

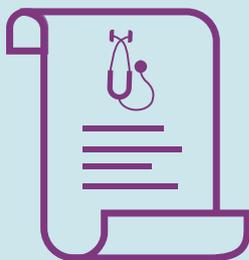


European
Commission

Factsheet for Class I Medical Devices



What You Need to Know About Regulation (EU) 2017/745



This factsheet is aimed at manufacturers of Class I medical devices. It covers devices that have already been placed on the market under Directive 93/42/EEC (MDD) and new devices intended to be placed on the market for the first time in accordance with Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 (MDR).

*For further information, consult **MDCG 2019-5 rev.1**.*



Changes in the classification of devices

The MDR introduces **new classification rules**, based on which manufacturers must determine the risk class of their devices. In doing so, manufacturers should be aware that these risk classes may differ from the class assigned under the MDD, e.g., devices may have been 'up-classified' from Class I to Class IIa/IIb/III. To classify a device under the MDR, the intended medical purpose of the device and its inherent risks should be taken into account.¹

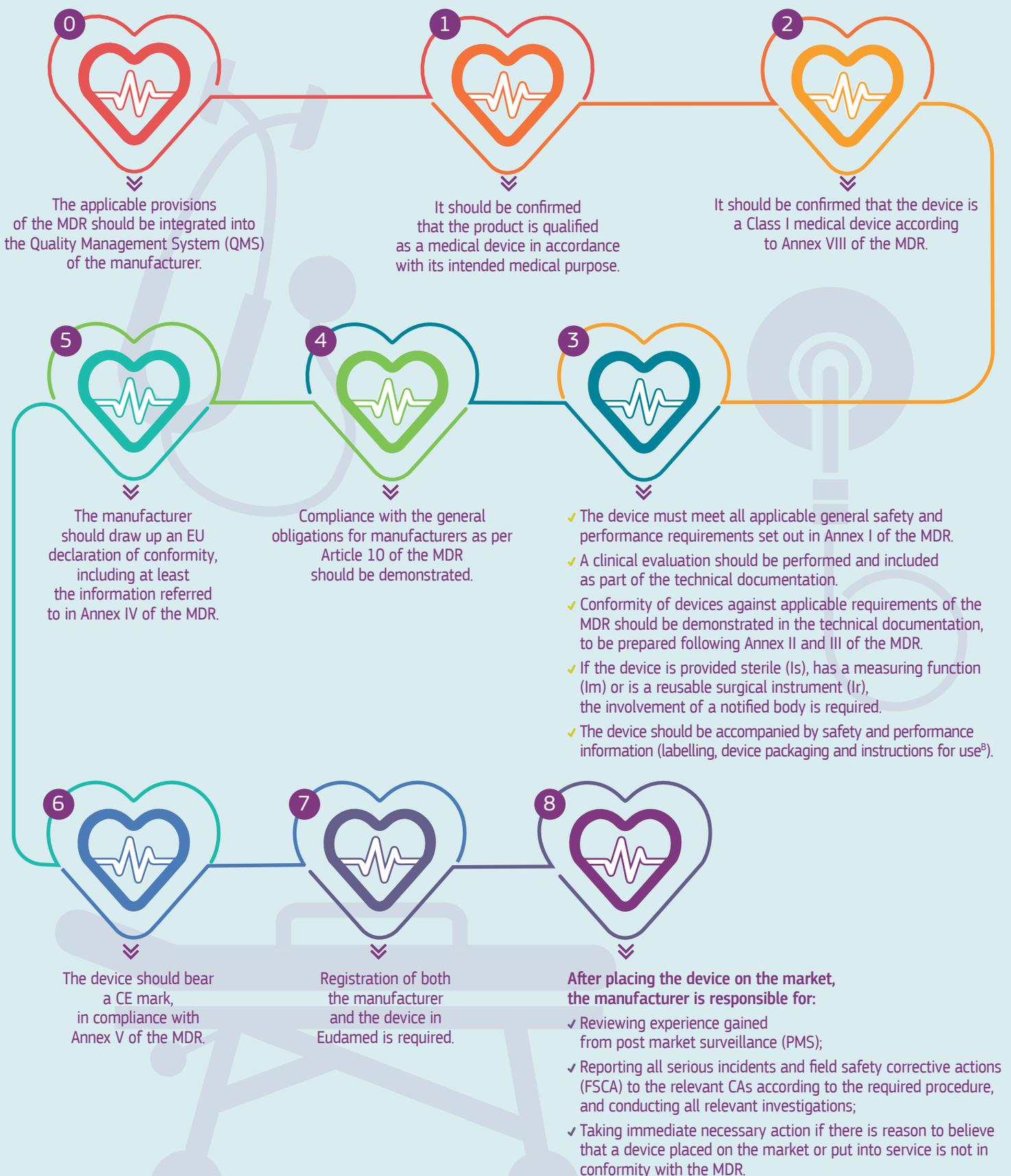


New requirements for manufacturers of Class I medical devices

Manufacturers that intend to place Class I medical devices on the market must demonstrate compliance with all the applicable requirements of the MDR. The **necessary steps** to ensure compliance are detailed in **MDCG 2019-5 rev.1** and are summarised below.

¹ Please consult Article 51 and Annex VIII of the MDR for classification rules

STEP-BY-STEP APPROACH FOR CLASS I MEDICAL DEVICE COMPLIANCE^A



^A Some of the described requirements are inter-dependent and can be performed in a different order than the one presented.

^B By way of derogation to the general principles, no instructions for use are required for Class I devices if they can be used properly and safely without such instruction.

In addition, *MDCG 2019-5 rev.1* outlines requirements applicable to devices of all risk classifications, including Class I. Noteworthy among these are the following:

- ✦ Manufacturers based in non-EU countries need to appoint **an authorised representative** based in an EU Member State before their device can be placed on the market. In all cases, manufacturers should identify a person responsible for regulatory compliance.
- ✦ UDI requirements (assignment, registration, labelling) apply to manufacturers of all devices placed on the EU market, except for custom-made or investigational devices. UDI Carrier labelling applies according to varied timelines based on risk class (See *UDI FAQ* or *UDI helpdesk Q&A*). Placing UDI-carriers on the labels of Class I devices will be required from 26 May 2025. Direct marking of the reusable devices (e.g. Class Ir) is applicable from 26 May 2027.

Frequently Asked Questions

1. How long is the transition period for MDD Class I devices that will require the involvement of a notified body for the first time under the MDR?

The Transitional Provisions established under Article 120 of the MDR also apply to Class I devices that were Class I under the MDD and will require the intervention of a notified body for the first time under the MDR. Under certain conditions, these devices can continue to be placed on the market until May 2024. After that date, the device can continue to be made available on the market via distributors, or put into service by end-users, until 27 May 2025.

2. When do MDD Class I medical devices that remain as Class I under the MDR need to meet the requirements of the MDR?

Class I medical devices placed on the market under the MDD, that continue to be Class I under the MDR, will need to comply with MDR requirements as of 26 May 2021.

3. Are instructions for use always required for Class I devices?

For Class I medical devices, it may not be necessary for instructions for use to accompany the device IF it can be used safely without the provision of such instructions (Annex I, Section 23.1(d)). In general, it is expected that instructions for use should accompany the device, unless the manufacturer can demonstrate safe and effective use without such instructions.

4. What are the language requirements for labels and instructions for use?

Manufacturers should ensure that the device is accompanied by information for labels and instructions for use in an official European Union language(s), as determined by the Member State in which the device is made available to the user or patient - MDR Article 10(11).

5. Does the MDR apply to accessories, parts or components of Class I medical devices?

Yes. The regulatory status of accessories of medical devices in the MDR is the same as it was under the MDD. If a product meets the definition of an “accessory for a medical device” (MDR Article 2(2)), the MDR applies and all of the requirements applicable to devices will apply.

It is worth noting that under the MDR (Article 23) parts and components of medical devices (including Class I) may be considered as devices in themselves, if claimed as such by the manufacturer and if specifically intended to replace a part or component of a device.

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