



## **3D Printing — Custom-Made vs. Adaptable Medical Devices and Their Requirements**

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### ***3D Printing of Medical Devices and Pharmaceuticals — Where Are We Now?***

“3D printing” and “additive manufacturing” are umbrella terms for a selection of techniques typically aimed at the precision customization of products tailored for the needs of a specific patient. To date, the major application of 3D-printed medical devices has been to produce surgical guides, musculoskeletal implants, hearing aids, orthotics, dental devices, and other devices that lend themselves to personalization. As the technology becomes more sophisticated, we are beginning to see the development of 3D-printed body parts, facial reconstructions, and even the possibility of [3D printing a human knee meniscus in outer space](#). Additionally, there is the potential for 3D-printed pharmaceuticals to be tailored across a range of metrics according to the preference or need of a particular patient; for example, tablet shape, porosity, and solubility could be adjusted on an individual basis, and there is even the possibility of combining several medicinal products within a single tablet.

In this article, we set out the major regulatory considerations for 3D-printed medical devices. In the next editions of *Swiss Life Sciences Briefing*, we will consider how these same considerations apply to medicinal products.

### ***Regulatory Considerations for Medical Devices***

A clear distinction must be made between the hardware (the 3D printer itself) and its output (the medical device). The printer will need to comply with the applicable rules and harmonized standards for machinery (Directive 2006/42/EC), whereas the medical devices it produces will need to comply with the applicable medical device rules (Regulation (EU) 2017/745 (EU MDR)). Applicable rules governing data, software, and potential use of artificial intelligence (AI) will also need to be complied with.

The following are a selection of the key considerations manufacturers will need to keep in mind when placing a 3D-printed medical device on the market. Identifying the applicable requirements is crucial for maintaining the compliance of the device in question.

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**Custom-made devices (CMDs).** Under the EU MDR, a medical device personalized for an individual patient or set of patients might be considered a CMD. This is defined in Article 2(3) [EU MDR](#) as

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

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

Therefore, to be clear, a 3D-printed medical device will not qualify as a CMD by default, but an assessment should be performed on a case-by-case basis. To qualify as a CMD, MDCG 2021-3 [guidance](#) confirms that a device must i) be subject to a written prescription with patient-specific design characteristics, ii) be intended for the sole use of a particular patient, and iii) not be mass-produced.

While CMD manufacturers must comply with the vast majority of the EU MDR requirements, including maintaining quality management and postmarket surveillance systems, the obligations of CMD manufacturers differ from those of conventional medical devices under the EU MDR in certain instances.

In summary, the key differences with regard to EU MDR requirements compared to conventional medical devices include

- ✓ the conformity assessment for CMDs is set out in Annex XIII and requires an **Annex XIII statement**, to be made available to the particular patient or user identified by a name, an acronym, or a numerical code in place of a declaration of conformity
- ✓ a **conformity assessment procedure** covering quality management system certification by a notified body is applicable to Class III implantable CMDs (Article 52(8) EU MDR)



- ✓ CMD manufacturers are **exempt** from unique device identifier registration, assignment and labeling requirements, and the requirement to produce a Summary of Safety and Clinical Performance (Article 32(1) EU MDR)
- ✓ though CMD manufacturers must appoint a **person responsible** for regulatory compliance (Article 15 EU MDR), they are not required to register them on the EUDAMED system

**Adaptable medical devices.** Adaptable medical devices are defined in the International Medical Device Regulators Forum (IMDRF) [Guidance](#) “Definitions for Personalized Medical Devices” as mass-produced products that must be adjusted or assembled at the point of care in accordance with the manufacturer’s validated instructions, to suit an individual patient’s specific anatomic-physiologic features. According to the IMDRF [Guidance](#), a device will be mass produced if it is based on standardized dimensions/designs, is not designed for a particular individual, and is typically produced in a homogenous batch. Adaptable medical devices differ from CMDs in that they are not specifically made in accordance with a written prescription to meet the needs of a particular patient.

**Patient-matched devices.** As for adaptable medical devices, the IMDRF [Guidance](#) defines an additional category of device that might be applicable to 3D-printed devices. A device is a patient-matched device if it is mass produced and is matched to a patient’s anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic reference or patient imaging. Such devices differ from CMDs because they are not dependent on a written prescription and differ from adaptable medical devices because they are solely under the responsibility of the manufacturer and do not require adaption or assemblage at the point of care.

**Identification of Responsibilities.** It is important to note that legal responsibilities under the EU MDR sit with different legal persons depending on whether the device qualifies as a CMD. Identifying the applicable responsibilities and liabilities in each case is a critical step in ensuring the compliance of 3D printed medical devices. For example, for CMDs, the authorized person issuing the written prescription holds responsibility for the design and intended purpose of the device, while the manufacturer is responsible for meeting the general safety and performance requirements (Article 2(3) and Annex XIII(1) EU MDR). For adaptable and patient-matched medical devices, it is the manufacturer that is responsible for the design, intended purpose, and general safety and performance requirements of the device. If an individual were to amend the intended purpose of an adaptable device, departing from the instructions of the manufacturer, then that person takes on the obligations of the manufacturer (Article 16(1) EU MDR).

## ***Conclusion***

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3D-printed devices offer vast opportunities for companies capitalizing on the accelerating trend of personalised healthcare. The EU MDR accommodates such products, though as described above, to remain in a state of compliance, manufacturers must be cognizant of the nuanced differences among CMDs, adaptable medical devices, and patient-matched devices and where the regulatory responsibilities sit in each case.

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