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Custom-Made Devices: Medical Device Coordination Group (MDCG) Clarifications

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Very recently, the Medical Device Coordination Group (MDCG) issued a Q&A document on custom-made devices ("*Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices"*) aiming to specify the medical devices falling under the category of custom-made devices as well as to clarify the specific obligations (if any) of the manufacturers of custom-made devices.

Pursuant to art. 2(3) of the Regulation (EU) 2017/745 (MDR) custom-made devices are defined as follows:

a. specifically made according to a written prescription of any person authorized by national law by virtue of that person's professional qualifications,

b. that give, under that person's responsibility, specific design characteristics and

c. that are intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, adaptable medical devices and patient-matched medical devices (as defined by the IMDRF Personalized Medical Devices in the final document "*Definitions for Personalized Medical Devices*") may not be considered as custom-made devices, since both categories are typically produced through mass production and/or in batches.

As far as 3D printed devices are concerned, according to the MDCG's Q&A, even though these devices are not classified as custom-made devices by default, an assessment based on the aforementioned definition should be performed on a case-by-case basis.

Additionally, as regards the obligations of custom-made devices manufacturers, MDR provides for specific differences and/or exceptions from the obligations of medical devices manufacturers that may be summarized as follows:

- The conformity assessment procedure is mandatory for all types of custom-made devices. However, custom-made devices shall be accompanied by a statement of the particular patient or user identified

by name, acronym or numerical code instead of a declaration of conformity.

- Implantable custom-made devices of Class III are subject to the conformity assessment procedure covering QMS certification by any notified body.
- Custom-made devices manufacturers are exempt from the device's UDI registration, assignment and labelling requirements.
- Even though a person responsible for regulatory compliance shall be appointed, the manufacturer is not required to register him/her in EUDAMED.
- Summary of Safety and Clinical Performance is not required.
- As far as post-market surveillance obligations are concerned, a report (for Class I custom-made devices) and a Periodic Safety Update Report (for class IIa, IIb and III custom-made devices) shall be established by the manufacturers as a part of the custom-made devices documentation. The Periodic Safety Update Report for class III implantable custom-made devices is not required to be sent to the notified bodies.

In light of the MDR's upcoming entry into force, the MDCG Q&A on custom-made devices is considered to be a useful roadmap for the classification of medical devices and the implementation of the legislative framework.

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