



POLICY BRIEF

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MEDICAL DEVICES REGULATION (MDR) – ITALIAN
IMPLEMENTATION UPDATE

DECREE OF 9TH JUNE 2023

CUSTOM-MADE DEVICES

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Ways of providing information on the manufacturer's identification data and the list of types of custom-made medical devices made available on the national territory. Decree 9th June 2023 (GU General Section 206 of 4th September 2023)¹	
BACKGROUND AND FIELD OF APPLICATION	<p>This decree implements the dispositions of Article 21 of the legislative decree 137/2022 implementing the MDR. Article 21 states that manufacturers of custom-made devices must present a list of all this kind of device to the competent authority. The decree of 9th June 2023 clarifies how and to whom the manufacturers must present this information. To be more specific, for custom-made device the MDR states that it is any device <i>‘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.’</i>² For instance, if a doctor prescribes a specific kind of prosthesis to be made, then this is a custom-made device if it is done according to the patient’s characteristics and needs. However,</p> <p><i>‘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’.</i></p>
HIGHLIGHTS	<ul style="list-style-type: none"> Article 1: it establishes that the addressees of the decree are the custom-made medical devices manufacturers. It is important to notice that if the custom-made device manufacturer is not EU-based, then the addressee of the decree is the manufacturer’s authorized representative with the legal seat in Italy. If that is not the case, whoever is designed to be responsible for the market in Italy needs to be compliant with the decree. Article 2: it states that the information concerning custom-made medical devices must be communicated to the Italian Health Ministry by safe electronic means which will be later on published on the Ministry site. Furthermore, manufacturers also need to update the information provided within 30 days if they modify the device or if they stop their economic activity.

¹ <https://www.gazzettaufficiale.it/eli/id/2023/09/04/23A04923/sg>.

² Article 2(3) MDR, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117, 5.5.2017, p. 1–175.



	<ul style="list-style-type: none">• Article 3: the manufacturers that have declared to be compliant with the MDR implementing decree will get an inscription number in a list for custom-made medical devices.• Article 4: manufacturers' personal data are stored for 15 years after they stop their economic activity.• Article 5: transitional measures concerning data communication are applicable starting from 1st September 2023. If one manufacturer had already been inscribed in the custom-made manufacturers' list, they have six months to comply with the instructions on how to communicate custom-made medical devices data set in Article 2 of this decree.
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