Information for Distributors

Obligations under the Medical Device Regulation (MDR) in the Medical Aids Sector (FAQ)

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1. WHAT ARE THE GENERAL OBLIGATIONS OF DISTRIBUTORS PURSUANT TO ARTICLE 14 OF THE MDR?

Before making a product available on the market, the distributor must verify the following formal requirements:

- Does the product bear a CE marking? Has an EU declaration of conformity been issued for the product? Has the product been provided with a label and instructions for use (in the right language)? Has the manufacturer assigned a UDI to the product? In order to meet the above requirements, the distributor may apply a sampling method with verifiable documentation that is representative of the devices supplied by that distributor.
- For imported products (manufacturers outside the EU/EEA): Does the label include the name and address of the importer?

If 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 inform the manufacturer (and, where applicable, the manufacturer's authorized representative and the importer). If applicable, it shall also inform the intermediary from which it acquired the product. If a distributor has reason to believe that the device presents a *serious risk* (see question 11 below) or is a *falsified device*, the distributor shall also inform the competent authorities.

The distributor shall document that the **storage or transport conditions** comply with the conditions set by the manufacturer (including the supervision of any logistics service providers charged with the storage and/or transport by the distributor).

After making a product available on the market, the distributor is subject to the same obligation to inform as before. As the products have already been delivered, the manufacturer (and, where applicable, the manufacturer's authorized representative and the importer) shall be informed *immediately* dof any non-compliance. Immediately is regularly defined as *without undue delay*. In the event of a serious risk or falsified device the competent authorities shall be informed *immediately in all Member States* in which the distributor made the product *available*. The distributor shall cooperate with the manufacturer and, where applicable, the competent authorities to ensure that the necessary corrective measures are taken.

Distributors shall *immediately* forward **all complaints or reports about suspected incidents related to a device they have made available to the manufacturer (and, where applicable, the manufacturer's authorized representative and the importer).** The distributor shall keep a **register** of all monitoring activities (complaints, non-conforming devices, recalls and withdrawals) and keep the manufacturer informed of such monitoring and provide them with any information upon their request. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal. Upon request by a competent authority, distributors shall provide samples of the device free of charge.

2. WHERE CAN DISTRIBUTORS FIND INFORMATION ON HOW THE GENERAL TERMS AND CONDITIONS OF DELIVERY AND PAYMENT CONTRACTUALLY AGREED BETWEEN THE MANUFACTURER AND THE DISTRIBUTOR SHOULD BE WORDED?

eurocom issued a best practice guide on this topic
→ see *„MDR-Praxisleitfaden – Umsetzung der Verordnung EU 2017/745 (MDR) – Händlerpflichten in der Lieferkette" ("Best Practice Guide on the MDR – Implementation of EU Regulation 2017/745 – Distributors' Obligations in the Supply Chain")* on www.eurocom-info.de
The best practice guide is currently only available in German.

3. WHICH GENERAL DEADLINES LAID DOWN IN THE MDR ARE RELEVANT FOR DISTRIBUTORS?

Distributors will have to fulfill their obligations at the very latest as of **May 26, 2020**, when the MDR takes effect.

"Sell-off period" (Article 120 Paragraph 4 MDR): Within the sell-off period, up to and including **May 27, 2025** distributors may continue to make devices available on the market that comply with the old directives: This requires that these devices were placed on the market by the manufacturer or importer *prior* to May 26, 2020. Certain devices, for which the manufacturer can take advantage of the so-called "grace period" pursuant to Article 120 Paragraph 3

MDR, can be placed on the market by the manufacturer until May 26, 2024, and sold off by the distributor until May 27, 2025. This "grace period" may be relevant for devices in Class IIa and higher, for which the manufacturer still uses a valid old certificate, as well as for Class I devices that will be classified in a higher class under the MDR (new class Ir, often medical software, material medical devices and products with nanomaterials) that are still placed on the market by the manufacturer with an EU declaration of conformity in accordance with EU Directive 93/42/EEC. In compliance with their obligations, distributors shall get acquainted with the various deadlines during the transitional period and shall check the EU declarations of conformity with this in mind.

For identification of products within the supply chain, distributors are required to keep all necessary documentation pursuant to Article 25 Paragraph 2 MDR available to the competent authorities for a period of at least 10 years (in case of implantable devices, for at least 15 years) after the last device covered by the EU declaration of conformity has been placed on the market. This includes information on the economic operators or health institutions who have directly supplied them with a device or to whom they have directly supplied a device.

4. WHY IS IT RELEVANT WHEN A PRODUCT WAS "PLACED ON THE MARKET" AND WHEN IS A PRODUCT REGARDED AS "PLACED ON THE MARKET"?

The moment a device is placed on the market, it has to comply with the requirements of the MDR. All products on the Union market have been placed on the market by the manufacturer or, in case of non-EU manufacturers, by the importer. "Placing on the market" means the **first** making available of a device (other than an investigational device) on the Union market; "Making available on the market" means any supply of a device (other than an investigational device) for distribution, consumption or use on the Union market in the course of a commercial activity. The device is therefore made available on the Union market by the distributors.

During the transitional period of the MDR, the exact moment a device was placed on the market is particularly relevant when it comes to the question of whether a product can still be sold (i. e. made available on the market) by the distributor (see question 3 above for further details about the sell-off period pursuant to Article 120 Paragraph 4 MDR).

5. WHAT ARE DISTRIBUTORS SUPPOSED TO DO IF THEY RECEIVE PRODUCTS AS OF MAY 26, 2020 THAT WERE PLACED ON THE MARKET BEFORE THIS DEADLINE, BUT DO NOT COMPLY WITH THE REQUIREMENTS OF THE MDR?

Devices that were placed on the market up to and including May 25, 2020 in compliance with the previous directive may be made available on the market by the distributor until and including May 27, 2025 (see question 3 above for further details about the sell-off period pursuant to Article 120 Paragraph 4 MDR). However, as of May 26, 2020, distributors must comply with their general obligations also with regard to these "old products", whereas these "old products" have to comply with the previous directive.

Distributors who do not acquire products directly from another distributor or the manufacturer but from an intermediary are not required to actively verify whether a certain product (e. g. class I with an EU declaration of conformity in accordance with the old directive) was really placed on the market before May 26, 2020. If a distributor acting with due diligence becomes aware of matters that give reason to believe that "old products" were illegally placed on the market after May 26, 2020, the distributor is required to comply with its general obligations, e. g. the duty to provide information and the prohibition to make these products available on the market.

6. WHAT OBLIGATIONS DO DISTRIBUTORS HAVE WITH REGARD TO THE TRACEABILITY OF DEVICES?

In general, distributors are required to cooperate with the other economic operators to achieve an **appropriate level of traceability** of devices (Article 25 Paragraph 1 MDR). This also requires contractual arrangements within the supply chain.

In particular, distributors are required to keep all necessary documentation pursuant to Article 25 Paragraph 2 MDR available *to the competent authorities* for a period of at least 10 years (in case of implantable devices, for at least 15 years) after the last device covered by the EU declaration of conformity has been placed on the market. This includes information on the economic operators or health institutions who have directly supplied them with a device or to whom they have directly supplied a device. In general, the distributor is *not* required to store and keep the UDI of each individual product from whom it was acquired or to whom it was delivered (exceptions under Article 27 Paragraph 8 MDR: Class III implantable devices and other products subject to the obligation to store data pursuant to an implementing act by the Commission).

7. WILL DISTRIBUTORS HAVE TO REGISTER IN EUDAMED?

No. However, Article 30 Paragraph 2 MDR contains a saving clause pursuant to which Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory. Such an obligation to register and to notify for distributors making products available **on the German market** could possibly be laid down in a regulation of the Federal Ministry of Health.

8. IN WHICH CASE DO OBLIGATIONS OF MANUFACTURERS APPLY TO DISTRIBUTORS AND WHAT DO THEY INVOLVE?

Distributors *may* be required to assume manufacturers' obligations if they engage in certain activities falling into the scope of product manufacturing. Examples include marketing a product under the distributor's own name or registered trademark, changing the intended purpose of a device, repackaging products or not only repairing used devices but fully refurbishing them.

To determine whether a distributor is required to assume manufacturers' obligations in accordance with the relevant provisions, the specific circumstances of each individual case have to be taken into consideration. Article 16 MDR contains important provisions and requirements applicable in the event a product

is marketed under the distributor's own brand name as well as in case of parallel distribution. The distributor may possibly be required to assume all manufacturers' obligations, as the MDR prescribes a clear assignment of roles.

9. IN WHICH CASE DO OBLIGATIONS OF IMPORTERS APPLY TO DISTRIBUTORS AND WHAT DO THEY INVOLVE?

Distributors are required to assume importers' obligations if they (also) place products from a third country on the Union market (Article 2 Number 33 MDR) as part of their product portfolio. Products are regarded as originating from a third country if the manufacturer identified on the product (Article 2 Number 30 MDR) is established outside the Union (special provisions with regard to the member states of the EEA and the future, currently uncertain, status of Switzerland must be taken into account). The general obligations of importers, as laid down in Article 13 MDR, must be observed depending on the product. For example, the importer is required to register under its own SRN (Single Registration Number) and has to put its name and address on the product or the packaging. As the importer is responsible for the first making available of a device on the Union market, it is subject to more extensive control obligations than the distributor.

10. WHAT ARE DISTRIBUTORS REQUIRED TO DO WHEN A USER REPORTS A FAULTY PRODUCT?

If the user's complaint is associated with a potential or actual non-conformity of the product with the requirements of the MDR, the regulatory obligation to act after making a product available on the market as laid down in Article 14 Paragraph 4 and 5 MDR must be observed (see question 1 above). Non-conformity must not necessarily be related to a safety issue. However, if the complaint is not associated with a potential non-conformity of the product with the MDR (e. g. if the customer has purchased the wrong size), the distributor is under no obligation to act under the MDR.

11. WHAT ARE THE DISTRIBUTORS' OBLIGATIONS IF A PRODUCT PRESENTS A "SERIOUS RISK" AND IF THERE ARE REPORTS OF INCIDENTS?

In the event a product presents a serious risk, the distributors' obligations depend on whether the distributor already made the product available on the market or not. See question 1 above for further information about the individual obligations to cooperate and to inform. However, the term "serious risk" is not clearly defined in the MDR. To determine whether a risk is "serious", the definitions of the terms "serious incident" (Article 2 Number 65 MDR) and "serious public health threat" (Article 2 Number 66 MDR) may serve as a guideline. In case of doubt, distributors should discuss the matter with the manufacturer.

The distributor is required to forward any reports from patients or users about suspected incidents *immediately* to the manufacturer (and, where applicable, the manufacturer's authorized representative and the importer) "Incident" means any malfunction or deterioration in the characteristics or performance of a product, including application errors due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effects (Article 2 Number 64 MDR). The manufacturer must evaluate whether this incident can be classified as a "serious incident" that has to be reported through the electronic system on vigilance.

12. WHAT IS THE UDI? WHICH ELEMENTS ARE INCLUDED IN THE MINIMUM STANDARD OF EUROCOM E. V. FOR 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.

eurocoms minimum standards for the UDI are based upon the Italian CND (Classificazione Nazionale Dispositivi Medici), the GS 1 code system, the Data Matrix barcode type, a minimum size of 6 mm and a minimum printing resolution of 600 dpi.

13. WHERE CAN DISTRIBUTORS CHECK WHAT THE SYMBOLS ON THE PRODUCT PACKAGING MEAN?

In addition to the information provided by the manufacturer in the product's manual, eurocom created a glossary of frequently used symbols available under *www.eurocom-info.de*.

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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.

Contact

eurocom e. V. – European Manufacturers Federation for
Compression Therapy and Orthopaedic Devices
Reinhardtstraße 15 · D - 10117 Berlin
Phone: +49 30 - 25 76 35 060 · Fax: +49 30 - 25 76 35 069
Mail: info@eurocom-info.de · www.eurocom-info.de