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1 Introduction

The development in the field of 3D printers means that they are also gaining in significance in medical technology. Their different areas of applications and use raise complex questions regarding the legal responsibility for medical devices that are manufactured using 3D printers.

2 Objective

This information sheet is intended for manufacturers and users of medical devices, who use 3D printing technology. It provides guidance on the most relevant applicable legal bases.

3 Scope

This information sheet exclusively addresses the use of 3D printers in the context of medical devices (excluding in-vitro diagnostics).

Valid legal texts and standards:

- European Medical Device Regulation
  - Regulation (EU) 2017/745 (EU-MDR)

- National legislation
  - Federal Act on Medicinal Products and Medical Devices (TPA; SR 812.21)
  - Medical Devices Ordinance (MedDO; SR 812.213)
  - Federal Act on Research involving Human Beings (HRA; SR 810.30)
  - Ordinance on Clinical Trials with Medical Devices (ClinO-MD; SR 810.306)

- Definitions and guidance documents:
  - MDCG 2021-3, *Questions and Answers on Custom-Made Devices*

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4 3D printers and medical device legislation

4.1 What is the medical device?

The qualification of a product as a medical device depends on its intended purpose.

This information sheet solely describes the case that the 3D printer itself is not a medical device, but used as production equipment for manufacturing of a medical device. Medical devices manufactured in this manner, including parts and components and accessories for medical devices, fall under the legal requirements for medical devices.

This information sheet does not cover software used in the context of 3D printers, or used as stand-alone software. It must be examined on a case-by-case basis, whether a software serves a specific medical purpose and qualifies as a medical device.

4.2 Who is responsible for 3D-printed medical devices under therapeutic products law?

Any person, who – including by means of a 3D printer – manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark, is considered as the manufacturer and must satisfy all associated legal obligations.[1]

Manufacturers are subject to the general obligations of economic operators and must, among other obligations, register with Swissmedic and notify certain medical devices.[2] Manufacturers must ensure that their medical devices fulfill the legal requirements upon placing them on the market or putting them into service.[3] Medical devices must meet the general safety and performance requirements as specified by Annex I EU-MDR, and as further substantiated by the designated applicable technical standards, common specifications, and pharmacopoeial requirements.[4]

Manufacturers must maintain a quality management system, including a system for risk management and for post-market surveillance.[5] When handling medical devices (e.g. during manufacturing, maintenance and reprocessing), manufacturers must take all measures necessary according to the state of the art to ensure that human health is not endangered.[6] Manufacturers are liable for damages caused by defective medical devices.[7]

4.3 Identification of requirements

For medical devices manufactured by 3D printers, the following cases can in principle be distinguished as listed in the table below.

The qualification of a 3D-printed product as a medical device within the framework of the applicable definitions of MedDO, EU-MDR and the European MDCG guidelines, is only feasible under overall consideration of all relevant features, including its intended purpose, use and accompanying documentation as defined by the manufacturer. The fulfillment of individual features provided in the table is therefore not indicative of a conclusive qualification. An individual case-by-case examination must always be made.

It falls within the responsibility of the manufacturer to identify the applicable requirements.

[1] Art. 4 para. 1 let. f MedDO
[2] Art. 55 MedDO, Art. 18, Art. 19 and Art. 108 MedDO
[3] Art. 46 para. 1 MedDO
[4] Art. 6 MedDO
[5] Art. 50 MedDO, Art. 47b TPA
[6] Art. 3 TPA
[7] Art. 47d TPA

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4.4 Tabular overview

	Custom-made device	Adaptable medical device	Devices which are mass-produced by means of industrial manufacturing processes („mass-produced medical device“ & „patient-matched medical device“)
Definitions	**‘Custom-made device’** means any device **specifically** made in accordance with a **written prescription** of any **person authorised by national law** by virtue of that person's professional qualifications which gives, **under that person's responsibility**, **specific design characteristics**, and is **intended for the sole use of a particular patient** exclusively to meet their **individual conditions and needs**.[8] Mass-produced **devices which need to be adapted** to meet the specific requirements of any professional user **and devices which are mass-produced by means of industrial manufacturing processes** in accordance with the written prescriptions of any authorised person **shall not** be considered to **be custom-made devices**.[8]	Adaptable medical devices are mass-produced medical devices which must be adapted, adjusted, assembled or shaped at the point of care, traditionally by a healthcare professional, in accordance with the manufacturer’s validated instructions to suit an individual patient’s specific anatomo-physiologic features prior to use.[9]	A mass-produced medical device is based on standardised dimensions / designs; that is not designed for a particular individual; and that is typically produced in a continuous production run or homogenous batch.[9] A patient-matched device[10] is matched to a patient’s anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and it is typically produced in a batch through a process that is capable of being validated and reproduced; and it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.[9]

[8] Art. 4 para. 2 MedDO i.c.w. Art. 2 point 3 EU-MDR
[9] See MDCG 2021-3, Questions and Answers on Custom-Made Devices
[10] Technical term ‘patient-matched device’, not identical to ‘adaptable medical device’

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	Custom-made device	**Adaptable medical device**	**Devices which are mass-produced by means of industrial manufacturing processes** („mass-produced medical device“ & „patient-matched medical device“)
General Safety and Performance Requirements	Art. 10 para. 1 MedDO i.c.w. Art. 2 pt. 3 and Annex XIII sect. 1 EU-MDR The authorised person issuing the written prescription is responsible for the design and intended purpose, the manufacturer is responsible for meeting the applicable general safety and performance requirements of the medical device.[9] General safety and performance requirements which have not been fully met must be indicated together with the grounds in the declaration according to Annex XIII EU-MDR.	Art. 6 MedDO i.c.w. Annex I EU-MDR The manufacturer is responsible for the design and manufacture, and for meeting the general safety and performance requirements of the medical device. Art. 4 let. f MedDO i.c.w. Art. 16 EU-MDR Adaptions of an individual device by the user must be made according to the intended purpose and instructions of the manufacturer, otherwise the user assumes the obligations as a manufacturer.	Art. 6 MedDO i.c.w. Annex I EU-MDR The manufacturer is responsible for the design and manufacture, and for meeting the general safety and performance requirements of the medical device.
Written Prescription	Yes, Art. 10 para. 1 MedDO i.c.w. Art. 2 pt. 3 and Annex XIII sect. 1 EU-MDR	No requirement	No requirement
(Conformity Assessment)-Procedure	Art. 10 MedDO i.c.w. Annex XIII EU-MDR For class III custom-made implantable devices, an additional conformity assessment according Chapter I of Annex IX or Part A of Annex XI must be performed, involving a notified body.	Art. 23 MedDO i.c.w. Art. 52, 54 and Annexes IX-XI EU-MDR	Art. 23 MedDO i.c.w. Art. 52, 54 and Annexes IX-XI EU-MDR
Declaration (of Conformity)	Art. 10 para. 1 MedDO i.c.w. Annex XIII sect. 1 EU-MDR	Art. 29 MedDO i.c.w. Annex IV EU-MDR	Art. 29 MedDO i.c.w. Annex IV EU-MDR
Conformity Marking	No, Art. 13 para. 2 let. a MedDO	Yes, Art. 13, 46 and Annex 5 MedDO or Annex V EU-MDR	Yes, Art. 13, 46 and Annex 5 MedDO or Annex V EU-MDR
Labelling	Art. 16 MedDO i.c.w. Annex I EU-MDR Label ‘custom-made device’	Art. 16 MedDO i.c.w. Annex I EU-MDR	Art. 16 MedDO i.c.w. Annex I EU-MDR

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	Custom-made device	**Adaptable medical device**	**Devices which are mass-produced by means of industrial manufacturing processes** („mass-produced medical device“ & „patient-matched medical device“)
Unique Device Identification (UDI)	No, Art. 17 para. 1 MedDO	Yes, Art. 17 MedDO i.c.w. Art. 27, 29 and Annex VI EU-MDR	Yes, Art. 17 MedDO i.c.w. Art. 27, 29 and Annex VI EU-MDR
Transitional Provisions for Legacy Devices	None	Art. 100, 101 MedDO	Art. 100, 101 MedDO

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Change history

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1.0	30.12.2022	New QM-Ident: MU600_00_017e_MB Old QM-Ident: MU500_00_002e_MB Changes due to regulatory revision of medical devices 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. The first version was created the 21.03.2016.	fro

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