofMedicalDevices/ucm500544.htm>.

<sup>22</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.14.

<sup>23</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.14.

<sup>24</sup> FDA, 'Medical Devices: Prices of 3D Printing Medical Devices', at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPri ntingofMedicalDevices/ucm500544.htm>.

<sup>25</sup> FDA, 'Medical Devices: Prices of 3D Printing Medical Devices', at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPri ntingofMedicalDevices/ucm500544.htm>.

<sup>26</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.15; Morrison et al, 'Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices', 8 Clinical & Translational Science 5, p.597.

<sup>27</sup> Morrison et al, 'Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices', 8 Clinical & Translational Science 5, p.597.

<sup>28</sup> Morrison et al, 'Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices', 8 Clinical & Translational Science 5, p.598.



#### 1.4.1.4. Qualification of 3D printed medical device (= output)

Firms who manufacture, (re)package, (re)label and/or import medical devices are regulated by the FDA's Center for Devices and Radiological Health (CDRH). This is no different for manufacturers who use 3D printing techniques. These manufactures, and the devices they produce, are subject to the same regulatory regime as applicable to other medical devices. This regime and the corresponding quality system requirements will be discussed in more detail in sections 1.4.2. and 1.4.3. below.

3D printed medical devices have thus far been approved as<sup>29</sup>:

- custom-made devices;
- patient-matched devices;
- standard-sized devices.

#### Custom-made devices

Custom-made devices must adhere to the custom device exemption under section 520(b)(2) [21 U.S.C. § 360j(b)]. As such these devices **do not need premarket approval nor need they adhere to mandatory performance standards** (though they still need to comply with FDA quality system requirements and standards). However, the custom device exemption also holds that these devices must be made to the exact specifications of an individual for a very specific purpose/need and the device as such may not be available in its finished form. Additionally, this exemption only applies **if less than five of these specific devices are manufactured per year**. This means that any large scale 3D printing/manufacturing operations could not be regulated under the custom-made device regime, and as such 3D printed devices are generally not considered custom-made. Instead, most 3D

printed medical devices are seen as customizable, and are referred to as patient-matched devices.

#### Patient-matched devices

Patient-matched devices are based on standard-sized templates that can be matched to a patient's anatomy by using techniques such as scaling while using patient specific anatomic references or imaging. In other words, *"patient-matched devices are often made by altering the features of a standard-sized device for each patient **within a pre-determined range of device designs and size limits**"*<sup>30</sup>. The device designs can be modified *"either directly by clinical staff, the device manufacturer, or a third party in response to clinical inputs"*, and *"these inputs may be acquired from individual measurements, clinical assessments, patient imaging, or a combination thereof"*<sup>31</sup>. Patient-matched devices are, therefore, customizable in the production process.

The same requirements and considerations regarding the design of the device regarding device design for standard-sized devices are applicable to patient-matched devices, with extra attention paid to the effects of the imaging data on the final device and the interactions with/between design models on the final device.<sup>32</sup>

<sup>29</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.7-8.

<sup>30</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.9.

<sup>31</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.8.

<sup>32</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.8.



### Standard-sized devices

Standard-sized devices are devices that are available in “*pre-established discrete sizes*” and can be printed according to the desired dimensional specifications. These devices are also considered regular medical devices and are regulated as such.<sup>33</sup>

A final relevant note is that concerning point of care manufacturing. According to the FDA, a manufacturer is “*any person who designs, manufactures, fabricates, assembles, or processes a finished device*”. As access to 3D printers is becoming increasingly widespread, the question remains how should point of care manufacturers<sup>34</sup> be regulated? While the most recent guidance of the FDA acknowledges the possibility of medical professionals and suppliers becoming manufacturers of medical devices, they have yet to provide any guidance on this topic.

#### 1.4.2. Applicable requirements for the placing on the market

The **general medical device type regime** includes a risk-based classification of class I, II, or III. The classification determines the regulatory requirements that must be met in order to gain access to the market.

In most cases this entails premarket notification with a 510(k) or Pre-Market Approval (PMA). The PMA route is reserved for high-risk devices with no similar device available yet on the market. For many of the remaining devices, the 510(k) procedure only requires the demonstration of

“*substantial equivalence*” with an existing medical device.<sup>35</sup> Safety and efficacy is the main concern of the FDA.

Most 3D printed devices that have received market approval in the USA have used the 510(k) pathway.<sup>36</sup> This means that their safety and efficacy were evaluated without considering the manufacturing process, and by doing so, the FDA has equated, at least substantially, 3D printed medical devices to conventionally manufactured devices as predicate devices.<sup>37</sup> 3D printed medical devices must adhere to the same standards and requirements as conventionally manufactured medical devices under USA law.

In terms of advertising, the USA has a markedly different approach to Belgium. In the USA, as long as the advertisements abide by the relevant requirements and regulations of the FDA and FTC (no false or misleading advertising, etc.), advertising aimed at the general public (direct-to-consumer advertising), as well as advertising aimed at physicians, is permitted<sup>38</sup>. As a similar approach will be unlikely in Belgium, no further details will be provided in this report on this subject.

<sup>33</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.7.

<sup>34</sup> 'Point of care manufacturer' is a manufacturer at or near the time and place of patient care.

<sup>35</sup> For more information regarding the placing on the market please visit the FDA's website at: [www.fda.gov](http://www.fda.gov)

<sup>36</sup> C.T. Davies et al, '3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles', (1st ed. 2015), [http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf)

[5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf) [<https://perma.cc/WS2V-K8C5>], at 4-5 in A. Nissan, 'NOTE – Regulating the three-dimensional future: how the FDA should structure a regulatory mechanism for additive manufacturing (3D printing).

<sup>37</sup> T. Lewis, '3D-Printed Medical Devices Spark FDA Evaluation', LiveScience, 4, 30 August 2013, 13, at: <http://www.livescience.com/39339-how-fda-regulates-3d-printed-devices.html>

<sup>38</sup> <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/ucm2005422.htm>



### 1.4.3. Quality system requirements

Quality system requirements currently only apply to “*end and complete device manufacturers*”<sup>39</sup> who intend to commercially distribute medical devices”.<sup>40</sup> Where finished device is defined as “*any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized*”<sup>41</sup>. Manufacturers being defined as “*any person who designs, manufactures, fabricates, assembles, or processes a finished device*”<sup>41</sup>. This system provides a loose framework that accommodates for a wide variety of devices.

According to the FDA guidance, “*manufacturers must establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Alternatively, where the results of a process cannot be fully verified by subsequent inspection and test, the process must be validated with a high degree of assurance and approved according to established procedures. FDA interprets these regulations to require manufacturers to establish procedures, including validation of the manufacturing process of AM devices, to ensure that the device can perform as intended*”<sup>42</sup>. While such stringent regulations on device design and process control are welcomed by traditional manufacturing facilities, smaller manufacturers (point of care

manufacturers) oppose such regulation as they may have a hard time conforming.

Another quality control tactic heralded by the FDA is that any alteration, or methods used to make alterations must be clearly limited by a clinically identified parameter or range within which such modifications can be made.<sup>43</sup> As James Coburn, a mechanical engineer at the FDA, mentioned:

*"We typically ask manufacturers to put safeguards on their products so you can't go beyond the design space, so that when you're patient-matching a device to someone, it will tell you when you have exceeded that limit and won't let you push beyond it." "So if somebody does try to go beyond that limit, they really have to circumvent the safeguards that are put in place, and sometimes that is a feasible option if you're a very specialized institution and sometimes that's something you can do with emergency use authorization. But in a general sense, we ask manufacturers to limit that to the design space that they've tested."*<sup>44</sup>

<sup>39</sup> Point-of-care manufacturers (hospital in house printing) is included in the definitions regarding quality system requirements if they produce a complete device and commercially distribute it. Commercial distribution is defined as: (...) - b) Commercial distribution means any distribution of a device intended for human use which is held or offered for sale. Title 21 – Food and Drugs, Chapter 1, subchapter H- Medical Devices, Part 807 subpart 1 General Provisions sec. 807.3

<sup>40</sup> Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, FDA, at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/> [https://perma.cc/9YWG-75CV].

<sup>41</sup> Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, FDA, at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/> [https://perma.cc/9YWG-75CV].

<sup>42</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.6.

<sup>43</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.8.

<sup>44</sup> B. Mitchell, 'How the FDA regulates 3-D printed devices', fedscoop, 27 August 2014, at: <https://www.fedscoop.com/how-the-fda-regulates-3-d-printed-devices/>.



Coburn went on to mention:

*"The biggest benefit of 3-D printing medical devices might not be printing something from scratch but rather the ability to further tailor a standard-sized piece." "A lot of these devices are traditional-sized devices, but they're using 3-D printing to create a shape or surface texture or some other feature they couldn't do with other manufacturing," "It's just another manufacturing process" "that's added to standard devices".<sup>45</sup>*

The regime used in the USA is helpfully summarized by Morrison et al:

*"Applying the same design and quality control strategies utilized in standard manufacturing methods with 3D printing will result in a controlled output and consistent production of devices. However, given the "custom" nature of many 3D-printed implants, further guidance is necessary to establish which quality control measures will be necessary for each device iteration".<sup>46</sup>*

### Key points

- The FDA's approach to qualifying the 3D printer centers on the printer's '*intended purpose*', which the FDA considers is that of a non-medical manufacturing tool warranting the printer's regulation as such and not as a 'medical device'.
- The design software used in 3D printing is qualified and evaluated in the same way as the software used in other medical device manufacturing. However, the FDA notes that software that makes modifications to the device design based on clinical input should include internal checks that prevent the user for exceeding the pre-established device specifications documented in the device master record.
- Input material is qualified and evaluated in the same way as the input material of any other manufacturing process using appropriate quality control systems ensuring 'homogenous and traceable manufacturing substrate'. The FDA must approve specialty materials used for implantation, and advises clear documentation of the input materials and their traceability, as well as specifications for commonly used input materials. Appropriate quality control systems applicable to both conventionally manufactured and 3D printed medical devices have been applied successfully.
- Manufacturers using 3D printed techniques and their printed devices are subject to the same regulatory regime as any other medical device. 3D printed medical devices have been approved as:

<sup>45</sup> B. Mitchell, 'How the FDA regulates 3-D printed devices', fedscoop, 27 August 2014, at: <https://www.fedscoop.com/how-the-fda-regulates-3-d-printed-devices/>.

<sup>46</sup> Morrison et al, 'Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices', 8 Clinical & Translational Science 5, p.599.



- Custom-made devices → premarket approval and mandatory performance standards are not required. They must be made to meet exact specifications for an individual for a very specific purpose/need. The exemption only applies if less than five of these specific devices are manufactured per year, excluding large scale 3D printing. Generally, 3D printed devices fail these requirements and are not considered custom-made, but rather customizable medical devices referred to as patient-matched devices.
- Patient-matched devices → These are matched to a patient's anatomy within a pre-determined range of device designs and size limits, and are based on standard-sized templates. The same requirements and considerations regarding the design of the device for standard-sized devices are applicable to patient-matched devices.
- Standard-sized devices → Devices that are available in '*pre-established discrete sizes*' and can be printed according to the desired dimensional specifications. These devices are also considered regular medical devices and are regulated as such.

For marketing, devices are categorized under Classes I, II, and III, depending on the associated risk. The classification determines the regulatory requirements that must be met before marketing is authorized. High-risk devices must gain Pre-Market Approval (PMA), where there is no similar device on the market. Most 3D printed devices however can qualify for the less rigorous 510(k) route, which requires only demonstration of 'substantial equivalence' with an existing medical device. 3D printed medical devices must adhere to the same standards and requirements as conventionally manufactured medical devices under USA law.

- Quality system requirements only apply to 'end and complete (finished) device manufacturers who intend to commercially distribute medical devices'. According to the FDA guidance, 'manufacturers must establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Where the results of a process cannot be fully verified by subsequent inspection and test, the process must be validated with a high degree of assurance and approved according to established procedures.'

**Table 1 – Overview of the legal qualification of 3D printing/3D printed medical devices in a selection of countries**

|                                                                                              | EU                                                                                                                         | Belgium | UK     | France                                                 | The Netherlands | USA                                                                                                                                                 |
|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------|--------|--------------------------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Are there specific provisions on 3D printing and medical devices?</b>                  | No                                                                                                                         | No      | No     | No                                                     | No              | No                                                                                                                                                  |
| <b>2. Can the 3D printer be qualified as a medical device?</b>                               | No, it is considered a machine under the machinery directive.                                                              | Cf. EU  | Cf. EU | Cf. EU                                                 | Cf. EU          | No                                                                                                                                                  |
| <b>3. Can the input material be qualified as a medical device?</b>                           | No, unless the input material has its own therapeutic or diagnostic intended purpose                                       | Cf. EU  | Cf. EU | Cf. EU                                                 | Cf. EU          | No, the FDA clears/approves finished medical devices rather than materials used in manufacturing.                                                   |
| <b>4. Can the 3D-printing software be qualified as a medical device?</b>                     | No for design software<br>Yes for preoperative/surgical planning software                                                  | Cf. EU  | Cf. EU | Cf. EU                                                 | Cf. EU          | Yes, for preoperative/surgical software. Also, the FDA has made several recommendations regarding the design software of 3D printed medical devices |
| <b>5. Can 3D-printed devices be qualified as a medical device?</b>                           | Yes                                                                                                                        | Cf. EU  | Cf. EU | Yes, but the position of ANSM gives some uncertainties | Cf. EU          | Yes                                                                                                                                                 |
| <b>6. Is there an exemption regime for 3D-printed medical devices?</b>                       | Yes, provided they meet the definition of a custom-made device, which will most likely no longer be the case under the MDR | Cf. EU  | Cf. EU | Cf. EU                                                 | Cf. EU          | Yes, there is an exemption regime if they meet the requirements for a custom-made device (ex. <5 devices manufactured per year).                    |
| <b>7. Is there an exemption regime for medical devices that are 3D-printed in hospitals?</b> | MDD: No<br>MDR: Yes, article 5(5) MDR, provided they meet certain conditions (e.g. no industrial scale)                    | Cf. EU  | Cf. EU | Cf. EU                                                 | Cf. EU          | No                                                                                                                                                  |



## 2. LIABILITY AND INSURANCE ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES UNDER VARIOUS NATIONAL REGIMES

### 2.1. United Kingdom

#### 2.1.1. Liability

Contractual liability will apply generally, and where damage arises from a failure to observe an appropriate standard of care, liability arises under the tort of negligence. Of most direct relevance, however, is the regime of liability for defective products, under which defendants are not required to be at fault, which is established by the Consumer Protection Act 1987 (“CPA”), which implements the Product Liability Directive (Directive 85/374). The CPA applies to, on the one hand, producers of products, those who hold themselves out as producers (e.g. by use of trade marks) and importers; and, on the other hand, suppliers who fail to identify such parties within a reasonable amount of time from the damage arising. Where two or more persons are liable for the same damage, they are jointly and severally liable. Liability under the CPA applies to “products” and the trigger for liability is a “defect” in that product, which arises when “*the safety of the product is not such as persons generally are entitled to expect*”. For those purposes “safety” is deemed to be “*safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury*”. A “product” means “*goods or electricity*” and, relevant to 3D medical devices, includes “*a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise*”. Software, however, is not deemed to be a “product”. Rather, its provision is deemed to be a service; and the supply

of that service is subject to implied warranties as to reasonable skill and care, which may be waived by express provision or by a course of behaviour.

Following the *Boston Scientific* case<sup>47</sup>, where the 3-D printed product is a standard (as distinct from a custom-made) device, products belonging to the same group or which form part of the same production series as a product known to have a potential defect may be deemed to be defective themselves.

The CPA deems the UKMDR to be “*safety regulations*”. Together, they provide that criminal liability applies to those who supply or who offer or agree to supply non-compliant medical devices (including in vitro diagnostic and active implantable medical devices) and accessories, and to those who expose or possess them for supply. Where an entity is not a medical device, then criminal liability for unsafe consumer products may arise under the General Product Safety Regulations 2005 (implementing the General Product Safety Directive - Directive 2001/95). The term “*product*” has a wider definition than under the CPA and does not exclude software. It does not include equipment used by service providers to supply a service to consumers, but it is certainly conceivable that, where consumers “*use*” software to design a medical device of some sort, then criminal liability could arise if the software were unsafe, although in practice it seems unlikely that such a device would comply with the appropriate standards for a custom-made medical device. Other safety regulations are also relevant in connection with hazardous goods etc, essentially in line with other EU states.

In the sphere of intellectual property (the subsistence of which is addressed in section 7.1.), liability may arise in connection with patents, patent applications, database right and design rights and trade marks in a way that may be regarded as essentially uniform across the territory of the European Union. An idiosyncrasy of UK law of relevance to 3D medical devices is the “*unregistered design right*” (“UDR”) arising under the Copyright, Designs and Patents Act 1988. Liability for UDR infringement is a function of subsistence

<sup>47</sup> Joined Cases C-503/13 and C-504/13 (*Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and another.*)



in 3D medical devices (discussed in section 7.1.). The seriousness of liability depends on whether the UDR infringement is primary or secondary. Primary infringement arises where a person, directly or otherwise, reproduces the design in which UDR subsists without a licence, or authorises another to do so. “*Reproduction*” includes making articles to that design or making a design document recording the design for the purpose of enabling such articles to be made. For these purposes, “*making articles to the design*” means copying the design so as to produce articles exactly or substantially to that design. Secondary infringement is a more serious grade of liability, prompted by the activities in question being undertaken by someone who knows or has reason to believe that the items in question are infringing articles.

Independent of data protection issues, medical data is confidential. As such, liability can arise in connection with a breach of confidence.

It is not possible to exclude liability for death or personal injury.

#### 2.1.2. Insurance

The market for insurance is generally flexible in the UK. Note, however, that because the NHS cannot take out policies of insurance: it insures itself by means of the NHS Litigation Authority.

#### Key points

- **UK law provide a comprehensive liability framework, comprising negligence, contract, product liability and product safety laws. This appears adequate for 3D-printed medical devices.**
- **Product liability arises on the basis of defects, not fault.**
- **Software is not deemed to be a ‘product’ for purposes of product liability law.**
- **Criminal sanctions are possible where a product is unsafe.**

## 2.2. France

As a preliminary remark, we shall point out that the French Law relating to the “*modernization of our healthcare system*” dated January 26, 2016 (the “*Healthcare Law*”) created “*class actions*” in the health sector. This judicial proceeding is already in force, and one class action has already been launched against a French pharmaceutical company.

Class actions enable patients, placed in a “*similar situation*” to initiate one single action, to seek compensation of their personal injuries, against the manufacturer, provider or supplier of a health product, on the basis that such product has caused them damaging injuries. Class actions may be launched against manufacturers or suppliers of medical devices.

To initiate the class action, a group of patients (a group being constituted by at least 2 patients) must first evidence, before the court, that they are suffering damages due to the use of the same products. Presumably the class-action system will not be suitable for custom-made devices, which obviously differ one from another, however, it is too early to know how French courts will interpret the notion of “*similarity*” of the products in the specific case of 3D custom-made devices.

During this first proceeding step, the court will have to determine whether the defendant(s) (manufacturer, supplier or provider) may be held liable for the damages caused by the device. If the defendant is held liable, the court will define the conditions of “*similarity*” to present, in order to be able to join the class action, and will order that the decision be advertised (by any means to be defined by the court: internet, TV, radio, ...at the costs of the defendant), so that potential other patients may join the class action (under a opt-in system). The patients who will join the class action at that stage will have to evidence that they present the same type of damages as those fixed by the court (conditions of “*similarity*”), after having being prescribed or used the same product. They will, however, not bear the burden of the proof as to the liability of the defendant, since this liability will have already been evidenced.



Once the period for joining the group (also fixed by the court) expires, the court then rules on the indemnification of the plaintiffs, as part of the second step of the proceedings.

The class action system was introduced in France with the intent to allow victims of defective health products to obtain indemnification, rapidly and at low costs (since the costs are mutualized between them). However, on the one hand we anticipate, taking into account the applicable legal timeframes of this proceeding, that it will take no less than 10-15 years for patients to be indemnified. On the other hand, being the target of a class action is obviously damaging in terms of reputation, so that it is obvious that launching a class action works as a powerful inducement to negotiate settlement agreements. In that sense the class action serves the interests of the patients.

**Whether the litigation, concerning a health product, is initiated on the basis of a class action or of the standard proceeding rules, and whether the litigation involves a medical device, custom-made or not, the action must be based on one of the available liability regimes existing in France, such as :**

- liability for defective product;
- specific fault-based liability for HCPs and/or hospitals ;
- general fault-based liability.

#### *2.2.1. Liability for defective product*

The definitions, scope and principles of such liability system are very similar to the definitions, scope and principles of the Product Liability Directive and the Product Liability Law in Belgium. As a consequence, the principles mentioned in section 5.6.2. of the report are also relevant for the way in which liability-issues should be handled in France.

However, certain specificities exist under French Law on the following points:

#### **Defective product**

It is worth noting that French law refers to "*legitimate*" expectation on the safety, whereas the word "*legitimately*" is not found under the European directive.

Many commentators state that the liability on defective product institute a presumption of fault on the producer. This is partially incorrect since, under French law, the patient has the burden of proof of the link between his/her damage and the defect. However, it is true that this regime does not require that the plaintiff proves a specific defect (which could be on the design, conception, manufacturing, ...) but, more simply, that the product did not provide the expected safety.

Hence, what matters is the "*safety*" a patient is entitled to legitimately expect. In order to assess the safety level, which may be legitimately expected, one should take into account how the safety of the product was presented, notably under the instructions for use, but not only. French courts have hence notably taken into account how the product was presented also under commercial brochures, advertisement. The intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended are also relevant.

In the case of implantable medical devices, the instructions for use are meant for the doctors only, so that the patient does not receive any information from the manufacturer. Doctors are, however, bound by a general obligation of information of the patients on the risks associated with their treatment. As part of this information, Doctors must, therefore, be in a position to inform the patients about all of the risks associated with the device. This may, obviously, be done only if the instructions for use delivered to the doctors contained clearly such information.

Therefore, manufacturers of medical devices must draft their instructions for use in a way that either the patients are directly informed of the risks of using the medical device (in the case where the devices are to be used by the patients) or that such information may be provided by the surgeon or doctor to the patients, so that patients are fully aware of the risks associated with the device, and cannot claim that they were, legitimately, expecting a



different level of security. Failing that, their liability could be held on the product liability legal basis.

### Damage

This specific liability system allows the compensation of any personal injury and any material damage above € 500, caused to property, which may be for professional use, it being excluded the cost of the defective product itself.

Also, pursuant to ECJ decision, dated March 5, 2015, in joined cases C - 503/13 and C - 504/13, any operation necessary to overcome the defect in the product may be indemnified, so that the producer is liable for the damages caused by a surgical operation necessary to replace a defective product.

### Statutory limit

The action is subject to a statutory limit of three years from the day the claimant knew or ought to have known of the damage, the defect and the identity of the producer. Such action may not intervene more than 10 years after the date of the first placing on the market of the product.

### Clauses which limit or exclude liability

Such clauses are forbidden, except for the ones between professionals for the damages caused to property which is not used by the victim mainly for his/her personal use.

**In practice**, such liability system may apply to a litigation concerning a 3D printed medical device. To our best knowledge there is no case law on that matter.

The most important issue as far as 3D printed medical devices are concerned, is to determine who will be responsible for the damage. Several actors are involved in the 3D printed of medical devices, such as notably the prescribing doctor, if the device is custom-made, the manufacturer as per the medical devices regulations, the 3D printer supplier, the software supplier, CAD file, the input material provider.

Under the defective product liability, may be held liable:

- the 3D device manufacturer of as per the definition of manufacturer found under regulations relating to medical devices, which is the same as the one under Belgium Law.

This does not raise any particular issues since the manufacturer of the device is the entity placing on the market the device in its own name, whereas the producer, within the meaning of the product liability regime may also be the person who presents him/herself as a producer by affixing his/her name, brand or other distinctive sign on the product.

The manufacturer may be a company, but also a HCP in the case where the 3D printed device was manufactured by that HCP (which is for instance typically the case for dental prosthetists). The same apply to the hospitals which would qualify as manufacturer as per the medical devices regulations.

On the contrary if the HCP is acting simply as the prescribing HCP, and does not endorse the quality of manufacturer as per the medical devices regulations, his liability could not be retained, according to us, under the defective product liability. This does not imply obviously that he would not incur any liability in case the damage is due to a wrong prescription, but such liability would be based on another regime (see below for the applicable regime applicable to HCPs);

- the manufacturer of the raw material and the manufacturer of any component of the 3D printed device (such as an electronic component).

These two categories of manufacturers are expressly referred under the definition of the producer, as per the defective product liability regime, so that their liability does not raise any legal difficulty. As above mentioned, in case of a damage caused by a default of a product incorporated into another one, the manufacturer of the component part and the one who performed the incorporation are severally liable, unless the producer of the component part proves that the defect is due to the conception of the product in which such component has been incorporated;



- the final 3D printed distributor supplier, if different from the manufacturer (a distributor for instance)

The provider may be held liable, but only on an ancillary basis, since he may exclude his liability by informing the injured person, within three months following the notification of the claim for indemnification, of the identity of the producer or of the person who supplied him with the device;

- the software supplier and/or of the CAD file

The issue here is to determine whether the software and CAD files used for the manufacturing of the 3D printed medical devices, which are intangible property, may be included in the notion of "*product*", so that developers of the software and/or of the CAD file may be held liable under that regime.

French law clearly states that the product must be a movable (in French "*bien meuble*"), without specifying whether such movable may be intangible or on the contrary should be exclusively tangible. Since the law does not make any distinction, one should not make any either.

Furthermore, French law includes into the notion of product, electricity, which is an intangible movable, which seems to confirm that intangible movables may fall under the scope of application of this regime.

Also, the French ministry of justice, in an official answer to deputies, on August 24, 1998, considered that software could be covered by the defective product liability law, since its intended purpose is to cover all movables.

Based on this, some consider that French law does not exclude intangible movables, such as software, from its scope of application.

However, there is no case-law determining whether software may be included in this notion or not.

Also, based on the white paper from the European Commission, dated July 28, 1999, the directive on defective product liability should only cover tangible products, and, therefore, not software.

Among the doctrine, some consider that intellectual works, as qualifies software for intellectual property rights, are not covered by this liability regime. Others consider that one should make a distinction between the case where the intangible form of the software (mostly data) is contained in a physical support (the hard ware for instance), and the case where it is not (applications on the web for instance). In the first case, because of the physical support, the software could be covered by the regime, whereas in the second part, it could not.

**As above mentioned no case-law has been ruled on the subject, so that the issue remains particularly important in the field of 3D printing.**

As part of the grounds of exemption of liability, the risks development exemption is presumably the one which will be the most debated in litigation involving 3D printed medical devices, and even more in the case of bio-printed products, for which there may be no sufficient data on the evolution of the product on patients. 3D medical devices are innovative, as far as their manufacturing is concerned, and the development of innovation implies, obviously, some risks of development. The risks development exemption was, therefore, hardly supported by the industry at the time French law transposed the Directive on defective product liability. However, further to the blood scandal in France, the legislators decided to exclude from the risk development exemption the "*elements of the human body as well as products issued from the human body*". Health products, such as medical devices, may, however, benefit from that exemption.

We should however draw your attention to the fact that a draft law should be presented to the French parliament in the coming months, which will aim at reforming the civil liability. **One of the purpose of the reform, as presented by the commission in charge of the reform in March 2017, will be to exclude some health products from the benefit of the risks development exemption.**

It is obvious that this modification of the liability regime and concerns medical devices, if it passes, will have tremendous consequences in the medical devices area, in France.



### 2.2.2. *Specific fault-based liability for healthcare actors (Article L. 1142-1 of PHC)*

Article L. 1142-1 of the PHC provides that, except when their liability may occur due to a defect of the product, HCPs and hospitals may be held liable for the consequential damages of acts they perform (whether acts of prevention, diagnostic or care), exclusively on a fault basis.

This article applies both in the public and the private sector.

As a consequence of this article, HCPs and hospitals may be held liable for damages due to a defective health products, used during a medical act. **This regime is based on a liability without fault:** HCPs and hospitals are bound by a general safety security obligations as to the health products they use. **Obviously, HCPs and hospitals may exercise a right of recourse against the producer of such defective products, under the defective product liability.**

As far as 3D printed custom-made medical devices are concerned, the prescriber HCP could obviously be held liable in the event, for instance, he would have transmitted incorrect data to the services provider in charge of printing the device. Such liability would, however, to be based on a fault, to be evidenced by the plaintiff.

### 2.2.3. *General fault-based liability (Articles 1240 et seq. of CC)*

This liability system is the same as the Belgium system, referred to under Article 1382 CC (Section **Error! Reference source not found.**).

Articles 1240 et seq. of CC provide for a liability system based on fault, under which three elements must be proven by the claimant:

- a fault;
- a damage; and
- a causal link between the fault and the damage.

This liability is applicable in non-contractual situations.

**In practice**, a patient could initiate an indemnification action, based on this fault based liability system, against a manufacturer, seller or provider involved in the manufacturing and placing on the market of a 3D printed medical device.

The fault may consist, for example, either in the knowledge of the risks linked to the use of the products whereas the manufacturer, seller or provider did not take any corrective measures or the non-compliance with a security norm.

Clauses which limits or excludes one party's liability cannot apply under such liability system.

Being based on a fault, such liability system is obviously less in favour patients, who preferably found their legal action on the liability for defective products.

### 2.2.4. *Insurance (Articles L. 1142-2, L. 1142-25 et seq. of PHC and L. 426-1 of the French Insurance Code)*

**Private HCPs, hospitals, manufacturers, and providers of finished health products (except labile blood products) must by law, be insured against damages suffered by third parties and consisting in personal injuries occurring during activities of prevention, diagnosis or care.**

The insurance contracts may be subscribed to for certain maximum coverage. Except for private HCPs, French rules do not impose any minimum coverage. As far as private HCPs are concerned, the insurance coverage may not be of less than 8 million euros by claims, and 15 million euros per year of insurance.

Failure to subscribe to such insurance is a criminal offense (sanctioned by a fine of up to € 225,000 for legal entities).

Disciplinary sanctions may also be pronounced against HCPs.

**In practice**, among the several actors involved in the 3D printed of medical devices, the following ones will be bound by the obligation of subscribing such specific insurance:



- the independent prescriber HCP;
- the **hospitals** where the device is used;
- the 3D device manufacturers and, as the case may be, the 3D device suppliers (whether custom-made or not)

As far as the other actors involved in the 3D printed of medical devices are concerned, such as the 3D printer manufacturer/supplier, the raw material, the software or CAD file, they are not bound by such insurance obligation, unless, the raw material and/or the software qualify as medical devices, in which case they will be considered as manufactured of health products, and be bound by the insurance obligation.

#### Key points

**The current French liability system is sufficient for the patient suffering damage as a result of a 3D printed medical device.**

**In case of liability claims, the Product Liability system will play a key role. But also, the other available liability systems existing in France, such as specific fault-based liability for HCPs and/or hospitals and general fault-based liability, can be applied in case of damage caused in the framework of the use of a 3D printed medical device.**

### 2.3. The Netherlands

Under the Dutch liability regime, medical devices, and consequently 3D printed medical devices, are considered auxiliary materials (hulpzaken).<sup>48</sup> As such, one could assume that the use of 3D printed medical devices would fall under article 6:77 of the Dutch Civil Code (BW) concerning liability when using auxiliary materials.

However, the legislator and the judiciary have deemed this article inappropriate when applied to the case of medical treatment relations. It is considered that, due to the nature of the agreement in the case of medical treatment contracts (that fall under the Dutch Law on Medical Treatments Agreements, the "*Wet op de geneeskundige behandelingsovereenkomst*"), **the medical professional and/or the hospital cannot be held responsible for the failure of a medical auxiliary material if a competent user could not have been reasonably expected to recognize the defect.** For more details regarding the reasoning of the legislator and the judiciary in this respect, see the relevant Parliamentary history<sup>49</sup> and case-law<sup>50</sup>.

This reasoning leads to some uncertainty with regard to custom-made 3D printed medical devices specified and prescribed by medical professionals. In the case where the medical professional has erroneously prescribed or specified a custom-made device in the prescription or post-prescription consultation with a printing service provider, the medical professional (the user) rather than the manufacturer can be held liable. This is not the case for non-custom-made medical devices as these will generally have evidence of their safety and efficacy on which the medical professional will base his/her decision to use the device. For the remainder of this section we will assume correct prescription and specification of the 3D printed device, indemnifying the user, the medical professional, and rendering other actors, the manufacturers, liable.

<sup>48</sup> Article 1 Law on medical devices ('Wet op de medische hulpmiddelen') of 15 January 1970.

<sup>49</sup> MvA II, Parl. Gech. P. 271-272 en MvT, TK 1989-1990, nr. 3, p. 44.

<sup>50</sup> Rb Arnhem 28 november 2012, ECLI:NL:RBARN:2012:BY6606; Rb Den Bosch 21 juli 2010, Letsel&Schade 2011, nr. 3; Rb Zeeland-West-Brabant 15

januari 2014, ECLI:NL:GHSHE:2014:4936; Rb Rotterdam 19 augustus 2015, ECLI:RBROT:2015:6179; Rb Amsterdam 10 januari 2016, ECLI:RBAMS:29016:212.



As a result of the abovementioned indemnification of the medical professional and the hospital, we end up in the product liability regime of article 6:185 BW: liability of the manufacturer.

Article 6:185 BW sets several requirements that must be met in order to fall under the regime of manufacturer liability, namely:

- there has to be a product;
- there has to be a manufacturer;
- there has to be a defect/deficiency of the product;
- the defect product must have caused damage.

Assuming in a liability case that there is damage and it has been caused by a defect/deficient product, we must now, in the case of 3D printed medical devices, identify what product caused the damage and who the manufacturers are in order to establish who is liable.

### 2.3.1. Product

A product under article 6:187 BW encompasses “*movables*” including movables after the components have become part of another movable or immovable property. In the case of 3D printing this comprises the following products:

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

The 3D printer, the input material, and the 3D printed medical device, are all, indisputably, products. However, in the Netherlands it has been argued by some scholars that the CAD file should also be considered an (information) product.<sup>51</sup> While this may seem counterintuitive, as a CAD file is not movable property, it is, however, a digital design of the 3D-model from which the final 3D printed product is created. The argument for the inclusion of CAD files in the definition of a product is based on the characterization of a CAD file and the intent of Directive 85/374/EEG on Product Liability, namely to ensure that a victim of damage can make a claim for redress from a responsible party. A CAD file contains all the essential information concerning the product to be printed. A CAD file can, therefore, be considered a digital version of the medical device. As such, it could be considered a product that can contain mistakes/faults/defects resulting in damage, if the CAD file, and consequently the resulting 3D print, are faulty.

The CAD file and the 3D printed medical device could thus both be considered products, however, despite being a digital version of, and therefore arguably, a medical device, the CAD file is a product that does not meet the requirements of a medical device conform the definition of a medical device in article 1 (2) (a) MDD:

*“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,*

<sup>51</sup> E.N. Spijkerman, ‘3D-printen: het nieuwe doe-het-zelfen – Een eerste verkenning van de aansprakelijkheids- en verzekeringsaspecten’, AV&S, oktober 2015/27, Afl. 5.



- 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;”*

As such, and in line with the qualification of these products under the EU regime, only the 3D printed medical device, the output, can be considered a medical device.

One consequence of not classifying the CAD file as a product, is that the designer of the CAD file, and therefore simultaneously the designer of the printed medical device, can never be held liable under the product liability regime (and victims must make their claims under tort law, “*onrechtmatige daad*”, which necessarily requires liability arising from a wrongful act, which is rarely the case, thus leaving the victim without recompense). This is because article 6:185 holds that a victim of damage due to faulty product can hold liable the manufacturer of the product, where a manufacturer is defined in article 6:187 BW, as:

- the manufacturer of an end-product, the manufacturer of input materials, the manufacturer of a component, and anyone who present or upholds the appearance of being a manufacturer by displaying their name, brand, or other identifiable signs on the product;
- anyone who introduces a product into the European Economic Area with the purpose of importing, selling, leasing, or otherwise providing the product for commercial activities; and
- if no manufacturer can be identified, any supplier will be considered a manufacturer.

Conform this definition, the following actors are considered producers of 3D printed medical devices under the Dutch product liability regime:

### 2.3.2. Producers

- the producer of the 3D printer;
- the producer of the input material;
- the producer of the 3D printed medical device (output);
- the supplier of the 3D printer;
- the supplier of the input material;
- the supplier of the 3D printed medical device (output);
- (the designer of the CAD file).

The producer of the 3D printer is considered a manufacturer as defined in article 6:187 BW. The producer of the 3D printer can be held liable for damage caused by fault of the faulty 3D printer. This producer, however, cannot be held liable for faults that lie with the input material or the 3D printed device as long as the printer is functioning correctly.

The producer of the input material is considered a producer as defined in article 6:187 BW. The producer of the input material is liable for any faults caused by faulty input material, even if this material has been integrated into, or become a part of, a 3D printed device (or other object).

The producer of the 3D printed medical device (output) is considered a producer as defined in article 6:187 BW as the producer is producing an end-product.

Before moving onto the question of liability of the CAD file designer, a brief note regarding the liability of suppliers. If it is unclear who the producer is of a faulty product, any of the suppliers can be held liable. The suppliers, however, have the chance to indemnify themselves if they can identify the producer to the victim.



As has been argued, a CAD file could potentially be considered an (information) product.<sup>52</sup> Provided this is the case, the CAD file designer would be considered a producer, regardless of whether or not they are a professional or private CAD file designer. Professional CAD file designers are already considered pseudo-manufacturers<sup>53</sup> as they use their brand, name, or other identifiable signs on their product (see the definition of a product in article 6:185 BW). If CAD files can be considered (information)products regardless of branding, then even private manufacturers, such as medical professionals with a 3D printer on their desk (which means they will not fall under the exception of article 6:185 (1)(c) BW), will be considered manufacturers and can be held liable under the product liability regime. This interpretation is in line with the purpose of Directive 85/374/EEG on Product Liability and thus, by widening the definition of a product to include (information) products, the Dutch regime seems accommodate for all aspects of liability for the 3D printing of medical devices.

As 3D printing seems to fall entirely within the regime of product liability, consumers will always be insured when issues regarding 3D printed medical devices arise.

### Key points

- **Article 6:77 BW does not govern the use of 3D printed medical devices and medical treatment relations.**
- **The medical professional and/or the hospital cannot be held responsible for the failure of a medical auxiliary material if a competent user could not have been reasonably expected to recognize the defect.**
- **If the medical professional has correctly, and not erroneously, prescribed or specified a custom-made device in the prescription or post-prescription consultation with a printing service provider, the medical professional (the user) is indemnified and the manufacturer is liable. This is not the case with erroneous subscription, however.**
- **Liability of the manufacturer is governed by Art. 6:185 BW, which requires:**
  - o **Product: Products are ‘movables’, therefore, software does not qualify as a product under EU PLD, meaning the designer of the file cannot be held liable<sup>54</sup>**
  - o **Producers or, when they cannot be identified, suppliers**
  - o **Defect/deficiency of the product**
  - o **Causation**
- **It is possible that the CAD file may be considered an (information) product, which would mean that the designer may be considered a producer for the purpose of the PLD.**

<sup>52</sup> E.N. Spijkerman, ‘3D-printen: het nieuwe doe-het-zelfen – Een eerste verkenning van de aansprakelijkheids- en verzekeringsaspecten’, AV&S, oktober 2015/27, Afl. 5.

<sup>53</sup> E.N. Spijkerman, ‘3D-printen: het nieuwe doe-het-zelfen – Een eerste verkenning van de aansprakelijkheids- en verzekeringsaspecten’, AV&S, oktober 2015/27, Afl. 5.

<sup>54</sup> Brief staatssecretaris van Justitie, *Kamerstukken ii* 1989/90, 29 656, nr. 17, p. 4; C. de Vey Mestdagh & J. Lunnens, ‘Nee hoor, u wilt helemaal niet naar Den Haag.: Over de techniek, het recht en de toekomst van de zelfrijdende auto’, *Ars Aequi* 2015, p. 267-280 (afl 4).



## 2.4. USA

In the USA the applicable liability regime to 3D printed medical devices is that of product liability. While this section does not presume to provide an extensive overview of product liability in the USA, we will try to highlight some aspects that are unique to 3D printed medical device liability.

The product liability is based on the “*chain-of-sale or control*”. In the case of 3D printing this leads to eight possible liability scenarios<sup>55</sup>:

- defective software or scanner for the creation of an original design;
- defective digital design;
- defective file;
- corrupted file from a download;
- defective 3D printer;
- defective input materials<sup>56</sup>;
- human error in digital design;
- human error in operation and post processing of printer and materials.

Scholars of product liability have concluded that it is unlikely that 3D printers will face strict liability with regard to products printed through their printers as the printer is considered merely a tool.<sup>57</sup> This is similar to the application of the regulation of medical devices, as the printer itself is not a medical device but merely enables the manufacturing of a medical device. However, designers and manufacturers of the printers and end products are in control of their product, and as such are responsible for its proper functioning and quality control measures.

But, as the possible defects/errors during the process of 3D printing can be located in different parts of the supply chain, it will be difficult to determine the liable parties in advance as it could be caused by different devices (see the abovementioned list).<sup>58</sup> The FDA could exercise control and appoint liability at any one of these stages of the process.

With regard to liability concerning data protection please see section 3.4.

<sup>55</sup> C.T. Davies et al, ‘3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles’, (1st ed. 2015), [http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf) [https://perma.cc/WS2V-K8C5], , at 18 in A. Nissan, ‘NOTE – Regulation the three-dimensional future: how the FDA should structure a regulatory mechanism for additive manufacturing (3D printing).

<sup>56</sup> Defective input materials were not mentioned in Davies et al, but are nonetheless relevant to the liability regime.

<sup>57</sup> C.T. Davies et al, ‘3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles’, (1st ed. 2015),

[http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf) [https://perma.cc/WS2V-K8C5], , at 18 in A. Nissan, ‘NOTE – Regulating the three-dimensional future: how the FDA should structure a regulatory mechanism for additive manufacturing (3D printing).

<sup>58</sup> A. Nissan, ‘NOTE – Regulating the three-dimensional future: how the FDA should structure a regulatory mechanism for additive manufacturing (3D printing).



### Key points

Applicable liability regime to 3D printed medical devices is that of product liability, which is based on 'chain-of-sale or control' and can lead to eight possible liability scenarios:

- Defective software or scanner for the creation of an original design
- Defective digital design
- Defective file
- Corrupted file from a download
- Defective 3D printer
- Defective input materials
- Human error in digital design
- Human error in operation and post-processing of printer and materials.

**Table 2 – Overview of liability and insurance concerning 3D printed medical devices in a selection of countries**

|                                                                                                                                                                     | EU                                                                                                                                                                                                            | Belgium | UK     | France                                                                                                                                                             | The Netherlands                                                                                                                                                       | USA                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Are there specific legal provisions on 3D printing and liability?</b>                                                                                         | No                                                                                                                                                                                                            | No      | No     | No                                                                                                                                                                 | No                                                                                                                                                                    | No                                                                                                                                                                 |
| <b>2. Is the product liability legislation applicable to 3D printed medical devices, the input material, the 3D printing software, the 3D printer?</b>              | Applicable to 3D printed medical devices, input material and 3D printer.<br>Not applicable to 3D printing software.                                                                                           | Cf. EU. | Cf. EU | Applicable to 3D printed medical devices, input material and 3D printer.<br>Also applicable to 3D printing software according to legal doctrine (no case law yet). | Applicable to 3D printed medical devices, input material and 3D printer.<br>Also it is arguably applicable to CAD files according to legal doctrine (no case law yet) | Yes, though the 3D printer is oftentimes seen as merely a tool and liability will lie elsewhere.                                                                   |
| <b>3. Who bears the main responsibility in case of a defective 3D printed medical device (e.g. 3D printed device manufacturer/supplier, hospital, surgeon,...)?</b> | Manufacturer (in case of outsourcing).<br>Hospital/doctor (in case of in-house printing).                                                                                                                     | Cf. EU  | Cf. EU | Cf. EU                                                                                                                                                             | Cf. EU                                                                                                                                                                | All producers involved in the production process and all actors in the supply chain are liable. Main responsibility depends on where in the chain the defect lies. |
| <b>4. Will it be difficult for a patient to claim compensation in case of a defective 3D printed medical device?</b>                                                | As the Product Liability Directive is based on the principle of no fault liability, it is made easier for the patient to claim compensation. However, it may still be difficult to identify the liable actor. | Cf. EU  | Cf. EU | Cf. EU                                                                                                                                                             | Cf. EU                                                                                                                                                                | No                                                                                                                                                                 |
| <b>5. Could a defective 3D printed medical device lead to criminal liability?</b>                                                                                   | /                                                                                                                                                                                                             | Yes     | Yes    | Yes                                                                                                                                                                | Yes                                                                                                                                                                   | Yes                                                                                                                                                                |



### 3. DATA PROTECTION ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES UNDER VARIOUS NATIONAL REGIMES

#### 3.1. United Kingdom

Directive 95/46 is implemented in the UK by the *Data Protection Act 1998*. The overall regime is, for present purposes, much the same as in other EU states. A hospital which collects biometric and associated data for processing for the purpose of 3D printing will be treated as a data controller. There is at present no requirement for data processors to register as such at the UK's competent authority, the Information Commissioner's Office ("ICO"). At the time of writing, many businesses are preparing to comply with the more exacting standards of the GDPR, which will come into effect at the end of May 2018, prior to the UK's exit from the European Union. Whether post-Brexit UK follows the developing acquis of EU law or develops an independent jurisprudence stemming from the same root is an open question. However, the ICO has indicated a reluctance to depart from the existing framework. In the near term, at least, such a divergence appears unlikely. On 7 August 2017, the UK government announced its intention of bringing forward a new Data Protection Bill (<https://www.gov.uk/government/news/government-to-strengthen-uk-data-protection-law>), to be published in September 2017. Limited information is available at the time of writing, but the proposals appear to repeat those of the GDPR.

#### Key points

- UK data protection law is currently in accordance with the European data protection regime.
- The hospital will be treated as data controller
- The UK will adopt the GDPR as a Member State before its departure from the European Union. UK data protection law is likely to reflect EU law post Brexit.

#### 3.2. France

The French laws and regulations do not differ significantly from the EU Directive.

In France, data protection is governed by Law No. 78-17 of 6 January 1978 on data processing, data files and individual liberties (the "*Data Protection Law*") which is the transposition of the European Union Directive 95/46/EC on data protection.

The Data Privacy Law was recently substantially amended by the Healthcare Law and Law No 2016-1321 for a Digital Republic dated October 7, 2016 (the "*Digital Republic Law*").

In addition, France has specific provisions relating to the hosting of personal health data.

##### 3.2.1. Personal data protection

As the PDPD, the 3 key notions of the Data Protection Law are:

- personal data and personal health data,
- data processing,
- data controller and data processor.
- Personal data and personal health data



The Data Protection Law has copied the PDPD's definition of "personal data" (Article 2 of the Data Protection Law).

- Data controller and data processor

The Data Protection Law has copied the PDPD's definition of "data controller"(Article 3 of the Data Protection Law).

The data controller is the person who decides on the implementation of the processing and determines the purposes and the means of the data processing. As a consequence, the data controller has decision-making power in the implementation of the processing, as opposed to the data processor who processes personal data on behalf of the data controller.

CNIL<sup>59</sup> is considering that in some cases (especially in the case of services using the cloud computing), it may not be obvious to determine who shall qualify as the data controller, between a services provider and its customers. As a general rule, the data controller should be the customer (and the service provider a data processor). However, in cases where the customer uses the services of a provider, and has no real control over the activities performed by the service provider (especially in terms of security), then the service provider may also qualify as a data controller.

Various operators, involved in the 3D printed medical devices' manufacturing, will :

- o collect the data (the prescribing HCP and/or the healthcare institution),
- o process the data (the manufacturer of the 3D medical device printed and/or the prescribing HCP and/or the healthcare institution).

Various operators, involved in the 3D printed medical devices' manufacturing, will:

- o collect the data (the prescribing HCP and/or the hospital),
- o process the data (the 3D device manufacturer and/or the prescribing HCP and/or the hospital).

The **hospital may be considered as a data controller** since the hospital may collect and process the data but also prints the medical device or model itself and afterwards uses the device or model (through the treating physician).

In the case where the device is not printed by the HCP or the hospital, but by a service provider, the finality and the technical means of the data treatment implemented for printing the device, are decided upon by such service provider. Also, based on the position of the CNIL, which also takes into account the level of control over the activities performed by services provider, **the manufacturer of the printed device may qualify as data controller. This position may obviously be modified with the GPDR.**

### 3.2.2. *The hosting of personal health data*

The regulations relating to the hosting of personal health data are **specific to France** and are codified under the following articles:

- Article L.1111-8 of PHC;
- Articles R.1111-9 et seq. of PHC.

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<sup>59</sup> CNIL is the French Data Protection Authority (in French "Commission Nationale de l'Informatique et des libertés")



### Scope of the regulation

Pursuant to Article L. 1111-8 of PHC, any person (whether an individual or a legal entity) who hosts personal health data collected within the course of activities of prevention, diagnosis, care or social and medico/social follow-up, on behalf of an individual or of a legal entity, who have produced or collected such data, or on behalf of the patient him/herself, must be duly certified as a "*health data hosting company*".

Therefore, if the three following conditions are met, personal health data collected must be hosted, only, by a certified company:

- the data qualifies as "*personal health data*";
- the data was collected within the course of activities of prevention, diagnosis, care or social and medico/social follow-up;
- on behalf of an individual (*i.e.*, HCPs) or of a legal entity (*i.e.*, hospital) who/which have produced or collected such data, or on behalf of the patient him/herself.

The certification is delivered by the French Minister for Health, further to an opinion of both CNIL and ASIP (the French agency of the Health Ministry responsible for sharing public health information), for 3 years (renewable).

### The legal obligations relating to the hosting of personal health data

The hosting of personal health data must comply with the main following obligations:

- the data subject must be duly informed of the hosting of his/her health data and may object to such hosting;
- the personal health data processing required by the hosting activity must comply with the Data Protection Law;
- a hosting agreement must be concluded between the hosting company and the individual or the legal entity transferring the data. Such agreement must contain mandatory provisions listed under Article R. 1111-13 of PHC. The template of such hosting agreement must be approved by ASIP as part of the certification process;

- the hosting company must designate a physician who will exercise some duties as "*hosting physician*" and will notably be in charge of warranting the confidentiality of the data. Such physician may be either an employee or an external provider of the hosting company.

Companies which are processing health data and which fall within the scope of applications of these regulations must be certified as hosting company (which is a real constraint from an operational and financial point of view) or must subcontract the hosting activity to a company already certified.

### Sanctions in case of non-compliance with this regulation

According to Article L. 1115-1 of PHC, the fact for an individual to host personal health data collected without being certified or without complying with the certification conditions may be punished by a fine of € 45,000 and three years of imprisonment. Such fine may be as high as € 225,000 for legal entities and additional penalties may be pronounced against the company such as notably a ban, definitive or during a maximum period of 5 years, to exercise, directly or indirectly, the occupational activity in the exercise of which the office was committed (Article L. 1115-2 of PHC).

### The new provisions issued by a French order relating to the personal data protection

We should draw your attention to the fact that an order No. 2017-27 dated January 12, 2017 relating to the personal data protection (the "*Order*") has modified the hosting regulations. The Order has not yet entered into force (it will at the latest, on January 1<sup>st</sup>, 2019, provided that some further decrees are published).

**In practice**, under the 3D medical devices' process, if health data are necessarily hosted, the issue is therefore to determine whether Article L. 1111-8 of PHC is applicable in this situation. No guidelines exist on the subject.



Two interpretations of Article L. 1111-8 of PHC may be made:

- we may consider that the purpose of the hosting activity is to ensure the safety and confidentiality of the data in the sole context of their hosting (as opposed to data treatment).

Indeed, ASIP specified that the purpose of the regulations relating on the hosting data is to "organize and supervise the deposit, the retention and the return of personal health data, under conditions which guarantee their confidentiality and security."

In addition, ASIP also specified the notion of "hosting" as follow:

*"The semantic has always associated with the term" hosting" two notions: reception and protection. This valuing connotation is particularly justified for personal health data.*

(...)

*The definition of hosting was specified by the debate relating to the law N°2004-575 of 21 June 2004 for the confidence in the digital economy, aiming to transpose the European directive of 2000. The hosting company was defined as company ensuring the permanent or at least permanent storage of data and whose functions go beyond direct storage, that is to say which excludes all processing. This form of deposit is defined by the storage of data which will be returned identically to the one which produced them. "*

In this context, we could argue that patient's personal health data which are collected by the HCP and the hospital are not "submitted" and "entrusted" to the manufacturing entity for ensuring safety and confidentiality but only for the manufacturing and the printing of the 3D medical device.

Thus, we may consider that the "submission" of data to the certified company is the action, by a HCP or a hospital, to "entrust" health data to a natural person or a legal entity which is distinct from the HCP or the hospital.

In this case, one may consider that the regulations relating to the hosting of health data do not apply in the field 3D process.

- however, one should also consider that Article L. 1111-8 is broadly drafted and does not specify for which purpose the hosting is made, so that it may apply to the transfer of health data from a HCP or a healthcare institution to any third party, such as a 3D printing services provider.

As a matter of practice, medical devices manufacturers which commercialises connected devices, and which process the data delivered by the device (for instance connected pacemakers) and which operate themselves the data treatment associated with such data (relating to the surveillance of the patients) must be certified as hosting companies, or must sub-contract the hosting activities to a certified hosting company.

On the other hand, CRO (clinical research organisations) which also host health data collected during clinical trials, do not have to be certified hosting company. ASIP considers that in their case the data are not processed as part of the medical activities, but only for the purpose of the research.

Based on this, the data collected in the process of the 3D printing activities, are highly to be considered as data participating to the medical care of the patient and should therefore require their hosting only through a certified hosting company.

### Key points

- **The French 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 strenghten the privacy protection of the patient and do not appear to present any specific problems with regard to the 3D printing of medical devices.**
- **CNIL, the Data Protection Authority supervises the processing activities concerning personal data, including data processed for 3D printing medical devices.**



- **According to the regulations relating to the hosting of personal health, which are specific to France, the data collected in the process of the 3D printing activities, are highly to be considered as data participating to the medical care of the patient and should therefore require their hosting only through a certified hosting company.**

### 3.3. The Netherlands

In all steps of the 3D printing chain personal data is transferred. From the patient health records, to the scan, to the CAD file, and to the final medical device there is identifiable personal information embedded in the files, meta files, or the device itself (for example an identification code which can be linked to an individual as a direct result of personalization of medical devices). In this chain, the healthcare organisation (hospital) is the controller, and as such responsible for compliance with data protection regulations and national laws. The hospital determines the goals and means of the processing as per the definition of controller, chooses the data to transfer and the party to transfer the data to (see art. 4(7) DPD and GDPR).

Directive 95/46/EC EU Data Protection has been implemented by the Personal Data Protection Act (DPA) of 6 July 2000 (Wet bescherming persoonsgegevens. “Wbp”). **While the laws and regulations do not differ significantly from the EU Directive, there are some additional aspects that are particular to the Netherlands.**

Pursuant to the DPA, health data is considered sensitive data, and in order to process sensitive data explicit consent from the data subject is required.<sup>60</sup>

A “controller” is the “natural or legal person, [...] which alone or jointly with others determines the purposes and means of the processing of personal

data”.<sup>61</sup> The controller must subject to the jurisdiction of the member state in which it is established.

Furthermore, the Netherlands has additional standards that must be met with regard to confidentiality for data exchange (NEN 7510), logging of processing (NEN 7512), and access to patient information (NEN 7513).

#### Key points

- **The Netherlands implements the EU Data Protection Directive 95/46/EC by the Personal Data Protection Act (DPA) of 6 July 2000, which adds some additional aspects that are particular to the Netherlands.**
- **The healthcare organisation (hospital) is considered the data controller.**

### 3.4. USA

Privacy and data security in the USA are not regulated by any one comprehensive law. There is one overarching consumer protection law, supplemented by several sector-specific federal laws, including the Health Insurance Portability and Accessibility Act of 1996 (HIPAA) which regulates health privacy.<sup>62</sup> In addition, the Health Information Technology for Economic and Clinical Health Act (HITECH) added and strengthened requirements under HIPAA. It was recognized that advancing technology could have a significant impact on the privacy of health information, and consequently provisions were incorporated mandating the adoption of Federal privacy protections in order to protect identifiable health

<sup>60</sup> Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 689.

<sup>61</sup> Article 2 (d) of Directive 1995/46.

<sup>62</sup> In addition to federal law there are relevant state laws, however, these will fall outside of the scope of this report. Note that the Privacy rule under HIPAA

represents the minimum requirements, as such, State law is allowed to supersede HIPAA where the privacy laws of that State are more stringent.; Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 1093.



information.<sup>63</sup> In the meantime the Department of Health and Human Services (HHS), responsible for the general enforcement under HIPAA, published 3 rules implementing HIPAA and HITECH Act:

- Privacy Rule: “set[s] national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically”<sup>64</sup>; and
- Security Rule: “sets national standards for protecting the confidentiality, integrity, and availability of electronic protected health information”<sup>65</sup>; and
- Breach Notification Rule: which “requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information”.<sup>66</sup>

HIPAA applies to “personally identifiable health information” which is defined as:

*“information (i) that is created or received by a health-care provider; (ii) that relates to the health or provision of health care; and (iii) as to which there is a reasonable basis to believe the information can be used to identify the individual”<sup>67</sup>.*

The HIPAA rules are applicable to covered entities’. These include health plans, health care clearinghouses, and health care providers that use electronic transactions. To a lesser extent HIPAA covers “business associates” of covered entities. Business associates are:

*“a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. A “business associate” also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate”<sup>68</sup>*

The definition further includes:

*“a “person that offers a personal health record to one or more individuals on behalf of the covered entity” and any other person that “provides data transmission services with respect to [personally identifiable health information] to a covered entity and that requires access on a routine basis to such”.<sup>69</sup>*

The HITECH Act ensures that HIPAA violations and their corresponding penalties can be extended to “business associates”. This is relevant for 3D printed medical devices as manufacturers and others who do not fall under the covered entities, can be held directly liable with regard to the handling of personally identifiable health information. Typically, the party controlling

<sup>63</sup> For more information see: [www.hhs.gov](https://www.hhs.gov/hipaa/for-professionals/index.html), ‘Health information Privacy: HIPAA for professionals’ at: <https://www.hhs.gov/hipaa/for-professionals/index.html>.

<sup>64</sup> ‘Health information Privacy: HIPAA for professionals’ at: <https://www.hhs.gov/hipaa/for-professionals/index.html>.

<sup>65</sup> ‘Health information Privacy: HIPAA for professionals’ at: <https://www.hhs.gov/hipaa/for-professionals/index.html>.

<sup>66</sup> ‘Health Information Privacy: Breach Notification Rule’, at: <https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html>.

<sup>67</sup> Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 1094.

<sup>68</sup> ‘Health Information Privacy: Business Associate Contracts’, at: <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>

<sup>69</sup> Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 1100.



the data (the health care organisation; hospital) is the party that is found liable.<sup>70</sup>

HIPAA only applies to *covered* health-care institutions and has no application outside of the group of covered entities it regulates. As such, personally identifiable health information that is found outside of the health industry, yet is used for the printing of 3D medical devices, will not be covered by these laws (for example 3D printed medical devices in the cosmetics industry).

Finally, covered entities can de-identify personally identifiable health information by “(i) *having a person with appropriate knowledge determine that the risk of identifying an individual is very small; or (ii) removing a list of identifiers specified in the rule*”<sup>71</sup>. This would mean that if the personal data passing through the 3D printing process chain is de-identified, the abovementioned rules will not apply.

**In the USA it is possible to de-identify personal information when disclosing the necessary information needed for 3D printing, and after receiving the final product, the covered entity can re-identify the information** (using undisclosed coding mechanisms).<sup>72</sup> This would mean that it is perhaps possible for parts of the chain of the 3D printing process to not be in possession of personally identifiable health information as defined in HIPAA. When considering the 18 relevant identifiers, as specified in the Rule as well as the nature of the 3D printing process (consider the necessary identification for patient-matched products or the requirement for safety and traceability), healthcare providers must analyse which information is being sent through the chain to decide whether or not HIPAA is applicable and whether or not consent must be obtained. **This is manifestly different from the European system where de-identified and re-identified information remains personally identifiable health information at all times.**

### Key points

- **Privacy and data security are not regulated by any one comprehensive law. There is an overarching consumer protection law, supplemented by several sector-specific federal laws, including the HIPAA and the HITECH.**
- **The Department of Health and Human Services (HSS) published 3 rules:**
  - 0 **Privacy Rule**
  - 0 **Security Rule**
  - 0 **Breach Notification Rule**
- **The HITECH Act ensures that HIPAA violations and their corresponding penalties can be extended to ‘business associates’, which is relevant for 3D printed medical devices since manufacturers don’t fall under the covered entities. They can therefore be held directly liable for the handling of personally identifiable health information.**
- **HIPAA applies to covered health-care institutions, and therefore does not cover identifiable health information used in 3D printing found outside of the health industry.**
- **It is possible to de-identify personal information when disclosing the necessary information needed for 3D printing, and after receiving the final product, the covered entity can re-identify the information. This is different from the EU system where de-identified and re-identified information remain personally identifiable health information at all times.**

<sup>70</sup> Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 1117.

<sup>71</sup> Ed. M. Kuschewsky, ‘Data Protection & Privacy: International Series’ United Kingdom: Thomson Reuters 2016, 1100.

<sup>72</sup> List of 18 HIPAA Identifiers can be found at: <https://www.hipaa.com/hipaa-protected-health-information-what-does-phi-include/>.


**Table 3 – Overview of data protection concerning 3D printing of medical devices in a selection of countries**

|                                                                                                                                                            | EU                                                  | Belgium | UK                             | France  | The Netherlands | USA                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|---------|--------------------------------|---------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Are there specific provisions on 3D printing and data protection?</b>                                                                                | No                                                  | No      | No                             | No      | No              | No                                                                                                                                        |
| <b>2. Which 3D printing data qualifies as protected personal data?</b>                                                                                     | Medical imaging, CAD-files, 3D-printed devices      | Cf. EU  | Cf. EU.                        | Cf. EU. | Cf. EU          | The 18 identifiers as determined by HIPAA are considered protected health information which can be necessary for the 3D printing process. |
| <b>3. Who bears the main responsibility for data protection in the context of 3D printing (e.g. hospital, 3D-printed device manufacturer/supplier,...)</b> | The hospital will most likely qualify as controller | Cf. EU  | Cf. EU.                        | Cf. EU  | Cf. EU          | The data controller is mainly responsible (generally the hospital will be the controller)                                                 |
| <b>4. Are there any particular data protection risks for 3D printing?</b>                                                                                  | No                                                  | No      | No The UK will adopt the GDPR. | No.     | No              | No                                                                                                                                        |



## 4. PATIENTS' RIGHTS ISSUES RELATED TO 3D PRINTING IN VARIOUS NATIONAL REGIMES

### 4.1. United Kingdom

There is no single instrument setting out specific patient rights. Instead, patients acquire rights as an incident of the general law. The requirement for consent to medical procedures is paramount, but certain other areas stand out. As medical records comprise confidential information, for example, patients have a right for such information not to be disclosed. The confidentiality right overlaps with the right of privacy under Article 8 of the European Convention on Human Rights, which patients acquire from the Human Rights Act 1998. Through the medium of the Lisbon Treaty, Article 7 of the EU Charter of Fundamental Rights and EU data protection law, UK patients enjoy a right to personal data protection, including the right for data to be processed fairly for specified purposes and on the basis of consent (or some other legitimate basis laid down by law) and the right of access to, and rectification of, personal data concerning him or her. Data protection law requires greater responsibility towards the processing of healthcare personal data; again, in accordance with the Data Protection Directive and, from 28 May 2018, the GDPR. Although the limited evidence on 3D printed medical devices should not directly impact the obtaining of consent, it will raise expectations as regards information on which consent is based, from the perspectives of product liability and data protection laws; similarly, a failure to inform that leads to a patient incurring damage that she or he would not otherwise incur may support a claim in negligence. Where consent is withdrawn during printing process, a private patient may be liable to pay the costs made so far, depending on the contractual and insurance framework. By contrast, an NHS patient would not be liable to pay as a result of withdrawing consent. A Protocol to the Lisbon Treaty on the application of the Charter to the United Kingdom (and Poland) states that *"the Charter reaffirms the rights, freedoms and principles recognised in the Union and makes those rights more visible, but does not create new rights or principles"*. The Protocol prevents UK courts from finding *"that the laws,*

*regulations or administrative provisions, practices or action of ... the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that [the Charter] reaffirms."* The *"rights, freedoms and principles"* referred to are those of the EU, which means that the UK acknowledged in the Protocol that the authority of those rights, such as the right to integrity and the right to life, apply by dint of EU law, irrespective of the Charter. How, and to what extent, those rights are secured in the event of the UK leaving the EU (*"Brexit"*) is matter of political uncertainty at the time of writing. However, the UK will adopt the GDPR (and therefore the extended subject rights that it brings) prior to Brexit, and the Information Commissioner's Office has suggested that it will not advocate changing the law following Brexit, while acknowledging the possibility of change in future years. On 7 August 2017, the UK government stated its intention of bringing forward a new Data Protection Bill, to be published in September 2017. On the limited information available to us, however, the proposed *"British"* Bill seems to mirror the GDPR closely.

Patients have redress, under the law of negligence, for damage caused as a result of a breach of a duty of care. The standard of care is usually taken to be that set by professional standards. In any event, negligence is not limited to clinical care: it would extend to negligence occurring at any stage in the delivery of a 3D medical device. Patients also have redress irrespective of fault in connection with defective goods under the CPA (see section 2.2.1).



### Key points

- **Patients acquire a broad range of rights under the general law, including confidentiality, negligence and rights over their personal data.**
- **Informed consent is required for medical procedures and for data processing. Where the procedure is new, as in the case of 3D-printing, patients are entitled to more detailed information to ensure that consent is truly informed.**
- **Private patients who withdraw their consent during the 3D printing process may be liable to pay the costs made so far, depending on the contractual and insurance framework**

## 4.2. France

The patient's rights in France do not differ significantly from those regulated by the EU. Some aspects specific to France will be discussed.

French law contains various provisions which refer to patient's right. We shall mention the following:

### 4.2.1. Medical secrecy

Article L. 1110-4 of PHC provides that, in principle, medical secrecy cover all data which come to the knowledge of HCPs, every staff member of the hospital and any other persons who, due to his/her function, is in relation with hospitals.

The medical secrecy is an absolute right of the patient and the persons bound by such obligation of secrecy may not be exonerated from such, even with the consent of the patient, unless if provided by law.

Information covered by the medical secrecy may be shared only in specific cases, as provided by law.

One of these legal exceptions authorizes HCP to share information concerning a patient, with one or more other identified HCPs, provided that the HCPs are all involved in the care of that patient, and that this information is strictly necessary for the coordination or continuity of care, prevention or medico-social and social follow-up.

When these HCPs belong to the same care team<sup>73</sup>, they may share information concerning the same person that is strictly necessary for the coordination or continuity of care or medico-social and social follow-up. In this situation, the patient's consent is not required.

On the contrary, the sharing of information necessary for the care of a person, between HCPs who are not part of the same care team, requires that an information be delivered by the HCP to patient, who must consent to such sharing.

<sup>73</sup> Article L.1110-12 of PHC defines the notion of a "care team" as a group of HCPs who directly participate, for the benefit of a patient, to the conduct of a diagnostic, a therapeutic, a handicap compensation, a pain relief or a loss of autonomy prevention act, or to the actions necessary to the coordination of some of these acts and who:

- 1° Either practise within the same healthcare institution, within the French Army Health Service, within the same social or medico-social services institution or in the framework of a cooperation, a shared

practice or a health coordination or medico-social coordination structure set in a list established by decree;

- 2° Either have been considered as members of the care team by the patient, who addresses to them for the conduct of the consultations and the acts prescribed by a HCP in charge of his care;
- 3° Or either practise in a group, including at least one HCP, presenting a formalised organisation and practices in accordance with a specification decided by a ministerial act.



Article 226-13 of the Criminal Code sanctions the violation of medical secrecy by one year imprisonment and a fine of up to €15,000 for natural persons and € 75,000 for legal entities.

**In practice**, 3D device manufacturers may not be considered as being of part of the “*care team*” since this legal notion only refers to HCPs.

One should determine whether 3D device manufacturers could be qualified as persons “*who, due to their functions, are in relation with healthcare institutions*”. To our best knowledge, the only case-law<sup>74</sup> on the subject, reveals that French courts pay a particular attention to the function of such person, and refuse to consider that they may not access to data covered by the medical secrecy, when such persons do not clearly participate to a care activity. As far as 3D device manufacturers are concerned, one could argue that the engineers participate in the care activities, since they manufacture the devices required for the care of the patient, however, we consider that such interpretation, which may be seen as too broad, would need to be confirmed by a French court.

As a consequence, data transferred, by the HCPs and/or the hospital, to the 3D device manufacturer should preferably be anonymized.

#### 4.2.2. The patient's right to information

##### General right of information

The right of information in France do not generally differ from the patient's right regulated by the EU.

The patient must be informed of his/her own health. Such information notably relates to the various investigations, treatments or preventive actions that are proposed, their usefulness, their possible urgency, their consequences, the normally predictable frequent or serious risks that they entail, as well as other possible solutions and the foreseeable consequences in case of refusal. Whether, after the performance of the investigations, treatments or preventive actions, new risks are identified, the patient

concerned must be informed, unless it is impossible to reach out for him (Article L. 1111-2 of PHC).

**In practice**, regarding the lack of evidence on 3D printed medical devices influencing the ability to obtain informed consent, the patient must be informed about this uncertainty.

Regarding the financial consequences for the patient in case of withdrawal of consent during printing process, it is not certain whether the social security accepts to reimburse the device. There is no case law on this point.

##### Specific right of information on some medical devices

Article R.5212-42 of PHC provides that, at the end of any care or aesthetics surgery act, which involves the use of the some listed medical devices, the HCP and the hospital must give to the patient a document indicating the identification of the used medical device (name, serial number or batch number), the name of the manufacturer or of its authorized representative and the trademark, the place and the date of use, the name of the doctor or the dental surgeon using the device and, as the case may be, the limited lifetime of the device and the potential necessity of undergoing further surgery, and, if necessary, any specific medical follow-up.

This obligation of information concerns:

- medical devices that incorporate a substance which, if used separately, may be considered to be a medicinal product derived from human blood;
- cardiac valves;
- other implantable medical devices, including dental implants (however ligations, sutures and osteosynthetic devices are not covered by this obligation);
- and obviously applies whether the devices are 3D printed or not.

<sup>74</sup> Appeal Court of Toulouse 2 october 2015



### Information relating to the costs

The right of information relating to the costs in France do not differ from this right regulated by the EU.

Article L. 1111-3-1 of PHC and Article D. 1112-67-1 of PHC provides that for any care provided within a hospital, the patient receives a document, at the end of his/her hospitalization, informing him/her notably about the cost of all the services received with the indication of the amount covered by the social security and, if applicable, the amount covered by his/her complementary insurance and the balance to be paid.

In addition, Article L.1111-3-2 of PHC provides that when the product which is used is a custom-made device, the standardized quote shall include, separately: the sale price of each device and of each service offered, the amount of the reimbursement by the social security and the balance eventually due.

- The violation of this obligation by the HCP or the hospital is criminally sanctioned (by a fine of up to € 3,000 for natural persons and € 15,000 for legal entities).
- **Right to access to the medical records and health data**
- The right to access to the medical records and health data in France do not differ from the right to access which is regulated by the EU.
- **Specific information for custom-made devices:**

Furthermore, Article R. 5211-51 of PHC provides that the patient can access to the conformity declaration relating to the custom-made device, which notably includes the name and address of the manufacturer, data identifying the device in question, a declaration that the device is intended for the exclusive use of a specific patient and the data enabling the latter to be identified, the name of the person who established the prescription, the specific characteristics of the product as indicated by the prescription.

### Key points

- **The lack of scientific knowledge on 3D printed medical devices does not prevent a valid informed consent. The HCP 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.**
- **HCPs who plan on using 3D printed medical devices should notably inform the patient on other possible solutions.**

### 4.3. The Netherlands

The patient's rights as with regard to 3D printed medical devices in the Netherlands do not differ significantly from those regulated by the EU. Some aspects specific to the Netherlands will be discussed.

#### Informed Consent

The interaction between patient and physician is subject to the laws of the Medical Treatment Contracts Act (overeenkomst inzake geneeskundige behandelings. "Wbgo"), where the patient-physician relationship is defined as treatment contract. There are two aspects to the informed consent in lieu of this contract

- the physician's duty to inform;
- the patient's consent.

Pursuant to the guidance to article 7:448(3) BW of the Wgbo, the physician's duty to inform will weigh heavier if the treatment is less conventional. As 3D printed medical devices are not yet the norm, the physician is therefore required to pay extra attention to this duty. However, besides this heavier duty to inform there is no national legislation specifically concerning 3D printed devices.

The patient must always give consent to be treated and he/she is free to retract this consent. There is no legal basis or jurisprudence yet regarding the retracting of consent after the 3D printed customized (and therefore not



reusable) medical device has been printed but the patient refuses treatment. This raises questions regarding reimbursement. These questions have not yet been dealt with in the Netherlands.

### Key points

- **Patient's rights regarding 3D printed medical devices in the Netherlands do not differ significantly from the EU.**
- **The Medical Treatment Contracts Act (overeenkomst inzake geneeskundige behandeling, Wbgo) governs the interaction between patient and physician.**
- **Informed consent covers (1) the physician's duty to inform, (2) the patient's consent**

## 4.4. USA

In the USA, failing to obtain informed consent will render the physician liable for negligence or battery and is regarded as medical malpractice.<sup>75</sup> This is true for all treatments and is therefore no different for “new” treatments such as 3D printed medical devices. In general, informed consent in cases relevant to 3D printing of medical devices is obtained by providing the patient with information and having a patient sign a consent form. As such, there is rarely a discussion on a lack of evidence of consent. Claims based on an alleged lack of informed consent usually arises from not properly informing the patient. In medical malpractice suits in the USA, the burden of proof lies with the patient who will have to prove that had he/she had the proper

information, he/she would have declined the treatment whereby avoiding the injury.<sup>76</sup> The burden of proof laws vary in stringency from state to state. A patient has the right to withdraw consent at any time, subject to practical limitations.<sup>77</sup>

Another relevant aspect is consent to the use of health data. Pursuant to the previously discussed Privacy Rule (see section 3.4.), a healthcare provider providing direct treatment to an individual is required to obtain consent before any use or disclosure of private health information necessary to carry out the treatment, payment or other healthcare operations.<sup>78</sup> Failing to do so will result in a lack of informed consent for the data processing, resulting in turn in liability of the physician. Also the covered entity is required to make an effort to minimize the amount of information that is disclosed without jeopardizing the treatment or other intended purpose of the disclosure.<sup>79</sup> The patient to be treated with a 3D printed medical device will therefore need to be asked for consent to disclose their personally identifiable health information to all the different actors in the 3D printing process.

<sup>75</sup> Pizzi LT, Goldfarb NI, Nash DB. Procedures For Obtaining Informed Consent in Shojania K, Duncan B, McDonald K, Wachter RM, eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment No. 43; AHRQ publication 01-E058. 2001:546-554, in: <http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage5.html>.

<sup>76</sup> Laws, Burden of Proof Overview, at: <http://malpractice.laws.com/burden-of-proof/burden-of-proof-overview>.

<sup>77</sup> West's Encyclopaedia of American Law, 2005 The Gale Group, Inc, 'Patient's Rights', at: <http://www.encyclopedia.com/social-sciences-and-law/law/law/patients-rights>.

<sup>78</sup> Ed. M. Kuschewsky, 'Data Protection & Privacy: International Series' United Kingdom: Thomson Reuters 2016, 1100.

<sup>79</sup> Ed. M. Kuschewsky, 'Data Protection & Privacy: International Series' United Kingdom: Thomson Reuters 2016, 1100.

**Key points**

- The physician will be liable for negligence or battery under medical malpractice if he/she fails to obtain informed consent. In general, informed consent in cases relevant to 3D printing of medical devices is obtained by providing the patient with information and having a patient sign a consent form. As such, there is rarely a discussion on a lack of evidence of consent.
- The Privacy Rule mentioned in section 3.4. requires the healthcare provider to obtain consent before any use or disclosure of health information and to minimize disclosure, failing to do so will also render them liable.
- Concerning the 3D printing process, the patient must consent to the disclosure and processing of their information to and by all the different actors in the 3D printing process.


**Table 4 – Overview of patients' rights concerning 3D printed medical devices in a selection of countries**

|                                                                                                          | EU | Belgium                                                                                                                                                                                  | UK                                                                                                                                                                                                                            | France                                                                                                                                             | The Netherlands                                                                                                                                     | USA                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------------|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Are there any specific provisions on 3D printing and patients' rights?</b>                         | No | No                                                                                                                                                                                       | No                                                                                                                                                                                                                            | No                                                                                                                                                 | No                                                                                                                                                  | No                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>2. How does the lack of evidence on 3D printing influence the ability to obtain informed consent?</b> | /  | Informed consent remains possible, but transparency about the lack of knowledge is required. The greater the uncertainty, the more elaborative the information on known risks should be. | It should not directly impact the obtaining of consent, although it raises expectations as regards information on which consent is based.                                                                                     | The patient must be informed about this uncertainty.                                                                                               | As the treatments with 3D printed medical devices are less conventional, the treating physician will have an increased duty to inform.              | The lack of evidence on 3D printed medical devices could jeopardize informed consent because the information available to provide to patients is limited. Therefore patients cannot be informed in detail about the treatment and its risks. However, often patients sign a consent form upon entering the hospital giving permission for general treatment. Depending on the (specialist) treatment provided, consent requirements may differ. |
| <b>3. What are the legal consequences of a withdrawal of consent during the 3D printing process?</b>     | /  | It can be argued that the patient must pay the costs made so far                                                                                                                         | Private patients could, at least in principle, be liable for costs incurred prior to withdrawal, depending on the contractual and insurance frameworks, NHS patients would not be liable in the event of withdrawing consent. | The patient is free to withdraw consent at all times, but is not certain whether the social security accepts to reimburse the device. No case law. | The patient is free to withdraw consent at all times, there is no legal basis or jurisprudence yet regarding the consequences of such a retraction. | Failing to obtain or withdrawing informed consent during the treatment process can result in liability based on negligence or battery and is regarded as medical malpractice.                                                                                                                                                                                                                                                                   |
| <b>4. Are there any other specific patients' rights issues with regard to 3D printing?</b>               | /  | No                                                                                                                                                                                       | No                                                                                                                                                                                                                            | No                                                                                                                                                 | No                                                                                                                                                  | No                                                                                                                                                                                                                                                                                                                                                                                                                                              |



## 5. TRACEABILITY ISSUES ASSOCIATED WITH 3D PRINTED MEDICAL DEVICES IN VARIOUS NATIONAL REGIMES

### 5.1. United Kingdom

Although the UK is bound by post-market surveillance obligation under MDD, IVDD and AIMDD, the directives are silent on traceability *per se*. However, EU obligations on custom-made devices apply to 3D-printed devices<sup>80</sup> and MHRA guidance<sup>81</sup> issued pursuant to regulation 65 of the Medical Devices Regulations 2002<sup>82</sup>, establishes a regime for the life cycle management of medical devices, under which healthcare organisations are obliged to establish a medical devices management group to develop and implement policies across the organization, including “*device management policies*” which must address “*the equipment life cycle (including: selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices*”). In particular, it must ensure that, whenever a medical device is used, it is traceable where possible. It also requires “*accurate and complete copies of records in paper or electronic form*” from receipt of a device, beginning with the results of delivery inspection, the individual device or batch identifier and any safety or functional tests. Such record should “*be made available for future inspection, review and copying e.g. for CQC [the Care Quality Commission, which regulates the provision of healthcare services in England], internal audits, traceability, investigations*”. Likewise, devices issued individually on long-term loan require systems to be put in place for device identification and traceability. An aspect of relevance to the 3-D printing of medical device

parts for repair purposes is the requirement that “*full traceability should be retained*” throughout the period of third-party repair, with a requirement to confirm whether “*you receiving the same device back or receiving “like for like”*”. The position is bolstered by a requirement that “*contractual agreement with a maintenance and / or repair service provider should specify the level and type of service required by the healthcare organisation and should include... availability, source and traceability of spare parts*”. The MHRA adds:

*“The healthcare organisation should ensure that they or the repair and maintenance service provider can:*

- *identify all spare parts replaced during the maintenance or repair of a particular device;*
- *trace all critical parts back to the supplier.*

*This will permit ready identification of those devices containing parts that need to be repaired or recalled. Not all spare parts are critical and the extent to which they need to be identified and related to the original piece of device will depend on several factors”*

A “*critical part*” for these purposes is “*a component that might reasonably be expected to cause the failure of a piece of equipment, in such a way that affects its safety or effectiveness and consequently results in death or injury to a user, should it stop working*”.

The greater traceability requirements of the MDR will apply within the UK after Brexit, whether or not the UK continues to follow the developing acquis of EU law or begins to develop a diverging jurisprudence, although the UK

<sup>80</sup> E.g. Article 15, Medical Devices Regulations 2002, which requires the statement required under Article VIII of the MDD to be maintained for five years in the case of a general medical device and indefinitely in the case of “documentation allowing an understanding of the device’s design, manufacture and performance and for custom-made active implantable device.

<sup>81</sup> Managing Medical Devices - Guidance for healthcare and social services organisations (April 2015).

<sup>82</sup> Which implements Article 10 of the Medical Devices Directive, Article 8 of Active Implantable Medical Devices Directive and Article 11(1) to 11(3) of the IVD Directive.



version seems likely, at least at present, to be isolated from EU institutional sharing.

### Key points

- **The UK medical device regime contains the same traceability tools as the EU medical device regime**
- **The UK requires compliance with statement obligations under Annex VIII MDD including the retention (unlimited in the case of 3D-Printed active implantable devices) of accurate and complete copies of records, beginning with the results of delivery inspection, to be made available for future inspection, review and copying e.g. by the English healthcare regulator.**
- **UK regulation sets device life cycle management requirements, including the establishment of medical devices management groups to develop and implement device management policies for selecting, acquiring, accepting, maintaining, repairing, monitoring, tracing and disposing or replacing medical devices.**
- **The UK requires traceability of critical parts of medical devices in maintenance and repair contracts.**

## 5.2. France

Traceability of medical devices in France is largely conducted conform the EU **legislation**. There are also no specific provisions relating to traceability of 3D printed medical devices.

### Traceability rules

Documentation and registration relating to the placing on the market

- **Medical devices**  
The manufacturers, and as the case may be, its authorized representatives or the distributors must:

- o declare themselves to ANSM by indicating notably which medical devices are concerned by their activity (Articles L. 5211-3-1, R. 5211-65 and R. 5211-65-1 of PHC);
- o communicate to ANSM information relating to medical devices of class II a, II b, III and active implantable medical devices, as well as copies of the labelling and the instructions for use (Article L. 5211-4 of PHC).

Also, any person who sterilizes, in a view to place them on the market, medical devices holding CE mark and intended by their manufacturers to be sterilized before use, or who assembles medical devices which are CE marked, in accordance with their intended purpose and in the limits of use provided by their manufacturers, and, as the case may be, their authorized representatives, must declare themselves to ANSM by notably indicating the address of their head office and the designation of the medical devices concerned (Article R. 5211-65 of PHC).

- **Custom-made devices**

Before placing on the market such devices, the manufacturer or its authorized representative must establish a documentation including notably (R. 5211-35 and R. 5211-51 of PHC): its name and address, the information allowing to identify the concerned device, the prescriber of this device and, as the case may be, the concerned hospital as well as the characteristics indicated in the medical prescription and a declaration indicating that the device is intended for the exclusive use by a particular patient and including the indications allowing the identification of this patient.

The manufacturer shall also prepare a documentation indicating the place(s) of manufacture, and allowing the understanding of the conception, manufacturing and performances of the device in order to assess its compliance with the "essential requirements regarding the security and the health" (Article 7 of Ministerial Order of March 10, 2010 laying down the conformity certification procedures set out in Articles R. 5211-39 and R. 5211-52, pursuant to Article R. 5211-53 of PHC).



Additional information, such as the lot number of the raw materials used for the manufacture of the custom-made device, may be included into this conformity declaration if the agreement between the manufacturer of the device and the HCP provides the communication of such information.

The retention of such data is the same as the retention period provided under the EU regulations.

ANSM may require from the manufacturer of such devices to communicate the list of the devices that it has produced and that have been put into service on the French territory, as well as the declarations and the documentation relating to them (Article R. 5211-35 of PHC).

Failure to present such declarations and documentation notably to ANSM may be punished by a financial penalty pronounced by ANSM (Articles R. 5461-4 and R. 5471-1 of PHC).

The manufacturers of custom-made devices with their head offices in France, which puts on the market in France, in the EU or in European Economic Area such devices must declare themselves to ANSM by indicating the address of their head offices and the devices concerned (Article R. 5211-65 of PHC).

For manufacturers of custom-made devices with their head offices outside EU or European Economic Area, their authorized representatives must declare themselves to ANSM by indicating the address of their head offices and the devices concerned.

- The use of the medical device

Articles L. 5212-3 and R. 5212-36 of PHC provide that the materiovigilance system involves, for the following medical devices, traceability obligations, from the delivery of the medical devices at the hospital until their use in/for patients.

- o medical devices that incorporate a substance which, if used separately, may be considered to be a medicinal product derived from human blood;

- o cardiac valves;
- o other implantable medical devices:
  - included dental implants;
  - except for ligations, sutures and osteosynthetic devices.

The legal representative of the hospital has to establish a written process describing the modalities under which data necessary for the traceability are collected, retained and made available to the public. Such data shall be kept for a period of ten years (Article R. 5212-37 of PHC).

Article R. 5212-38 of PHC provides that the pharmacist of the internal pharmacy, must record data relating to the delivery of such medical devices. This record includes the following information:

- o the identification of each medical device: name, serial number or lot number, name of the manufacturer or its authorized representative;
- o the date of the delivery of the medical device to the relevant hospital department;
- o the identification of the hospital department which used the device.
- Besides, each hospital department has to complete such information by recording:
  - o the date of use;
  - o the identification of the patient (notably full name and date of birth);
  - o the name of the doctor or the dental surgeon using the device.
- Under the traceability rules, Article R. 5212-40 of PHC provides that the medical file of the patient must also contain:
  - o the identification of the medical device: name, serial number or batch number, name of the manufacturer or of its authorized representative;



- o the date of use;
- o the name of the doctor or the dental surgeon using the device.
- o if necessary, the specific medical follow-up.

We draw your attention to the fact that another requirement has been created by the Healthcare Law. This new requirement is codified under Articles L.5212-2-1 and L.5212-2-2 of PHC which provide that, **for certain medical devices (which will be listed under a Ministerial Order to be published) hospitals and aesthetic surgery installations must fill in a register created for the traceability of such medical devices.** The content of this register will be specified under a Ministerial Order. The access to this register is allowed, for public health reasons, to the Health Minister, ANSM and the French National Agency for Public Health. Since the Ministerial Orders have not been yet published, these provisions are not yet in force.

According to Article R.5212-41 of PHC, the above mentioned traceability rules must also apply when the above listed medical devices of Article R. 5212-36 of PHC are used outside hospital by a doctor or a dental surgeon. In such a case, data must be recorded in the medical file of the patient or in any document allowing the identification and the localization of the batch from which the device was used, as well as in any document identifying patients for whom the medical devices of a batch were used. Such data shall be kept during:

- o 10 years; or
- o 40 years for implantable device incorporating a substance which, if used separately, can be considered to be a medicinal product derived from human blood.

The medical file of the patient must include:

- o the identification of the medical device: name, serial number or lot number, name of the manufacturer or of its authorized representative;
- o the place of use;

- o the date of use;
- o the name of the doctor or the dental surgeon using the device.

### Labelling and instructions for use's rules

The French regulation relating to the labelling and the instructions for use do not differ from the labelling and instructions for use regulated by the EU since the Annex I of the European Directive 93/42/CEE has been transposed in France by the Ministerial Order dated April 20, 2006 (Article R. 5211-24 of PHC).

However, the label and the instructions for use must be written in French.

### Key points

- **The traceability of 3D printed medical devices under the French regulations will ultimately depend on the qualification and the category of these devices.**
- **Custom-made 3D printed medical devices are to be traced in a similar way as under the medical device's regulation.**
- **For certain medical devices (which will be listed under a Ministerial Order to be published) hospitals and aesthetic surgery installations must fill in a register created for the traceability of such medical devices.**



### 5.3. The Netherlands

Traceability of 3D printed medical devices in the Netherlands is **largely conducted conform the EU regulations**. However, since 2015 the Netherlands has implemented a national registry for implantable devices (het Landelijk Implantaten Register, “LIR”).<sup>83</sup> The LIR is a registry to gather information about the implants placed in patients and the patients themselves. It was created to enable quick identification of patients in cases of recall of the devices or to identify the device when it is causing problems for the patient.

In order to ensure 100% traceability, the registry requires specific information<sup>84</sup> regarding the patient, the health professional, the implant or prosthesis etc. Because the registry contains personal information, the privacy laws of the EU and the Netherlands are applicable to the LIR and the involved health professionals and health care organisations.

The LIR could be particularly relevant to the traceability of all aspects involved in 3D manufacturing (from input material to the printer used), as well as traceability of the end-product (for example batch numbers) regarding 3D printed implantable medical devices (including 3D printed custom-made devices) in order to ensure full traceability of the device and the corresponding patient.

#### Key points

- **Traceability of 3D printed medical devices in the Netherlands is largely similar to that required under the EU regulations.**
- **Since 2015, the additional LIR register has been introduced to gather information about implants placed in patients and the patients themselves, as well as health professional. EU and NL privacy laws apply to the register.**

### 5.4. USA

There are two main aspects relevant to traceability of 3D printed medical devices in the USA.

- traceability of the medical (implantable) device;
- labelling.

<sup>83</sup> Implantatenregister, ‘<http://learningsupport.nl/zorginstellingen/registratie-medische-hulpmiddelen/implantatenregister.html>’; In order to guarantee a national registry, the Ministry of Health is in the process of making it a legal requirement to register an implant based on a bill offered to the chamber on 31 May 2016 and awaiting approval, see: Volksgezondheidszorg, ‘Landelijk Implantatenregister’ at: [https://bronnen.zorggegevens.nl/Bron?naam=Landelijk-Implantatenregister;Rijksinstituut voor Volksgezondheid, ‘Registratie van implantaten in](https://bronnen.zorggegevens.nl/Bron?naam=Landelijk-Implantatenregister;Rijksinstituut%20voor%20Volksgezondheid,%20Registratie%20van%20implantaten%20in%20Nederland)

Nederland: Inventarisatie en pilot: RIVM Rapport 2014-0089’, 27 november 2014, p. 54, at: <http://www.rivm.nl/dsresource?objectid=38087cb9-818c-421d-988a-7095979f62d9&type=org&disposition=inline>.

<sup>84</sup> Net2Legal Consultants, ‘Privacy Impact Assessment(PIA) Landelijk Implantatenregister: Een PIA voor twee fasen bij de ontwikkeling van een landelijk implantatenregister’, Ministerie VWS, 28 januari 2015, at: <file:///C:/Users/mlcpi/Downloads/privacy-impact-assessment-pia-landelijk-implantatenregister.pdf>



#### 5.4.1. Traceability of the medical (implantable) device

The USA requires manufacturers to assign a UDI to their products using authorized codes as well as labelling their products with those codes “*in human and machine readable formats*”, and to publish data about the products in a UDI database. The UDI includes a device identifier (DI) as well as a product identifier (P) which includes for example, serial numbers manufacturing and expiration dates, lot/batch numbers, etc.

Manufacturers can be required to track devices through the entire production process. They will receive tracking orders after the FDA clearance or approval if their product is on the tracking list. **This is particularly relevant to 3D printed medical devices, as continued tracking enables traceability of all parts of the process and materials.**

#### 5.4.2. Labelling

The FDA states that “*device labelling should be developed in accordance with applicable regulations, device-specific guidance documents, and consensus standards*”.<sup>85</sup> Labelling can be related to traceability when the labels include relevant information used to safeguard the 3D printing process.

As such, the FDA also recommends **that 3D printed patient-matched devices should comply with additional labelling requirements because different parties are able to modify the design of the device** (such as clinical staff or manufacturers). **For these reasons, the following additional labelling requirements are recommended for patient-matched 3D printed devices**<sup>86</sup>:

- patient identifier;
- details identifying use, such as anatomical location (e.g., left distal femoral surgical guide); and

<sup>85</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.25.

- final design iteration or version used to produce the device.

The FDA also notes that it might be beneficial to match the expiration date to the imaging date or the design finalization date rather than the standardized methods for determining shelf life. In the same vein, patients may change during the imaging-printing process so labels should include a precaution directing medical professionals to exercise caution and check for possible anatomical changes prior to performing a procedure.

#### Key points

- **Concerning the traceability of input materials, the regime is the same as that for all materials used in the industry using the quality control systems. Recycling of 3D printed input materials poses unaddressed issues for traceability**
- **Concerning the traceability of the medical implantable device, there is requirement to assign UDI to products. Additional requirements concerning labelling and the publication of data about products in UDI database, as well as obligations of manufacturers to track devices through entire production process (which can enable traceability of all parts of the process and materials in 3D printing) apply.**
- **The FDA recommends that 3D printed patient-matched devices should comply with additional labelling requirements because the design of the device can be altered by different parties. These additional requirements are patient identification, details identifying use, and final design iteration or version used to produce device information.**

<sup>86</sup> FDA Draft Guidance for Industry and Food and Drug Administration Staff, 'Technical Considerations for Additive Manufactured Devices', 10 May 2016, p.25.


**Table 5 – Overview of the traceability of 3D printed medical devices in a selection of countries**

| 2                                                                                | EU                                                                                                                                            | Belgium                                                                                            | UK                                                                                                                                                                                      | France                                                                                                                                                                                        | The Netherlands                          | USA                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Are there any specific provisions on 3D printing and traceability?</b>     | No                                                                                                                                            | No                                                                                                 | No                                                                                                                                                                                      | No,.                                                                                                                                                                                          | No                                       | No                                                                                                                                                                                                                                                     |
| <b>2. What are the most important traceability tools for 3D printed devices?</b> | For custom-made devices: labelling + Annex VIII/XIII statement<br>For standard MD's: labelling + UDI + implant card                           | Cf. EU<br>Additionally:<br>- implant register for implants -<br>FAMHP guidelines for standard MD's | Cf. EU<br>Additionally:<br>-record retention;<br>-device life cycle management requirements;<br>-traceability of critical parts of medical devices in maintenance and repair contracts. | Cf. EU<br>A register for the traceability of certain medical devices (the list of which is not yet known – but will presumably cover implantable devices) is in the process of being created. | Cf. EU<br>Additionally: the LIR register | For the medical (implantable) device: UDI, labelling with authorized codes, data publication in UDI database<br>Labelling requirements including patient identifier, details identifying use, final design iteration or version used to produce device |
| <b>3. Are there any particular traceability issues for 3D printing?</b>          | -no central registration of Annex VIII/XIII statement for custom-made devices<br>-application of UDI to 3D printed customizable standard MD's | Cf. EU<br>Additionally:<br>notification to FAMHP of 3D printed customizable standard MD's          | No                                                                                                                                                                                      | No                                                                                                                                                                                            | No                                       | No.                                                                                                                                                                                                                                                    |



## 6. REIMBURSEMENT ISSUES UNDER VARIOUS NATIONAL REGIMES

### 6.1. United Kingdom

The UK has no reimbursement mechanism specific to 3D applications. NHS commissioners reimburse providers using two relevant mechanisms. The “*national tariff*”<sup>87</sup> is a list of over 1,100 different prices that are fixed nationally each year based on reported provider costs (the approach is sometimes described as “*payment by results*” - PbR). Although the national tariff has a new “*innovation and technology*” tariff offshoot, the aim of which is to encourage the uptake and spread of innovative medical technologies that benefit patients, **no 3D printed medical devices are listed**. As the **national tariff does not include 3D printed medical devices, reimbursement will be on the basis local negotiation between providers and commissioners**. Nevertheless, the principles of determining the national tariff are likely to be adopted on a local basis: **the time necessary for the 3D pre-surgical planning (and the post-surgical follow-up) would be included as cost, but the price will be fixed to reflect costs that a reasonably efficient provider ought to incur in supplying those services at the appropriate quality**; and inefficient providers will not be fully reimbursed. To that extent, reimbursement is conditional on evidence. Commissioners may be expected to assess; first, what constitutes reasonable efficiency in a given case; and second, the cost structure relevant to the specific 3D printed device in question: matters which will involve commercial discussion with innovators. There is no “*orphan*” status for 3D printed medical devices, but these products certainly have potential to fall, on a case-by-case basis (i.e. not as a general class of

3D printed devices), under a **future accelerated access scheme**. In the UK’s recent Accelerated Access Review<sup>88</sup> (“AAR”), “*3D-printed heart for pre-surgical preparation*” was listed as an example of a type of product that could be considered for accelerated access and the flexible pricing and reimbursement framework. The AAR suggests that NICE (see next paragraph) identify “strategically important products that can deliver a step change in costs or outcomes” in the course of undertaking a health technology assessment, awarding such products a “transformative designation”, which would place them on accelerated access pathway. However, the AAR notes that this “is most likely to happen post CE mark for medical devices”: i.e. the proposed scheme would not to expedite the process of securing CE marking. Indeed, it states that, “the timing of CE marking is unlikely to change under the new pathway”.

Outside the wider NHS purchasing system, which does not make a special case of 3D printed medical devices, the National Institutes for Health and Care Excellence (“NICE”) is empowered to issue recommendations about the use of particular medical devices, active implantable medical devices and in vitro diagnostic medical devices within England<sup>89</sup>. It may also “*recommend that relevant health bodies provide funding*” within a minimum period of three months “*to ensure that the health technology be made available for the purposes of treatment of patients*”<sup>90</sup>. Such a recommendation is binding on “*relevant health bodies*”<sup>91</sup>, of which NHS England (the former “*NHS Commissioning Board*”) is of greatest relevance, because it is responsible for arranging for the provision of NHS services in England. Particular 3D printed medical devices might be expected to form the subject of future technology appraisals, but no such appraisal was recorded in the most recent (February 2017) summary of technology appraisals.

<sup>87</sup> <https://improvement.nhs.uk/resources/national-tariff-1719/>

<sup>88</sup> Accelerated Access Review – Review of innovative medicines and medical technologies (October 2016)

<sup>89</sup> Regulation 5, National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations (SI 2013/259).

<sup>90</sup> Regulation 7(1), 2013 Regulations.

<sup>91</sup> Regulation 7(6) 2013 Regulations.



The UK does not restrict the use of innovative techniques/devices to particular users. Only reimbursed products are available from NHS clinics: where such products are not available from the NHS, the patient or the patient's insurer will have to pay.

### Key points

- **The reimbursement of 3D printed medical devices is not specifically regulated in the UK.**
- **The general UK reimbursement system applies to 3D printed medical devices.**
- **3D-printed devices bearing a 'transformative designation' may in future acquire 'accelerated access' to reimbursement.**

## 6.2. France

Medical devices, once they hold CE marking or if they are custom-made, may be reimbursed.

There are several ways in France for a medical device to be reimbursed by the French social security, such as :

### 6.2.1. *Reimbursement of medical devices listed on the LPPR (Articles L. 165-1 and R. 165-1 et seq. of SSC)*

The LPPR contains a list of medical devices (which may be custom-made devices) which are reimbursed by the French social security. The reimbursement is made to the patients themselves (for devices bought directly by them) or to the HCP or healthcare institution which purchased them (for instance for implantable devices).

The lines of the LPPR refers to :

- either generic products, for which a description to the technical characteristics of the device must be complied with in order to be reimbursed as per such line;

- or "*trademark lines*" for specific (mostly innovative) devices – in which case the line concern only one device, referenced by its trademark.

### Generic lines

Manufacturers of medical devices which are listed under a generic line, may directly commercialize their devices, once CE marked, as reimbursed products. Obviously, manufacturers should pay particular attention to the wording of the generic line and make sure that the technical characteristics of the device strictly comply with theirs.

Manufacturers must notify ANSM that they are launching on the market devices, as reimbursed products by indicating to which line they are referring to claim such reimbursement. ANSM may pronounce a financial penalty in case such declaration has not been made:

- within 3 months from the inscription on the LPPR (the penalty must not exceed 5% of the turnover realised in France by the manufacturer or the distributor during the last fiscal year for the product or the group of products concerned);
- under an electronic form (the penalty must not exceed 0,2 % of the turnover realised in France by the manufacturer or the distributor during the last fiscal year for the product or the group of products concerned).

Once the product is on the market as a reimbursed product ANSM may control the adequacy of the device to the technic characteristics required under the generic line. The non-compliance may give rise to financial penalty as high as 10% of the turnover excluding tax made in France during the last fiscal year for the product(s) concerned, pronounced by CEPS, for the manufacturer, its authorized representative, or distributor (Articles L. 165-1-2 and R. 165-46 *et seq.* of CSS).

The price of reimbursement of devices listed under generic lines is fixed by the ministries of health and of the social security, upon the opinion of the CEPS (a committee from the Ministry of health, which assesses the costs of the devices and proposes their reimbursement prices).



In this situation, the manufacturers who decide to use one of the generic lines are not in a position to discuss the reimbursement price, which is already fixed for all devices falling into such generic line.

**Custom-made devices** may also be listed under the LPPR. This is the case, as a matter of example for some ortheses. The reimbursement price is fixed by the Minister of Health after discussions with the manufacturer, in the same way as above described. In such cases, the LPPR provides for specific conditions which the device must comply with, and the **reimbursement is allowed on a patient by patient cases** : the patient to whom the device is prescribed, must submit an approval file completed by the prescriber, to the social security.

Generic lines are regularly reviewed by the CNEDiMTS<sup>92</sup> so that the description of their main characteristics may be modified. Lines may also be cancelled (generic lines are defined for a 5 year period).

Up to now, the generic lines of the LPPR do not contain any specific conditions relating to the manufacturing process followed by the manufacturer. **Whether the device is 3D printed or not, it may be included into a generic line as long as its main characteristics correspond to those described under the line.** If no generic line exists, the manufacturer may request the creation of a specific line, a "trademark" line.

### Trademark lines

Devices which would not be concerned by any of the existing generic lines, may be reimbursed under a trademark line, the creation of which must be requested by the manufacturer (or the distributor). This concerns mostly innovative devices, but also devices which may induce a significant impact on the health insurance system, or on public health requirements, or on the

control and/or the difficulty of defining minimal technical specifications for that type of device.

In order to create such a trademark line the manufacturer must follow a 2-step process:

A first step, managed by the CNEDiMTS, which aims at assessing the scientific and medical actual benefit of the device (in French "SA" or "Service Attendu"). The "Service Attendu" is necessarily of a clinical value: it aims at assessing the clinical improvement of the patient health state and is assessed for all of the indications of the device.

The file submitted by the manufacturer for such assessment must allow the CNEDiMTS to answer the following questions:

- which medical need the device covers?
- what is the current and standard strategy treatment?
- how does the device fit in this strategy?
- is the clinical effect of the device sufficient taking into account its side effects and risks of use?
- are the evidence provided by the manufacturer sufficiently relevant?
- does the device have an interest for the public health?

The assessment made by CNEDiMTS is essentially clinical, whereas, as many health businesses claim, non- clinical criteria may be interesting when assessing the value added of their devices within the healthcare systems (such as the impacts on the organization of the care system, on the training of the HCPs, on the environment...).

The evidence which must be provided to the CNEDiMTS are, as a matter of consequence, essentially clinical: clinical studies (the gold standard being double blinded randomized clinical trials implemented in France), but also



observational studies, with or without controlled groups, cohort studies retrospective studies,

In this view, and in order to save time, it is fundamental that when conducting the project for the clinical evidence required for CE marking, manufacturers should also anticipate the requirements to be satisfied for reimbursement.

Once the CNEDiMTS consider that the device presents an actual benefit, the same CNEDiMTS will then also assess the "*added clinical value*" (ACV) of the device in relation to a comparable product, procedure or service or a group of comparable well-defined procedures, products or services, considered to be the current gold standard according to available scientific data, and regardless of whether this gold standard is, or is not, reimbursed.

The ACV is then ranked from major (ACV I) to null (ACV V).

The criteria used for ranking the ACV are, here again, clinical: mortality, morbidity, compensation for a disability reduction in undesirable effects.

Those clinical criteria are, therefore, also evidenced by randomized, controlled clinical trials using a primary validated judgment criterion. It is only in exceptional situations where such data are not available that the clinical evidence may be supported by literature.

Medical devices presenting a ACV V (null) cannot be reimbursed. The higher rank a medical device obtains, the better, in theory, is its manufacturer in a position to negotiate a high price of reimbursement. In practice a weak ACV (for instance IV) does not allow the manufacturer to request a higher price than those of comparable products or services (when they exist), however, the legal rules does not prevent the authorities to list a medical device on the LPPR, having an ACV, at a price inferior to those of the comparable devices already listed.

In any event, a medical device which would present some benefit in terms of costs, but would present no actual clinical benefit (ACV V) would not be reimbursed in France, under a trademark line. **This may be typically the case of 3D printed medical devices.**

The device may also require some specific surveillance which may be included as part of the conditions for its reimbursement, such as the request

for post-marketing studies. The outcome of such studies must be presented to the CNEDiMTS, at the time of the request for the renewal of the reimbursement. Depending on the assessment of such studies the CNEDiMTS may decide not to renew the reimbursement, or to modify the ACV (which is then taking into consideration as for the reimbursement price).

The CNEDiMTS may also consider that the use of the device should be reserved only to certain well-trained healthcare institutions. The criteria for being referenced as such well-trained healthcare institutions are determined on a case-by-case basis depending on the nature of the device.

Trademark lines, once created, have a validity duration of 5 years, however, depending on the level of data on the device, at the time of the creation of the line, the CNEDiMTS may indicate that the device should be reimbursed for a shorter period.

The second and final step is the determination of the reimbursement price, this step is managed by the CEPS.

The assessment made by CEPS is exclusively medico-economic.

The CEPS determines the price of reimbursement of medical devices either through a decision, or through a convention.

The decision are taken by the CEPS without any negotiations, the conventions are concluded after a negotiation with the manufacturers (and, as the case may be, the organisations representing them) or the distributors (and, as the case may be, the organisations representing).

For innovative devices, the convention entered into with the manufacturers often contains an undertaking on the sales volumes. In case the effective sales exceed the anticipated sales volumes indicated under the convention, the manufacturers has to reimburse the social security.

The prices are determined by taking into account principally the clinical value, and potentially its added medical value, as the case may be, the results of additional studies which may have been requested, the reimbursed prices of comparable medical devices or services, the sales volumes which are anticipated, and the foreseeable and truly conditions of use.



The prices may be either a maximum selling price or reimbursement price by the social security, in which case the device may be sold at a higher price.

#### *6.2.2. Reimbursement of innovative medical devices and services (Articles L. 165-1-1 and R. 165-63 and seq. of SSC)*

Any medical device or any innovative service likely to have a clinical or a health-economic benefit can exceptionally and for a limited time, be partly or fully reimbursed provided that a clinical or a health-economic study, which must meet certain conditions, is conducted.

The innovative nature of the medical device or the service is notably assessed with regards to its degree of novelty, if it is not already subject to a reimbursement in the requested indications, if the risks for the patient, and as the case may be, for the user, have been prior characterized, as evidenced by clinical studies available, and if it is able to significantly meet any relevant medical need or to significantly reduce health expenses.

The novelty may be considered as characterized if the device introduces notably:

- a new method of action which radically transforms the diagnostic, the prognostic or the therapeutic of the patients;
- a new method of action which radically transforms the medical act in relation with the use of existing devices;
- a radical transformation of the care organization;
- the introduction of a new technology with a class of existing products.

The risks relating to the device, which will be assessed, are mainly of two kinds: the risks directly relating to the technology, including the risks linked to the bad observance of the patient or those of misuse, and the risks linked to the surgical technic (notably the competence of the medical team, the technical means required, the training of the HCPs...).

The authorities consider that it is necessary for the manufacturer to be able to present at least phase II clinical studies.

The manufacturer must furthermore evidence that the device will allow a clinical benefit which not currently covered (or which is insufficiently covered) and a reduction of the public expenses due to a medical-economic benefit.

The reimbursement is decided by a Ministerial Order from both the ministries for Health and Social Security after an opinion from HAS. Such reimbursement is exclusive of any other form of reimbursement or funding, for the indications specified under such Ministerial Order.

The clinical or health-economic study which must be conducted, must be proposed by the applicant of the request.

The Ministerial Order specifies notably the reimbursed lump sum per patient (which includes the reimbursement of the act, and as the case may be, the reimbursement of hospitalization expenses of the medical device or services associated), the number of patients concerned, the time of the reimbursement, the particular conditions of use, the list of the health institutions for which the Health Insurance is reimbursing this lump sum, and determines the studies for which the implementation of the innovative treatment must lead, as well as the conditions of the lump sum allowance.

Using this system, the use of the medical device is then exclusively reserved to certain trained healthcare institutions.

Medical devices or innovative act cannot be reimbursed, notably, if they do not meet the general conditions for which reimbursement is permitted.

#### **In practice,**

As above mentioned the conditions for a device to be reimbursed do not provide for any specifics as far as 3D printed devices are concerned. They may, therefore, be reimbursed as any other medical devices, and be listed on the LPPR, either under a generic line, or under a trademark line. Depending on the negotiations with the authorities (CEPS, CNEDiMTS and Ministry of Health), the time necessary for the 3D pre-surgical planning (and the post-surgical follow-up) could be included into the reimbursement price.



3D printed devices may constitute an innovation (for which no reimbursement exists), however, to be reimbursed, innovative devices must primarily demonstrate that they present a medical innovation.

Some 3D printed custom-made devices, for which no reimbursement procedure exists, may be paid by the hospitals through their internal funds. This was used notably by some French hospitals for implantable custom-made orbital floors. The devices could also have been charged to the patients.

#### Key points

- Since the regulation concerning the reimbursement of medical devices is a competence of the Member States, France has a specific reimbursement system for medical devices
- France has no specific regulation for reimbursement of 3D printed medical devices
- Therefore, 3D printed medical devices may be reimbursed as any other medical devices as set out by French law

<sup>93</sup> For more information about the DBC system please see: Beleidsregel BR/REG-17166 Toetsingskader dbc-systeem at: [https://www.nza.nl/1048076/1048090/BR\\_REG\\_17166\\_Beleidsregel\\_Toetsingskader dbc\\_systeem.pdf](https://www.nza.nl/1048076/1048090/BR_REG_17166_Beleidsregel_Toetsingskader dbc_systeem.pdf); [https://www.nza.nl/1048076/1048107/CI\\_16\\_45c\\_Aangepaste\\_beleidsregel\\_toetsingskader dbc\\_systeem.pdf](https://www.nza.nl/1048076/1048107/CI_16_45c_Aangepaste_beleidsregel_toetsingskader dbc_systeem.pdf); <https://www.nza.nl/publicaties/Voorlichting/voorlichting-2013/van-rontgenfoto-tot-rekening/>; and the website of NZA at: <https://www.nza.nl/zorgonderwerpen/zorgonderwerpen/ziekenhuiszorg/veel-gestelde-vragen/dbc-systematiek/>.

<sup>94</sup> For an overview of all medical devices currently being reimbursed in the Netherlands see: <http://www.hulpmiddelenwijzer.nl/>.

### 6.3. The Netherlands

Reimbursement in the Netherlands is based on a system of **diagnosis-treatment combinations** (diagnose-behandelcombinaties, “DBC”).<sup>93</sup> There are several relevant aspects of DBCs with regard to the reimbursement of 3D printed medical devices.

The first relevant aspect is whether or not a medical device or technology is on the list of treatments that will be reimbursed.<sup>94</sup> Second, the eventual reimbursement depends on two things:

- the DBCs;
- the patient’s health insurance policy.

A DBC is the total package of treatments (including medical devices) and support services (including time spent to 3D -re-operative planning) provided by health institutions needed to cure or treat a specific disease or disability.<sup>95</sup> The cost of the whole DBC package can be claimed from the health insurance company or from the patient themselves.<sup>96</sup> In general, all specialized medical care is covered by the basic health insurance package, and if it is covered by the basic health insurance package then it is part of the DBC.<sup>97</sup> Therefore, **3D printed medical devices that are considered accepted care conform the current state of science and practice will be covered by the DBCs.**

<sup>95</sup> Nederlandse Zorgautoriteit, ‘DBC-systematiek; at: <https://www.nza.nl/zorgonderwerpen/zorgonderwerpen/ziekenhuiszorg/veel-gestelde-vragen/dbc-systematiek/>; Rijksoverheid, ‘Zorgverzekering: Waarvoor ben ik verzekerd via het basispakket van de zorgverzekering?’, at: <https://www.rijksoverheid.nl/onderwerpen/zorgverzekering/vraag-en-antwoord/wat-zit-er-in-het-basispakket-van-de-zorgverzekering>.

<sup>96</sup> Nederlandse Zorgautoriteit, ‘DBC-systematiek; at: <https://www.nza.nl/zorgonderwerpen/zorgonderwerpen/ziekenhuiszorg/veel-gestelde-vragen/dbc-systematiek/>.

<sup>97</sup> Zorg Instituut Nederland, ‘Medisch-specialistische zorg (Zvw) at: <https://www.zorginstituutnederland.nl/Verzekerde+zorg/m/medisch-specialistische-zorg-zvw>.



If a manufacturer can convince the NZA (Dutch Healthcare Authority) that a certain technology should become the standard of care, or at the least an accepted treatment, for a certain disease or disability, the NZA can take up the new technology in the DBCs, which will result in health insurance companies reimbursing such treatment.

However, if there is insufficient scientific evidence to support the claim that a certain form of treatment of medical device can be considered “*accepted care conform the current state of science and practice*”, then the treatment or medical device will be considered experimental.<sup>98</sup> 3D printed medical devices can sometimes be custom-made devices and/or will not have gathered enough scientific evidence to support their safety and efficacy. As such it will be difficult to support their inclusion into the basic health insurance package. Since 2012, experimental treatments can be “**conditionally included**” into the basic health insurance package.<sup>99</sup> Conditional inclusion serves two purposes: first patients can have access to the experimental treatment, and second, by providing access to the treatment, insight into the efficacy and cost-benefits of the treatment can be gained.<sup>100</sup> Following the period of conditional inclusion a decision is made

regarding final acceptance of or exclusion from the basic health insurance package.<sup>101</sup>

The NZA develops each DBC in collaboration with stakeholders in the industry and companies in this particular branch. Innovations and corrections to existing DBCs are taken into consideration. Only health care professionals and health insurance companies can ask for correction/amendments to the existing DBCs, so if an innovative technology or medical device wants to become part of the DBCs, the health insurance companies are possible partners to introduce new technology.<sup>102</sup>

Each healthcare organisation negotiates what care will be covered and the prices for each DBC with every health insurance company.<sup>103</sup> If the healthcare organisation exceeds the costs of the DBC or provides treatment that is not covered by the contract between the healthcare organisation and the insurance company (for example by using a more expensive/experimental 3D printed medical device, rather than the standard device) then in most cases<sup>104</sup> the healthcare can (but is not required to) claim the full reimbursement from the insurance company who, in turn, can claim

<sup>98</sup> Artikel 2.1 (2) Besluit Zorgverzekering

<sup>99</sup> Rijksoverheid, ‘Nieuwe behandeling bij erfelijke borstkanker voorwaardelijk toegelaten tot het basispakket’, at: <https://www.rijksoverheid.nl/actueel/nieuws/2016/12/29/nieuwe-behandeling-bij-erfelijke-borstkanker-voorwaardelijk-toegelaten-tot-het-basispakket>.

<sup>100</sup> Rijksoverheid, ‘Nieuwe behandeling bij erfelijke borstkanker voorwaardelijk toegelaten tot het basispakket’, at: <https://www.rijksoverheid.nl/actueel/nieuws/2016/12/29/nieuwe-behandeling-bij-erfelijke-borstkanker-voorwaardelijk-toegelaten-tot-het-basispakket>.

<sup>101</sup> Rijksoverheid, ‘Nieuwe behandeling bij erfelijke borstkanker voorwaardelijk toegelaten tot het basispakket’, at: <https://www.rijksoverheid.nl/actueel/nieuws/2016/12/29/nieuwe-behandeling-bij-erfelijke-borstkanker-voorwaardelijk-toegelaten-tot-het-basispakket>.

<sup>102</sup> The following link provides the possibilities for a producer of medical technology to market their innovation on the dutch market: [https://www.youtube.com/watch?v=6IN\\_ggqqiJI](https://www.youtube.com/watch?v=6IN_ggqqiJI).

<sup>103</sup> Consumentenbond, ‘Veelgestelde vragen over de ziekenhuisrekening’, at: <https://www.consumentenbond.nl/zorgkosten/veelgestelde-vragen-over-de-ziekenhuisrekening>.

<sup>104</sup> Occasioanlly, under certain circumstance, the hospital will send an invoice to the patient directly, see: Maxima Medisch Centrum, ‘Veelgestelde vragen: Factuur’, at: [https://www.mmc.nl/patienten/patienteninformatie/kosten/veelgestelde\\_vragen\\_over\\_kosten/veelgestelde\\_vragen\\_factuur](https://www.mmc.nl/patienten/patienteninformatie/kosten/veelgestelde_vragen_over_kosten/veelgestelde_vragen_factuur); Consumentenbond, ‘Veelgestelde vragen over de ziekenhuisrekening’, at: <https://www.consumentenbond.nl/zorgkosten/veelgestelde-vragen-over-de-ziekenhuisrekening>.



the costs of care that were not covered by the DBCs from the patient via invoice.<sup>105</sup>

With regard to experimental (custom-made) 3D printed medical devices that fall outside of the “*conditional inclusion*” and have not received market authorization, patients can enrol in clinical trial programs, in which case the medical device and treatment are financed by the sponsor of the clinical trial. For use of experimental medical devices in clinical trials, permission is needed from the “*Healthcare Inspectorate*” (Inspectie voor de Gezondheidszorg, “IGZ”).<sup>106</sup>

**Depending on the agreements that have been made between healthcare organisation and insurance companies, as well as the status of the treatment or medical device (accepted or experimental), 3D printed medical devices, and all the corresponding required care and support services will be reimbursed in the Netherlands.**

#### Key points

- **Reimbursement is based on a system of diagnosis-treatment combinations**
- **The cost of the DBC package can be claimed from the health insurance company.**
- **3D printed medical device can be covered by the DBC where they are considered to conform to the current state of science and practice.**
- **It is also possible for health insurance companies to reimburse treatment taken up by the DBC after it has been convinced by the manufacturer to consider a certain technology as a standard of care. If unconvinced, the treatment will be considered experimental and will be excluded from the basic health insurance package. Nevertheless, it may be conditionally included, pending a final decision.**

#### 6.4. USA

There is no existing guidance or regulations regarding specifically the reimbursement of 3D printed medical devices.

#### Key points

- **No guidance or regulation of reimbursement of 3D medical devices**

<sup>105</sup> Consumentenbond, ‘Veelgestelde vragen over de ziekenhuisrekening’, at: <https://www.consumentenbond.nl/zorgkosten/veelgestelde-vragen-over-de-ziekenhuisrekening>.

<sup>106</sup> Inspectie voor de Gezondheidszorg, ‘Klinisch onderzoek medische hulpmiddelen’, at: [https://www.igz.nl/onderwerpen/medische-](https://www.igz.nl/onderwerpen/medische-technologie/markttoelating/klinisch-onderzoek/)

[technologie/markttoelating/klinisch-onderzoek/](https://www.igz.nl/onderwerpen/medische-technologie/markttoelating/klinisch-onderzoek/); Centrale Commissie Mensgebonden Onderzoek, ‘Onderzoek met medische hulpmiddelen’, at: <http://www.ccmo.nl/nl/onderzoek-met-medische-hulpmiddelen>.

**Table 6 – Overview of the reimbursement of 3D printed medical devices in a selection of countries**

| EU                                                                                              | Belgium                                | UK                       | France | The Netherlands | USA                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------|--------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Is there a specific reimbursement regime for 3D printed medical devices?                     | No                                     | No                       | No     | No              | No                                                                                                                                                                                                    |
| 2. Is there a specific reimbursement regime for custom made devices?                            | No                                     | No                       | No     | No              | No, and considering the current healthcare reform taking place it is difficult to say anything with certainty with regard to reimbursement.                                                           |
| 3. Are there 3D printed medical devices being reimbursed by the national health insurance?      | Yes                                    | We are not aware of any. | Yes    | Yes             | Market authorization is a prerequisite to reimbursement. 3D printed medical devices go through the 510(k) process, which considers 3D printed devices as 'substantially equivalent' to other devices. |
| 4. Is it allowed to charge the costs related to the 3D printed medical devices to the patients? | Yes, but only under certain conditions | Yes                      | Yes    | Yes             | Yes                                                                                                                                                                                                   |



## 7. INTELLECTUAL PROPERTY ISSUES UNDER VARIOUS NATIONAL REGIMES

### 7.1. United Kingdom

UK and European Community intellectual property rights apply in throughout the UK and there is no geographic sub-division of IP rights in the UK. Thus, it is not possible, for example, to obtain a Scottish patent, a Welsh trade mark, an English registered design or Northern Irish copyright. There are two broad categories of IP in the UK. Firstly, there are Community rights that apply across the European Union, which include Community Trade Marks, and registered and unregistered Community Designs. Secondly, there are national rights that apply only in the UK, which include national trade marks, national patents, copyright, registered and unregistered designs and European patents that are validated in the UK.

Section 60(1) of the Patent Act 1977 lays down the acts of direct infringement. It covers several different acts, including 'making', 'disposing of, offering to dispose of, or using', 'importing' and 'keeping' the invention'. The key point with regard to the interpretation of the 'making' the patented invention relates to the fact that, even though it is clear infringement to make copies of someone else's existing invention, it is unclear whether and to what extent purchasing a protected item and subsequently modifying or repairing it is allowed.<sup>107</sup> The action of 'repairing' has been generally accepted as a legitimate act, whereas 'making' is considered to be unlawful. However, the distinction between what constitutes 'repair' and what should be considered as 'making' the patented invention is often blurred and unclear.<sup>108</sup> This question also comes back in the context of the exhaustion principle: even though the patent right is exhausted (within the domestic market) once the product is sold, the buyer should be able to do whatever he wishes to with the acquired product, as far as his activities do not amount to 'making' the product.<sup>109</sup> Being the digital representation of a physical

object, a CAD file can be easily customised, modified, distributed and printed out via a 3D printer. Within this framework, it seems clear that there would exist a direct infringement every time when someone would use a 3D printer to print out a patented item without permission from a CAD file.

Generally speaking, there are at least two major problems with pursuing direct infringement actions in the context of 3D printing. First are the difficulties with regard to tracking every individual direct infringement. That is likely to be expensive and/or difficult and time consuming. Infringement might therefore become widespread and uncontrollable and IP rights might become hardly enforceable. One must keep in mind that a large proportion of infringing acts may be excused by exception like the private and non-commercial acts or the usage in research and experimental purposes.

Secondly, it may be well challenging for the right holders of the protected products to prove where is the line for the customers replacing the parts and customers manufacturing an existing protected product. As earlier mentioned, the issue related to 'repairing' and 'making' the patented product is still rather blurry and hence it might carry certain risks for the patentees. Situation with direct infringement claims could likely frustrate the patent holders and they could consequently step out and look for another strategy to protect their intellectual property. Hence, actions for indirect patent infringement claims might appear more attractive.

An object may be protected by copyright where it can be classed as an "artistic work" (this discounts many manufactured articles but specifically protects "sculptures" and "works of artistic craftsmanship"<sup>110</sup>). Attempts to rely on copyright to protect functional objects before the UK courts have been largely unsuccessful. For example, a model of a dental impression tray<sup>111</sup> has been found not to be a sculpture.

According to the Copyright, Designs and Patents Act from 1988<sup>112</sup>, the graphic design contained within a CAD file is likely to constitute an artistic work in the form of 'a graphic work, photograph, sculpture or collage,

<sup>107</sup> Ballardini, 406

<sup>108</sup> Idem.

<sup>109</sup> Idem.

<sup>110</sup> Section 4, Copyright, Designs and Patents Act 1988

<sup>111</sup> J&S Davis (Holdings) v Wright Health Group [1988] RPC 403

<sup>112</sup> Copyright, Designs and Patents Act 1988, s 4(1)(1).



irrespective of artistic quality'.<sup>113</sup> However, it will also probably constitute a 'design document', and there is no copyright infringement by actually making the article whose design is contained within such a document, unless the design is for an artistic work.<sup>114</sup> 'Design document' is defined as any record of a design, whether in the form of a drawing, a written description, a photograph, data stored in a computer or otherwise'. While it would seem that the designs would attract copyright protection, making objects from them, by virtue of section 51 of the Copyright, Designs and Patents Act (CDPA), without the copyright owner's permission would not be an infringement, so long as those objects themselves do not constitute artistic works.<sup>115</sup> However, unauthorised copying of the file itself would still be a copyright infringement in UK law, and unregistered design rights may also be infringed by making an object from such a file.<sup>116</sup> In addition, if the design is based on or embodies pre-existing artwork, then it may be an infringement of the copyright in that work. However, if an artistic work has already been exploited with the copyright holder's permission via commercial industrial process, then the work is only protected for 25 years from when it has first been marketed, and so after that 25-year period, it can be copied by making objects of any descriptions without there being an infringement, even though the original design would still receive full-term copyright protection.<sup>117</sup>

Registered design in UK law have been heavily influenced by EU law and are a subject of continental harmonisation via the Design Directive<sup>118</sup> and the Community Design Regulation.<sup>119</sup> As a result, design rights can be registered either in the UK on the national level, or a designer can decide to

protect his design at European level. Next to the 'must fit' exception<sup>120</sup>, component parts of a complex product may only be protected as registered designs if they are visible to the user in ordinary use in addition to being of novel and individual design<sup>121</sup>. UK law also includes an exception to infringement for registered designs which have been copied 'privately and for purposes which are not commercial'.<sup>122</sup> Therefore, printing an object at home for an individual's own usage will not infringe any registered design right. On contrary, non-commercial uses which are not personal are not covered by this exception, but they do enjoy a separate 'fair dealing' exception.<sup>123</sup>

Unregistered design rights exist as from the moment of their creation and to this extend they are similar to the copyright.<sup>124</sup> An unregistered design right can protect the shape and configuration of an object but not its surface decoration or method of construction.<sup>125</sup> The requirement of originality for such designs persists (just like in the copyright regime), as well as a 'must fit' exception<sup>126</sup>. Again, actual copying is required to establish infringement which can be performed either by making objects to the design or by making a design document encompassing the design for the purpose of enabling such objects to be made.<sup>127</sup> It would seem that sharing design rights on file-sharing web platforms that contained an unauthorised version of the protected design would constitute an infringement of that design right.<sup>128</sup> But if it would be done for non-commercial purposes, this would seem to fall

<sup>113</sup> Daly, A, Socio-Legal Aspects of the 3D printing Revolution, pg 26

<sup>114</sup> Idem.

<sup>115</sup> Idem.

<sup>116</sup> Idem.

<sup>117</sup> Bradshaw, S, Bowyer, A, Haufe, P, The Intellectual Property Implications of Low-Cost 3D Printing, 2010, SCRIPTed, 7(1), 5 – 31.

<sup>118</sup> Council Directive 98/71/EC of 13 October 1998 on the legal protection of designs [1998] OJ L289/28

<sup>119</sup> Council Regulation (EC) 6/2002 of 12 Decemeber 2001 on Community Designs [2002] OJ L3/1

<sup>120</sup> 'Must fit' exception applies to products whose shape is determined by the need to connect to or fit into or another product.

<sup>121</sup> Registered Designs Act 1949, s 1B(8).

<sup>122</sup> Registered Designs Act 1949, s 7A (2)(a).

<sup>123</sup> Registered Designs Act 1949, s 7A (2)(b).

<sup>124</sup> Copyright, Designs and Patents Act 1988, s 226(2).

<sup>125</sup> Copyright, Designs and Patents Act 1988, s 213 (2), (3)(a), (3)(c).

<sup>126</sup> Look footnote 83

<sup>127</sup> Copyright, Designs and Patents Act 1988, s 226 (1)

<sup>128</sup> Mendis, The Clone Wars – Episode 1, 2013, pg 165.



within the implicit exception to infringement.<sup>129</sup> The position may be different for the file-sharing web platforms if it would be proven that they profit in some way from the file-sharing activities. In that case, they might be held liable for indirect infringement.

**Key points:**

- **UK and European Community intellectual property rights apply in throughout the UK (there is no geographic sub-division of IP rights in the UK).**
- **Two broad categories of IP in the UK: community rights that apply across the European Union (include Community Trade Marks, registered and unregistered Community Designs) and national rights that apply only in the UK (include national trade marks, national patents, copyright, registered and unregistered designs and European patents that are validated in the UK).**
- **The distinction between what constitutes ‘repair’ (legitimate) and what should be considered as ‘making’ (unlawful) the patented invention is often blurred and unclear.**
- **An object may be protected by copyright where it can be classed as an “artistic work”.**
- **Design rights can be registered either in the UK on the national level, or a designer can decide to protect his design at European level.**

<sup>129</sup> Socio-Legal Aspects of the 3D Printing Revolution, pg 35

<sup>130</sup> Malaty, Elsa, Rostama, Guilda, 3D printing and IP law. WIPO Magazine (February 2017).  
[www.wipo.int/wipo\\_magazine/en/2017/01/article\\_0006.html](http://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html) (last visited on 11 March 2017)

<sup>131</sup> Article L613-5, Article L613-7 of the French Intellectual Property Code

<sup>132</sup> Baud, Emmanuel, Fortunet, Edouard, Patents, trademarks, copyright and designs in France: overview. <https://uk.practicallaw.thomsonreuters.com/3-501->

## 7.2. France

French Intellectual Property Code lays down the rules regarding the intellectual property law. What is specific for the French patent law is the additional infringement ground, namely if the 3D printed object is protected by patent, Article L 613-4 of the Intellectual Property Code of France prohibits supplying or offering to supply the means to use the invention without authorization. Following this approach, patent right holders should be able to seek compensation from third parties for supplying or offering to supply 3D printed files on the grounds that these are an ‘essential element of the invention covered by the patent’.<sup>130</sup> So-called ‘authorised acts’ are not considered to be infringing, such as private non-commercial use; experimental use; improvised preparation for individual use in a pharmacy; or personal prior use.<sup>131</sup>

Copyright in France arises automatically as well, by the mere act of creation. To qualify for protection, no registration is required. It is however recommended to proceed with some sort of filing (for example, via an envelope Soleau or with a bailiff) so as to evidence the date of creation of the work.<sup>132</sup> What is interesting is that in under French law, there is no exception to copyright protection for the use of a work for pedagogical purposes; the reproduction of a work to be distributed to students in an educational setting must be authorized by the owner of the rights of the reproduced work.<sup>133 134</sup> That might be significant when using 3D printed models of the medical devices for educational purposes.

Trademark law is also governed by the rules of Intellectual Property Code. To be registered as a trade mark in France, a sign must be: a) capable of graphical representation (this will no longer apply to EU marks as of 1

[8767?\\_lrTS=20170411141128142&transitionType=Default&contextData=%28sc.Default%29&firstPage=true&bhcp=1](http://8767?_lrTS=20170411141128142&transitionType=Default&contextData=%28sc.Default%29&firstPage=true&bhcp=1) (last visited on 16 March 2017)

<sup>133</sup> Article L122-5, IPC

<sup>134</sup> Copyright in France  
<http://www.casalonga.com/documentation/Copyright/copyright-in-france-230/?lang=en> (last visited on 15 March 2017)



October 2017 and national trade marks on implementation of Directive 2015/2436); b) distinctive; c) not deceptive; d) lawful and e) available (cumulative requirements).<sup>135</sup> Registration of trademarks is necessary,<sup>136</sup> since only well-known trademarks can be granted protection without registration under Article 6 bis of the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).

#### Key points:

- **French Intellectual Property Code as an IP codex**
- **Additional infringement ground of patents: supplying or offering to supply the means to use the invention without authorization**
- **There is no exception to copyright protection for the use of a work for pedagogical purposes – the reproduction of a work to be distributed to students in an educational setting must be authorized by the owner of the rights of the reproduced work; this might have consequences on using 3D printed models of the medical devices for educational purposes**

### 7.3. The Netherlands

Patent protection in the Netherlands is regulated by law in the Dutch Patent Act 1995, which came into force 1 April 1995<sup>137</sup>. Until that time the Patent Act 1910 was in force. A patent covering the Netherlands can be obtained through three different routes: through the direct filing of a national patent application with the Netherlands Patent Office (Dutch: Octrooiencentrum Nederland) (direct national route), through the filing of a European patent application (European route), or through the filing of an international application under the Patent Cooperation Treaty followed by the entry into European phase of said international application (Euro-PCT route).<sup>138</sup>

According to the Dutch Copyright Law (called Auteurswet), a Dutch copyright (called auteursrecht) is the exclusive right of the author of a work of literature, science or art, to publish and duplicate such work.<sup>139</sup> In certain circumstances, one is allowed to make a copy of copyright materials. According to Dutch Auteurswet article 16b and 16c § 1,[4] and Wet op de Naburige rechten article 10, 'reproducing a piece of literature, science or art' is not seen as infringement to copyright if in line with the following: a) The home copy is not, direct or indirect, means for monetary gain; b) The copy serves exclusively to own practice, study or use; c) The number of copies are limited, or the creator of additional copies compensates the holder.

The Belgium law has similar regulation in their Auteurswet (art. 22 § 1, 5°). On 10 April 2014, the European Court of Justice ruled the Dutch exclusion for home-copying to be infringing the directive 2001/29/EG - article 5 § 2- b and § 5<sup>140</sup>. According to EU directive, this makes homecopying unlawful. There have been other cases in which Dutch Auteurswet has been ruled unlawful. The Netherlands however has not changed said article nor

<sup>135</sup> Articles L711-1 to L711-4 of the French Intellectual Property Code

<sup>136</sup> Article L. 712-1, IPC

<sup>137</sup> Rijkswet van 15 december 1994, houdende regels met betrekking tot octrooien

<sup>138</sup> National Enterprise Agency, Apply for patent.  
<http://english.rvo.nl/topics/innovation/patents-other-ip-rights/apply-patent>  
(last visited 02 April 2017)

<sup>139</sup> Wet van 23 september 1912, houdende nieuwe regeling van het auteursrecht (Auteurswet 1912, tekst geldend op: 01-07-2015), Article 1

<sup>140</sup> Case C-435/12, ACI Adam BV v. Stichting de ThuisKopie, E.C.J. Apr. 10, 2014)



complied to the request to make prosecuting those whom homecopy possible.

Trademark registration in the Netherlands can be made either through the Benelux Office for Intellectual Property or through the World Intellectual Property Organization.

### Key points

- **There are three different routes for obtaining a patent right: direct national route, European route, Euro-PCT route**

## 7.4. USA

Patents protect new, useful, and non-obvious inventions from copying, after an application for the patent has been filed and granted by the United States Patent and Trademark Office ('USPTO').<sup>141</sup> The requirements for obtaining a patent therefore include the elements of novelty, non-obviousness and usefulness. Whether a patent application will be considered as novel an inventive, that will be judged against the 'prior art'<sup>142</sup>, and the provisional invention must also not be 'obvious' to another person with similar skills and knowledge in the same technology.<sup>143</sup> Many of the processes used in 3D printing are patented. There are two main types of patents under the US law: utility patents and design patents, both of which are applicable to 3D printing.

Utility patents cover inventions that are "a new and useful process, machine, manufacture, or composition of matter".<sup>144</sup> Design patents, registered design rights in the USA, cover "any new, original and ornamental design for an

article of manufacture."<sup>145</sup> 3D objects can probably be protected by both copyright and design patents, but because one needs to file an application to obtain a patent, design patent infringements are not so common.<sup>146</sup> However, in contrast to utility patents, design patents can be obtained in about one year under standard examination, and in approximately three to four months under expedited examination, which allows the design patents to come into force while the product is still in the heart of its life cycle<sup>147</sup>. This could be a valuable tool in fighting 3D printed counterfeited medical devices.

There is no exemption for non-commercial use under US patent law and the copyright fair use provision does not extend to patents.<sup>148</sup> Applying the model that exists in the USA to the consumer 3D printing means that any legal entity that uses, sells, offers for sale or imports the patented item without the requisite authority of the patent holder would be liable for direct infringement, regardless of the intentions of the patent infringer.<sup>149</sup>

CAD files are not to be considered as "components" of a patented product. Therefore, patent law is not applicable to the entities that create the patent infringing CAD file, even in the case when they would be subsequently able to sell the CAD file.<sup>150</sup> Consequently, patent law does not become relevant for 3D printing until the patented good is printed, and this is something that the legislature needs to change in order to effectively apply patent protection to commercial 3D printing.<sup>151</sup>

In addition, in many cases, it will not be considered as illegal to manufacture replacement parts of a patented item, under a condition that those individual parts are not themselves covered by a specific patent, and so long as the

<sup>141</sup> Youngstrom, Evan R, 3D Printing and Healthcare: Will Laws, Lawyers, and Companies Stand in the Way of Patient Care? Pace Intellectual Property, Sports & Entertainment Law Forum, Vol. 5, Number 1, Spring 2016

<sup>142</sup> Prior art is all the inventions already in existence before.

<sup>143</sup> Socio-Legal Aspects, pg. 29.

<sup>144</sup> 35 US Code § 101 (2012)

<sup>145</sup> 35 US Code § 171 (2012)

<sup>146</sup> Thrier, Marcus, op.cit., 380

<sup>147</sup> Pierce, Justin Schwarz, Steven. Time to put strategies in place for 3D printing. United States 3D Printing. Managing ip.com, April 2015

<sup>148</sup> 35 US Code § 271

<sup>149</sup> Twomey, Peter. A New Dimension to Intellectual Property Infringement: An Evaluation of the Intellectual Property Issues Associated with 3D Printing. Trinity College Law Review, 2014, Vol. 17, 14 – 36.

<sup>150</sup> Idem.

<sup>151</sup> Idem.



repair does not constitute a reconstruction of the item in its entirety from constituent parts.<sup>152</sup>

The Patent and Copyright Clause of the Constitution empowers Congress “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>153</sup> The goal of both patent and copyrights is to give creators a limited monopoly over the fruits of their intellectual labours.<sup>154</sup>

Broadly speaking, the purpose of contemporary IP is to encourage creation and innovation through the award of exclusive rights over such creations and innovations for a certain period of time for creators/ inventors or their assignees. This stems from the ‘Copyright Clause’ Of the US Constitution: *‘To promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’* Whether the grant of IPRs is actually justified and whether it does really promote the creativity and innovation is contested.<sup>155</sup> Under the 1976 Copyright Act copyright owners are given certain exclusive rights. In order to be entitled with copyright, one must have a creation that falls under the scope of the list of eight categories worthy of copyright protection.<sup>156</sup> The list specifically excludes useful articles, i.e. an article having an intrinsic utilitarian function that is not merely to portray the appearance of the article or to convey information.<sup>157</sup> In other words, this means that the court will not grant a monopoly over the functional aspects of the work if a work is functional. The reason for that is that it would be considered that that monopoly would go against the purpose of Copyright act, and that is to promote the progress of science and useful Arts, as stated in the U.S. Constitution.<sup>158</sup>

The 3D printer implicates the exclusive rights of authors in at least two ways: the digital blueprint and the object produced by the 3D printer. Both of them easily meet the “fixation” requirement, and as long as it can be classified as an expression, and has the requisite amount of originality, copyright protection will immediately attach as soon as the object/programming is complete.<sup>159</sup>

Long before the Internet revolution, in 1984, the Supreme Court decided in the case *Sony Corporation of America v. Universal City Studios, Inc.*, that “the sale of copying equipment, like the sale of other articles of commerce, does not constitute contributory infringement if the product is widely used for legitimate, unobjectionable purposes”. The case dealt with VCRs<sup>160</sup>, but the argument also applies to 3D printers.<sup>161</sup>

In 1998, when the Digital Millennium Copyright Act (DMCA) was passed, the concept of “safe harbour” and takedown notices was introduced to exempt Internet intermediaries from copyright infringement liability under certain criteria, as set down in the Section 512 of the DMCA. In order to fall under the scope of the safe harbour, Internet intermediaries must comply with certain requirements. They must have no knowledge of the infringing act, cannot receive a financial benefit directly attributed to the infringing activity and the service provider must promptly block access to alleged infringing material or remove such material from their systems as soon as the copyright holder (or his agent) notifies the intermediary of an infringement claim.<sup>162</sup><sup>163</sup> However, the issue when dealing with 3D printer digital blueprints is that there is indication that the take down notices can be used for frivolous claims in regard to actual copyright protection. It is therefore important to remember that the fact that a notice has been issued, does not necessarily mean that the claim can be supported in court.<sup>164</sup> However,

<sup>152</sup> Socio-Legal Aspects of the 3D Printing Revolution, pg. 30

<sup>153</sup> US Constitution. Art. I, § 8, cl.8.

<sup>154</sup> Thierer; Marcus, op.cit., 380

<sup>155</sup> Daly, A., Socio-Legal Aspects of the 3D Printing Revolution, op.cit.

<sup>156</sup> 17 U.S. Code § 102 (2012)

<sup>157</sup> 17 U.S. Code § 101 (2012)

<sup>158</sup> U.S. Constitution, Article I, § 8, cl.8.

<sup>159</sup> Swanson, Sarah. Op.cit., 422.

<sup>160</sup> VCR is an abbreviation of the videocassette recorder.

<sup>161</sup> Thierer; Marcus, op.cit., 380

<sup>162</sup> Swanson, Sarah. Op.cit., 422

<sup>163</sup> 17 U.S. Code § 512 (2012) – Limitations on liability relating to material online.

<sup>164</sup> Swanson, Sarah. Op.cit., 422



copyright owners were not completely satisfied with the given evolution of the new system that was just established in hope that it will preserve the copyrights in the online world so then they used governmental pressure to implement a system called the Copyright Alert Program (CAP) – a “graduated response” system in which rightsholders work with Internet service providers to identify and send warning notices to infringers. If the infringements persist, ISPs must enact “mitigation measures” that may include temporarily throttling the speed of the user’s Internet connection and could include permanently disconnecting the user from the Internet.<sup>165</sup>

It follows that the manufacturers of 3D printers are not likely to be sued for copyright infringement unless they advertise their devices in such a way that would directly promote copyright infringement.

Some authors like Thierer and Marcus, argue that the online platforms used to share designs will be treated no differently from services used to share music and films, i.e. in case they would host infringing content, they will receive DMCA takedown notices and will likely remove the infringing content.<sup>166</sup> In case they would refuse to do so, they would lose their safe harbour protection and would be held liable. However, DMCA system seems to be unable to provide the effective protection of copyright. Therefore, one must search for the alternative ways of protection. Fingerprinting is an example of such alternative and it stands for type of the robust digital watermarking technology that automatically searches the Internet for infringing copies of those works and sends the takedown notice and/or settlement agreements.<sup>167</sup>

It is most likely that similar technologies for searching for 3D models that infringe copyrights will be created soon in short period from now. In fact,

researchers are already developing 3D facial recognition systems (*Animetrics* is an example of such a technology developer).<sup>168</sup>

As for whether the 3D printed object itself will attract copyright protection, under the US law a broad category of sculptural works can enjoy copyright protection, but any ‘useful article’<sup>169</sup> is excluded from this protection. If the object embodies both aesthetic and useful qualities, the severability test will have to be applied, resulting in decorative or aesthetic elements of the object enjoying copyright protection.

*Computer program – is it copyrightable in the USA?*

Computer programs were not given their own category. The copyright owner could register the work as either a literary work, protecting the program code, or as an audio-visual work protecting the user interface.<sup>170</sup> Some suggest that a way to update the copyright system in the US is to give the digital blueprint or 3D object its own category of protection, just like it has been done with sound recordings and architectural works.<sup>171</sup>

In common law jurisdictions, trademark claims are often brought together with the claims relating to the tort of ‘passing off’ (or ‘misappropriation’ in the USA), whereby the goodwill of a trader is appropriated in a way which causes confusion as to the origin of goods.<sup>172</sup> Passing off only applies to uses which are not private as others must be misled.

<sup>165</sup> Thierer; Marcus, op.cit., 380

<sup>166</sup> Thrier; Marcus, op.cit., 380

<sup>167</sup> Idem.

<sup>168</sup> Idem.

<sup>169</sup> Useful article is an article having an intrinsic utilitarian function that is not merely to portray the appearance of the article or to convey information. 17 U.S.C. § 101-02 (2006).

<sup>170</sup> Swanson, Sarah. Op. cit., 422

<sup>171</sup> Idem.

<sup>172</sup> Socio-Legal Aspects of the 3D Printing Revolution, pg 38



### Key points

- Requirements for obtaining a patent include the elements of novelty, non-obviousness and usefulness.
- Utility patents cover inventions that are “a new and useful process, machine, manufacture, or composition of matter.
- Design patents, registered design rights in the USA, cover “any new, original and ornamental design for an article of manufacture”.
- Design patents can be obtained in about one year under standard examination, and in approximately three to four months under expedited examination, which allows the design patents to come into force while the product is still in the heart of its life cycle which could be a valuable tool in fighting 3D printed counterfeited medical devices.
- No exemption for non-commercial use under US patent law and the copyright fair use provision does not extend to patents.
- CAD files are not to be considered as “components” of a patented product, hence patent law does not become relevant for 3D printing until the patented good is printed.
- Digital Millennium Copyright Act (DMCA) introduced the concept of “safe harbour” and takedown notices to exempt Internet intermediaries from copyright infringement liability under certain criteria.
- No special category for computer programs – can copyright the work as either a literary work, protecting the program code, or as an audio-visual work protecting the user interface.