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1 Introduction

Developments in the field of 3D printing have meant that 3D printers are gaining in significance in medical technology. Although the placing on the market of medical devices is subject to clear legal provisions, the wide variety of uses and applications involved has created uncertainty in the marketplace. 3D printers also open up new business models, which in turn raise new questions as regards the legal responsibility for the medical device in question.

2 Objective

This Information Sheet is intended for manufacturers, distributors and users of 3D printers who use this technology to manufacture medical devices. It provides guidance on the relevant legal bases and their implementation by Swissmedic.

3 Scope

This Information Sheet only addresses the use of 3D printers for classical and active implantable medical devices. It does not deal with the use of 3D printers to manufacture medicinal products (e.g. for "personalised medicine").

Valid legal texts and standards:

- European Medical Device Directives
  - Directive 93/42/EEC
  - Directive 90/385/EEC
- National legislation
  - TPA
  - MedDO
  - HRA
  - ClinO

Guidance:

- Swissmedic Guide to the regulation of medical devices

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4 3D printers and medical device legislation

3D printers can be used in various forms. Differing legal bases apply to the medical devices manufactured on them, depending on the form concerned.
Medical devices manufactured on 3D printers can essentially be divided into three groups: "custom-made devices"; "customised devices" (mass-production medical devices that have been adapted); and "mass-production devices". The following table illustrates the differences between the three groups:

	Custom-made devices	**Customised devices**	**Mass-production devices**
Description and example	A medical device produced specifically for a certain patient (e.g. custom-fit bone substitute).	A mass-production medical device that is adapted to a specific patient before use. (e.g.: a mass-production crown that is adapted for the patient by a dental technician). These mass-production devices are not considered to be custom-made even though they have been adapted.	A medical device that is manufactured on a 3D printer in a standardised process and that is not individually adapted (i.e. to a specific patient) before use. (e.g. hip implant manufactured on a production line).
Requirements pertaining to the 3D printer	Production facilities (incl. 3D printers) must be validated. *References: Manufacturing requirements specified in Annex I of Directive 93/42/EEC and Annex I of Directive 90/385/EEC. Harmonised standards for medical devices specify the detailed requirements*.	Production facilities (incl. 3D printers) must be validated. *References: Manufacturing requirements specified in Annex I of Directive 93/42/EEC and Annex I of Directive 90/385/EEC. Harmonised standards for medical devices specify the detailed requirements*.	Production facilities (incl. 3D printers) must be validated. *References: Manufacturing requirements specified in Annex I of Directive 93/42/EEC and Annex I of Directive 90/385/EEC. Harmonised standards for medical devices specify the detailed requirements*.
Requirements pertaining to the medical device and manufacturer	The medical device produced on the printer must satisfy the essential requirements set out in Annex I Directive 93/42/EEC and Directive 90/385/EEC. Exceptions are possible and must be justified in each case. If the essential requirements are not fully met, the reasons must be stated in writing in the custom manufacturer's declaration. No CE marking is affixed to the device. The custom manufacturer's declaration must be prepared and must accompany the device at all times. The	The medical device produced on the printer must satisfy the essential requirements set out in Annex I Directive 93/42/EEC and Directive 90/385/EEC. The manufacturer must demonstrate compliance and prepares a declaration of conformity. A recognised conformity assessment body for medical devices must have issued an EC certificate (does not apply to non-sterile Class I medical devices without a measuring function).	The medical device produced on the printer must satisfy the essential requirements set out in Annex I Directive 93/42/EEC and Directive 90/385/EEC. The manufacturer must demonstrate compliance and prepares a declaration of conformity. A recognised conformity assessment body for medical devices must have issued an EC certificate (does not apply to non-sterile Class I medical devices without a measuring function).

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	declaration is given to the prescriber / patient. Custom manufacturers domiciled in Switzerland must be registered with Swissmedic. For other obligations see "Guide to the regulation of medical devices."	The user should adapt the individual device to his/her personal requirements in line with the manufacturer's instructions, otherwise he/she assumes the manufacturer's obligations. For other obligations, see "Guide to the regulation of medical devices"	For other obligations see "Guide to the regulation of medical devices"
Legal bases	Art. 1a, Art. 6 and Annex 3 clause 10 MedDO	Art. 1a, 2nd section and Annex 3 MedDO	Art. 1, 2nd section and Annex 3 MedDO

4.1 What is the medical device?

The 3D printer, being hardware, is not a medical device. However, it can be used to produce a medical device. The situation is different for the software for a 3D printer. This software may be classified as a medical device depending on its functionality and intended use. This should be verified in each individual case. For more information, please refer to our Information Sheet for medical device standalone software.

4.2 Who is legally responsible for 3D-printed medical devices?

Anyone who manufactures medical devices with a 3D printer and places them on the market for the first time (including distribution and dispensing) is deemed to be the manufacturer and must satisfy all the associated legal obligations. This includes compliance with the requirements pertaining to the manufacture and first placing on the market of the medical device.

4.2.1 Legal responsibility for custom-made devices

Unless specific design solutions are stipulated by the prescriber (e.g: a doctor), the custom manufacturer bears full responsibility for demonstrating the technical and clinical suitability of the solutions it adopts. Custom manufacturers therefore tend to adopt technical solutions and design solutions whose suitability has been proven. If there is any uncertainty, they request additional information from the prescriber.
If a custom manufacturer offers innovative technical solutions or designs, the testing needed to demonstrate compliance with the "*Essential requirements"* can be extensive. The scope of testing varies according to the risks, claims and degree of innovation. If the device is made to measure, the design also has to be clinically validated. In particular, a *"Clinical evaluation"* must be prepared. Clinical trials may be needed to obtain the necessary clinical data. Further information about the *Clinical evaluation* can be found in the European guideline MEDDEV 2.7.1.
Anyone, including doctors and technical services at a hospital, who prints and thereby manufactures medical devices becomes the manufacturer and must satisfy all the associated legal obligations.

4.2.2 Clinical trials of custom-made devices (investigations with human subjects)

a. Category C clinical trials ("Pre-market trials")
Here the suitability of specific design solutions for patients has not yet been established and is therefore the subject of the investigation. The investigational devices have not yet systematically satisfied the *Essential requirements*.
Examples include prototype trials and validation studies.

b. Category A clinical trials ("Post-market trials")
Here the devices' suitability for the intended patients has essentially been demonstrated.

Further information on clinical trials can be found in Information Sheet BW101_50_002e_MB.

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5 Penal provisions

For information on the penal provisions for misdemeanours and contraventions, see Art. 86 - 90 TPA.

Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
01	**02.05.2016**	**New QM ident: MU500_00_002e_MB** **Old QM ident: MU000_00_007e_MB** **The remaining content of the document was not reviewed and stays unchanged.**	**sel**
01	**21.03.2016**	**First version**	**bbe**

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