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Regulatory framework for 3D printed custom-made devices in Europe

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Abstract: Additive manufacturing (AM) has been growing continuously over the past 20 years, enabling unprecedented tailoring to the anatomy of each patient. In Europe, custom-made devices qualify for an exemption and pass a simplified approval process. New technologies, like AM, provoke questions about the adequacy of the current regulatory framework for custom-made devices. This article addresses the regulatory requirements for such devices in Europe and discusses the implications for AM. It concludes that the legal framework for custom-made devices entails uncertainties which need to be resolved to guide manufacturers through the regulatory requirements, highlighting the specific areas of focus for AM.

I. Introduction

Additive manufacturing (AM) is a specific 3D printing process. However, these terms are often used as synonyms. Over the past 20 years, 3D printing technologies have experienced substantial growth. Advancement in technology, fall in prices, and improved quality make 3D printing applicable and reliable for industrial applications, including medical device manufacturing [1]. The growing interest in AM by the healthcare sector is confirmed by the exponential growth of PubMed indexed publications since 2000 (see Fig. 1). A great advantage of AM is that medical devices can be produced in smaller quantities, according to patient's individual needs. Nowadays, among others, dental prosthesis, orthoses, implants, and models for surgical planning are manufactured as custom-made devices using 3D printing. Thus, raising concerns about the current regulation of custom-made devices [2].

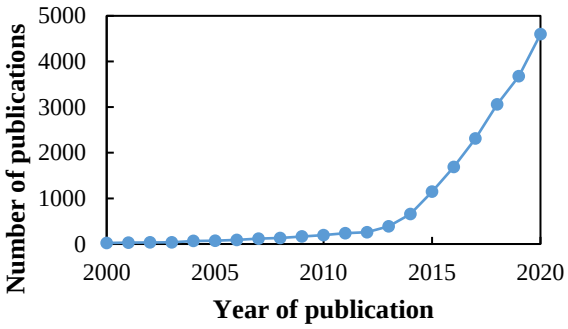

Figure 1: PubMed trends showing an increasing number of indexed publications on "3D printing" OR "additive manufacturing" OR "rapid prototyping" (any field).

In Europe and in many other jurisdictions as well, custom-made devices qualify for an exemption and therefore are subject to a simplified pre-market approval process. But this regulation was introduced in times where the manufacture of a custom-made device was associated with relatively low risks due to a lack of complexity. Since then, the applications have evolved. New technologies, such as AM, enable the production of custom-made devices in larger quantities as well as the manufacture of highly complex devices on a case-by-case basis. Thereby, raising questions regarding the adequacy of the current regulatory framework for custom-made medical devices.

Hence, this article elucidates the regulatory requirements for custom-made devices in Europe and discusses the consequences for additively manufactured medical devices.

II. Regulatory Framework in Europe

In May 2021, the European Medical Device Regulation (MDR) replaced the Medical Device Directive (93/42/EEC) and the Directive on Active Implantable Medical Devices (90/385/EEC). The MDR, as the previous directive, comprises an exemption for custom-made devices. The term custom-made device is defined in Article 2(3) 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. "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"* are delineated from the custom-made device exemption. According to the MDR, such devices are not considered custom-made [3].

In the field, there is disagreement about the impact of the extension of the current definition on 3D printed medical devices. This is because it is unclear how industrial manufacturing processes are to be understood under terms

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of the MDR. There is a view that custom-made devices manufactured with AM do not meet the MDR definition because AM is an industrial production process [4]. On the other hand, it is argued that the production method is not decisive for classifying as a custom-made device. This opinion is supported, for example, by the European and International Federation of Dental Laboratory Owners (FEPPD), and by the German Society for Interprofessional Provision of Aids e. V. (Deutsche Gesellschaft für interprofessionelle Hilfsmittelversorgung e. V., DGIHV). The associations refer to a written reply of the European Commission (Ref. Ares (2017) 4450987-12/09/2017), which states *"to be a custom-made device, a device must fall under the definition of Article 2(3) MDR. […] the method of manufacturing is not decisive for the qualification as custom-made device"* [5, 6]. It should be noted that the Commission's response letter is not a legally binding document. Therefore, the stance of the associations on custom-made devices should not be seen as obliging.

Until today, the European Commission did not issue any legally binding documents clarifying the second section of the MDR definition of a custom-made device. However, a Q&A-document on this topic was published by the Medical Device Coordination Group (MDCG) – an expert committee requested by the MDR – in March 2021 [7]. According to Article 105 MDR, the expert committee shall, among other things, contribute to an *„effective and harmonised implementation of this Regulation"*. Hence, the MDCG elaborates and publishes guidance documents on different subjects of the MDR. Although, the application of the MDCG-documents is generally expected, those guidelines have no binding legal force. According to the MDCG-document 2021-3, a custom-made device is defined as *"any device that:*

- *is 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*
- *specific design characteristics provided under that person's responsibility; and*
- *is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs"* [7].

Moreover, the MDCG specifies two additional categories of personalized medical devices: *patient-matched medical devices* and *adaptable medical devices*. Such devices are not covered by the definition of a custom-made device and consequently do not pass a simplified approval process, according to the MDCG. The MDR, however, does not include the term *patient-matched medical device* nor *adaptable medical device*. Rather, the MDCG has introduced these terms without further explanation from the international context and refers to the International Medical Device Regulators Forum (IMDRF) [8]. Furthermore, the definition of a custom-made device as provided in the MDR is not congruent with the one given in the Q&A-document. Article 2(3) stipulates that *"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"* [3]. As in the document 2021-3, those products are defined as patient-matched. However, according to the MDCG, a written prescription is not mandatory for patient-matched devices. Unfortunately, the MDCG-document on custom-made devices has not removed ambiguity as previously hoped, but rather increased uncertainty. Especially in AM, the lack of clarity remains, as the question – whether 3D printing is one of the industrial manufacturing processes – was not conclusively answered by the Q&A-document.

III. Conclusions

Currently, the European Union (EU) is lagging behind when it comes to regulatory requirements for custom-made devices fabricated using AM. In recent years, many jurisdictions adapted their legislation to technical developments. For example, in 2016, the U.S. Food and Drug Administration (FDA) released a technical amendment, revising the FDA's definition and criteria for custom-made devices and limiting the production of such devices to a certain quantity. Followed by a guidance, covering technical considerations for additively manufactured medical devices in 2017 [9]. In addition, Australia recently revised its regulatory framework for personalized medical devices in accordance with the recommendations by the IMDRF [10]. However, the focus of present medical device regulation in Europe is mainly on traditionally manufactured devices. It remains to be seen if the EU will follow existing guidelines, e.g., those of the FDA or the IMDRF, or possibly issue its own legal provisions. In conclusion, the EU is leaning more toward the IMDRF as evidenced by the Q&A-document 2021-3 published by the MDCG.

AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest.

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