Clarifications on the Medical Device Regulation (MDR) – Information for international business partners

The Regulation (EU) 2017/745 (Medical Device Regulation – **MDR**), which came into force on May 26, 2021, contains several new requirements for manufacturers and distributors of medical devices. We would like to offer practical advice for international suppliers and customers on how to fulfill their obligations in a legally sound manner. We have listed below some important questions and answers on cooperation in the supply chain.

1. What does “placing on the market” mean? What does “making available on the market” mean?

“Placing on the market” means the **first** making available of CE marked devices and custom-made devices on the Union market. The term **making available on the market** means any supply of a device for distribution, consumption or use on the Union market in the course of a commercial activity.

The devices are thus placed on the market by the manufacturers, as they are the first to release the device into the supply chain. For devices manufactured outside the Union, the importer established in the Union is also regarded as the one placing the devices on the market. The term “placing on the market” always refers to a specific device.

Typical activities of distributors include the acquisition of devices from the manufacturer, importer or intermediary as well as holding and supplying devices to customers. The device is therefore made available on the market by the distributor.

2. What new information must be included in the EU declaration of conformity?

The EU declaration of conformity for CE marked products is issued by the manufacturer. **Annex IV of the MDR** can be used as a checklist for the information that must be provided.

Compared with the *EU declaration of conformity* under prior law (which followed the model structure set out in Annex III of Decision No 768/2008/EC), the EU declaration of conformity must now also include the Single Registration Number (**SRN**) of the manufacturer and, where appropriate, of the EU authorized representative ("EC Rep"), the **Basic UDI-DI** as well as the **intended purpose** of the product.

The following must be considered with regard to the SRN: The economic operator is informed of the SRN by the respective competent authority after registering with the European databank EUDAMED. Companies assuming different roles as manufacturer, representative and/or importer must register for each role separately and receive a separate SRN for each role. This means that one company can hold more than one SRN. If the economic operator has not yet been informed of the SRN, the manufacturer is permitted to issue the EU declaration of conformity without including the missing SRN. Such an EU declaration of conformity also complies with the MDR.

3. What obligations do distributors have under the MDR?

Pursuant to Articles 14 and 25 of the MDR, distributors now have a number of clearly defined obligations when making a product available on the market. In particular, distributors have to fulfill certain testing and information obligations before making a product available on the market (the following obligations in the supply chain refer to goods with CE marking; please note that there are special labelling obligations for custom-made devices, see paragraph 7):

i. Does the product bear a CE marking and has the manufacturer issued an EU declaration of conformity?

ii. Has the product been provided with a compliant label and instructions for use?

In particular, the **label** on the device must include the following information (the relevant requirements are set out in detail in Annex I Sections 23.2 and 23.3 of the MDR):

- the name/trade name of the device and details necessary to identify the device
- the name and address of the manufacturer (usually indicated by a black "factory" symbol) and, where appropriate, the name and address of the representative ("EC Rep")
- the lot number or serial number
- the UDI carrier (machine-readable – data matrix code), possibly also in human readable form (for class I devices, the UDI carrier is mandatory as of May 26, 2025, at the latest)
- where applicable, an indication of the time limit for using the device safely; if this information is not relevant for the device in question, the date of manufacture must be indicated
- where applicable, an indication of the fact that the device is intended for single use
- an indication that the device is a medical device (possibly by an "MD" symbol, see https://www.eurocom-info.de/wp-content/uploads/2020/03/2020-02-21_Eurocom_Symbolliste_Medizinprodukte_final.pdf)

The additional particulars to be included in the **instructions for use** are set out in Annex I Section 23.4 of the MDR.

Is this information made available in the language(s) accepted in the sales region? The languages accepted are defined by the Member State in which the device is to be marketed; as a rule, it is the official language of the respective Member State, but there may be exceptions, e.g. conditions under which instructions for use in English are sufficient for professional users (see Section 8 Paragraph 2 of the German Law on the Implementation of EU Regulations with Regard to Medical Devices (MPDG)).

iii. Has the manufacturer issued a UDI for the device (the UDI is not the same as the Basic UDI-DI indicated in the EU declaration of conformity)? As UDI carriers are not mandatory for class I devices during the transitional period until May 26, 2025, this information may have to be requested from the manufacturer/provided by the manufacturer separately.

The distributor may fulfill the testing obligations under (i) to (iii) by means of representative sampling procedures. These sampling procedures must be documented by the distributor. A checklist for incoming goods for distributors is available under the following link: *https://www.eurocom-info.de/wp-content/uploads/2020/12/Eurocom_CheckWareneingang_%C6%92_Stand-11-2020.pdf*

iv. For imported devices: Are the name and address of the importer indicated as well? This concerns devices whose manufacturer named on the label has its registered office in a third country (including the UK and Switzerland). The distributor is required to ensure that the storage and transport conditions comply with the conditions set by the manufacturer.

v. Where a distributor has reason to believe that a device is not in conformity with the MDR, it shall not make the device available on the market and shall immediately inform the manufacturer. In the event the device presents a serious risk (i.e. might lead to the death or a serious deterioration in the state of health of a patient), the distributor shall also immediately inform the competent authorities. The same requirement for immediate information applies if the distributor has reason to believe that a device which it has already made available on the market is not in conformity with the MDR. The distributor shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals and is required to provide this information to the manufacturer upon request.

Detailed information on further obligations of distributors under the MDR is available in the following FAQ: https://www.eurocom-info.de/wp-content/uploads/2020/03/Eurocom_Haendlerpflichten_FAQ_EN.pdf

4. Will distributors have to register as well?

Pursuant to the MDR, distributors are not required to register in EUDAMED as economic operators. However, the MDR permits the EU Member States to request that distributors are also registered in their national databases. Such national registration obligations are already in place in some Member States and may be introduced by other states in the future. Distributors are required to inform themselves of the existing regulations in their country.

5. How are distributors required to cooperate with regard to the traceability of devices?

In general, all distributors are required to cooperate with the manufacturer and other economic operators to achieve an appropriate level of traceability of devices along the supply chain. It is strongly recommended that the cooperation between the manufacturer and the distributor is contractually agreed upon and documented.

Pursuant to Article 25 Paragraph 2 MDR, distributors are required to identify **to the competent authorities** for a period of 10 years after the last device has been placed on the market who has directly supplied them with the device and to whom they have directly supplied the device (with the exception of devices supplied to consumers/lay persons).

6. In which case do obligations of manufacturers apply to distributors?

Distributors may be required to assume manufacturers' obligations if they engage in certain activities falling into the scope of product manufacturing. These cases are governed by Article 16 MDR:

- making devices available on the market under its name/private brand, unless a written agreement with a manufacturer exists whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers;
- changing the intended purpose of a device already placed on the market;
- modifying a device already placed on the market in such a way that compliance with the applicable requirements may be affected, i.e. that was not considered by the manufacturer within the scope of the conformity assessment procedure.

The special requirements applying to distributors providing translations of the instructions for use and making them available in their country as well as to the repackaging of devices are set out in detail in Article 16 Paragraph 3 and 4 MDR. *Pursuant to these regulations, distributors should only carry out these activities in close cooperation with the manufacturer*.

7. What is the definition of a custom-made device and may intermediate products for manufacturing custom-made devices bear a CE marking?

A custom-made device means any medical device intended for the **sole use of a particular patient** exclusively to meet their individual conditions and needs. This device must be specifically made in accordance with a **written prescription** of any person authorized by national law by virtue of that person's professional qualifications. The written prescription must include **specific design characteristics of the device**.

Custom-made devices do not bear a CE marking and do not require a UDI. The label shall bear the words "custom-made device." The manufacturer does not issue an EU declaration of conformity for custom-made devices; they are subject to the conformity assessment procedure and a declaration pursuant to Annex XIII of the MDR.

Mass-produced devices which only need to be adapted to meet the specific requirements of a particular patient are not considered as custom-made devices. This is the case whenever the adaptation was already intended by the manufacturer during the conformity assessment procedure and the adaptation is performed within this scope. Devices for which a written prescription was issued, but which are mass-produced by means of industrial manufacturing processes, are also not considered as custom-made devices.

Intermediate products may bear a CE marking if they were specifically intended by the manufacturer to be used to manufacture custom-made devices (e.g. orthotic or prosthetic components).

Further information is available in the Q&A document MDCG 2021-3 as well as the eurocom guideline:

Products with CE marking: https://www.eurocom-info.de/wp-content/uploads/2019/10/Praxisleitfaden_eurocom_Orthesen_Prothesen.pdf

Products without CE marking: https://www.eurocom-info.de/wp-content/uploads/2019/10/Praxisleitfaden_eurocom_Einlagenversorgung.pdf

8. What is the difference between the indication of the date of manufacture (white factory symbol) and the use-by date (hourglass symbol)?

The date of manufacture of a medical device is indicated by a white factory symbol:

The hourglass symbol indicates the date after which the medical device can no longer be used safely. This date must only be indicated if this is relevant for the device in question. The manufacturer is thus not necessarily required to include this information with every product. If the date until which the device can be used safely is not indicated the date of manufacture must be included; if necessary, the manufacturer shall describe the characteristics that may indicate that a product is no longer safe for use (e.g. visible changes in the material). The date of manufacture may be included as part of the device's lot number or serial number.

9. What is the UDI?

The purpose of the UDI (Unique Device Identification) system is to permit the identification of products on the market. The system involves the production of a UDI code (consisting of a static UDI device identifier and a UDI production identifier), placing the UDI on the label of the device or on its packaging (i.e. the machine and/or human readable UDI carrier) and the establishment of a UDI database as part of EUDAMED. Various transitional periods apply with regard to the obligation to place the UDI carrier on the packaging, depending upon the class of the device concerned. For class I devices, the UDI carrier must be placed on the packaging as of May 26, 2025. The UDI database is not expected to be fully operational before May 2022.

Please note that the distributors are required to verify whether the manufacturer issued a UDI. As long as the UDI database is not fully operational and it is not yet mandatory to place the UDI carrier on the packaging, you may request this information from the manufacturer.

See also: https://www.eurocom-info.de/wp-content/uploads/2020/11/Praxisleitfaden_eurocom_UDI-Umsetzung-2_final-2.pdf

10. Supply chain from supplier to manufacturer

Suppliers provide the manufacturer with complete medical devices or materials and components for manufacturing m edical devices. To ensure that the manufacturers' obligations are documented and distributed properly among the partners as part of the quality management system, the supply relationship between the manufacturer and the supplier must be regulated by means of a contract.

All products, components and materials delivered to the manufacturer must comply with the general safety and performance requirements (e.g. with regard to biocompatibility) for the manufacturer to be able to confirm that the finished product complies with the requirements of the MDR.

See also: https://www.eurocom-info.de/wp-content/uploads/2019/10/Praxisleitfaden-Lieferanten_EN.pdf

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About eurocom

eurocom e.V. is the European manufacturers federation for compression therapy and orthopaedic devices. We consider ourselves as a contributor and partner in the healthcare market and we are committed to spreading the knowlegde about the medical benefits, efficiency and cost-effectiveness of compression therapy and orthopaedic devices. In addition, eurocom creates concepts for ensuring the current and the future supply of assistive devices. Almost all European companies for compression therapy and orthopedic devices operating in the German market belong to our association.

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