FAQs

on the new **European Medical Device Regulation**

Brief Introduction

The "MDR", what is it?

The European Medical Device Regulation (EU) 2017/745 (MDR) is a new set of regulations that governs the development, production and distribution of medical devices in Europe. It replaces the existing Medical Device Directive (93/42/EEC) (MDD), close to being 30 years old.

What has changed compared to the MDD?

The MDR is a regulation that brings more uniformity within the EU and places more emphasis on safety and traceability. The general safety and performance requirements stated in the MDD have been considerably extended. Some of the key changes include a more rigorous post-market surveillance, more stringent documentation, and a systematic clinical evaluation of Class IIa medical devices (including our blood bank refrigerators, plasma storage freezers, plasma contact shock freezers, and ultra-low freezers).

When does the MDR apply?

The MDR entered into force in May 2017 and was set to come into application from 26 May 2020. However, in light of the COVID-19 outbreak, the EU extended the transitional period by one year, moving the date of application to 26 May 2021. The decision aimed to avoid a potential market disruption and the shortage of vitally important medical devices during an unexpected public health crisis.

Obligations for Manufacturers

Do all manufacturers need to comply?

In contrast to the MDD (directive), the MDR (regulation) is legally enforceable in all EU Member States, paving the way to a more harmonized legal framework for medical devices in the Union. Therefore, the regulation applies to all manufacturers placing medical devices on the EU market. Those include manufacturers outside Europe.

When do manufacturers need to comply with the new MDR?

The transition period (2017-2021) allows manufacturers to prepare for the MDR. From 26 May 2021, the new medical devices placed on the European market will have to conform to the new MDR. Devices with valid MDD certificate may continue to be placed on the market until 25 May 2025, date after which only MDR certified devices will be allowed for sales across all Member States.

B Medical Systems Compliance

Is B Medical Systems MDR-certified?

B Medical Systems became the first manufacturer of medical refrigeration and vaccine cold chain solutions worldwide to obtain the MDR certification. The certificate was issued by the notified body TÜV SÜD under the regulation (EU) 2017/745, much before the new MDR would have come into full application.

Concretely, what has changed for B Medical Systems?

The MDR brings stringent requirements, introducing new responsibilities for manufacturers. B Medical Systems took early action to adapt its risk and quality management systems, which must include clinical/performance evaluations and post-market surveillance. Under the MDR, each medical device will have a Unique Device Identifier (UDI). All UDIs and related information will be publicly available in the new European Database – EUDAMED.

Will the CE mark remain on our devices?

The CE marking indicates to customers that a device conforms to the general safety and performance requirements of the MDR and can be legally sold within the EU. As MDR-certified manufacturer, we have successfully passed the conformity assessment and can continue applying the CE label to our devices.

CE

Is the MDR applicable to our entire product line?

Regardless of their risk class, all medical devices placed on the EU market are subject to the new MDR. Our whole portfolio therefore falls under the MDR with the following classification: class I (medical refrigeration and vaccine cold chain solutions, °B Connected software) and class IIa (blood management solutions).

Do we have compliance for our entire product line?

The transition is a complex and time-consuming process for medical device manufacturers. For now, all our Precision, Premium, and CSF models are compliant with the new MDR. We will apply for compliance for all other models, as soon as their technical documentation meet the new requirements.

Who will be in charge at B Medical Systems?

Our Head of Quality Assurance (Person Responsible for Regulatory Compliance acc. to MDR) will be res-ponsible for all aspects of compliance with the requirements of the new regulation. In conformity with the MDR, he will ensure you permanent and continuous availability for regulatory compliance.

Patients & Users Benefits

How does the MDR benefit our customers?

The MDR certification ensures that the medical devices we produce and distribute meet high standards of quality and safety set forth in the regulations. It also certifies the uninterrupted availability of our devices – where competition products may become temporarily unavailable due to delay in certification.

Distribution Network

Does the MDR affect me, as a European distributor?

As distributor in the European Union, you must verify that each MDR-certified device bears a Unique Device Identifier and ensure that the storage and transport conditions are appropriate. You must also co-operate with B Medical Systems to achieve an appropriate level of traceability, by kee-ping a register of complaints, non-conforming devices, recalls and withdrawals. (Art.14)

Do I need to recall the devices placed on the EU market?

No, you do not need to recall the devices placed on the EU market under the MDD.

Can I continue placing devices on the EU market?

You can still place your stock of B Medical Systems devices cer-tified under MDD on the EU market until 31.07.2021 (expiry date of our MDD certificate). Until then, MDD-certified and MDR-certified medical devices will co-exist. Following that date, your sales will be limited to the MDR-certified devices. For now, all our Precision, Premium and CSF models are certi-fied. We are working on the transition for all other models.

Does the MDR matter to me, as a distributor active outside Europe?

Our MDR certification brings an extra layer of quality assu-rance for all end-users. Regardless of their location, your customers can rest assured that we have put systems in place to deliver safe, efficient, and reliable devices.

Sources:

[1] https://ec.europa.eu/docsroom/documents/33622
[2] https://ec.europa.eu/health/md_newregulations/getting_ready/authorised_representatives_importers_distributors_en
[3] https://ec.europa.eu/health/md_newregulations/getting_ready/healthcare_professionals_health_en

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