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inform

The new Medical Device Regulation (EU) 2017/745 and related obligations of economic operators

After the application date of the new Medical Device Regulation (EU) 2017/745 ("MDR") was postponed by 12 months due to the coronavirus pandemic last year (→ Sempermed has informed), the MDR will now finally start to apply on **26 May 2021**.

While in the Medical Device Directive 93/42/EEC ("MDD") the responsibilities of manufacturers were in focus, the new MDR expands the spectrum and also takes into account additional market participants, collectively referred to as "economic operators". According to Article 2 (35) of the MDR, the term economic operator means either *"a **manufacturer**, an **authorised representative**, an **importer**, a **distributor***" and persons placing on the market **systems and procedure packs** as per definitions of MDR Article 22.

One of the most important changes stemming from the MDR is that companies involved in the supply chain of medical devices must evaluate what their role is and what new responsibilities arise as a result.

Below we present the definitions of economic operators and list the main responsibilities arising from the MDR:

Roles and responsibilities of the manufacturer and its authorised representative

According to MDR Article 2 (30), the term **manufacturer** defines "*a natural or legal person who **manufactures** or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and **markets** that device **under its name or trademark***".

The following obligations are the responsibility of the manufacturer:

- Design and manufacture of the medical devices in accordance with the requirements of the Regulation | MDR Article 10 (1).
- Establishment of a risk management system | MDR Article 10 (2)
- Conducting the clinical evaluation | MDR Article 10 (3)
- Compiling the technical documentation | MDR Article 10 (4)
- Selection of an appropriate conformity assessment procedure | MDR Article 10 (6)

- Establishment of a UDI system | MDR Article 10 (7) and Article 27
- Registration as economic operator and of the devices in EUDAMED | MDR Article 10 (7) and Articles 29 and 31
- Keep the technical documentation, declarations of conformity and EU-certificates available for the competent authority | MDR Article 10 (8)
- Establishment of a quality management system | MDR Article 10 (9)
- Responsibility of product labelling and provision of information | MDR Article 10 (10) and MDR Annex I Section 23
- Establishment of a system for surveillance of medical devices placed on the market | MDR Article 10 (10); MDR Article 83
- Designation of a person responsible for regulatory compliance | MDR Article 15

When all these obligations have been fulfilled, the manufacturer issues a declaration of conformity (MDR Article 19) and affixes the CE marking to the products (MDR Article 20).

Manufacturers established outside the EU/EEA must conclude a contract with an **authorised representative within the EU/EEA**. The obligations of the authorised representative are set out in MDR Article 11 and mainly include verifying that the manufacturer has fulfilled his obligations.

Roles and responsibilities of importers

According to MDR Article 2 (33) the term importer defines *„ any natural or legal person established within the Union that **places a device from a third country on the Union market**“*.

MDR Article 13 describes the general obligations of importers. The importer has extensive control obligations and must cooperate with the market surveillance authorities. Before placing a product on the market, he must check whether:

- the device bears the CE marking and an EU declaration of conformity has been issued
- the manufacturer is known and an authorised representative has been appointed
- the device is labelled in accordance with the MDR in the applicable national language
- the manufacturer has issued a UDI for the device (as soon as applicable)
- the device is registered in EUDAMED (as soon as applicable)

If there is a suspicion that a product does not comply with the Regulation, the importer must not place the product on the market and must inform the manufacturer and its authorised representative. Importers are also obliged to **keep a register of complaints**, non-conforming products, recalls and withdrawals and to provide information to the manufacturer, authorised representative and distributor | MDR Article 13 (6). In case of serious risk or suspicion of counterfeiting, the competent authority must also be informed.

Importers must ensure that the manufacturer's requirements for **storage and transport conditions** are met while the device is under their responsibility | MDR Article 13 (5). They must include their **name and contact address** on the device or a document accompanying the device | MDR Article 13 (3). Importers must keep a copy of the **EU declaration of conformity** and, if applicable, a copy of the **EU notified body certificate** for a device for at least 10 years after the last device covered by the EU

declaration of conformity has been placed on the market | MDR Article 13 (9). MDR Article 31 requires importers to register in **EUDAMED** and keep information in EUDAMED up to date. Registration of economic operators in EUDAMED is possible on a voluntary basis since 1.12.2020. The obligation to register starts according to MDR Article 123(3)(d) six months after the European Commission has declared EUDAMED fully functional. The latter is currently planned for May 2022.

With reference to MDR Article 25, both importers and distributors must cooperate with manufacturers or their authorised representatives to achieve an adequate level of **traceability** of devices. They must be able to provide the competent authority with information on the economic operator from whom they have directly obtained a product for a period of at least 10 years and must be able to name all economic operators and healthcare facilities to which a product has been directly supplied.

Roles and responsibilities of distributors

According to MDR Article 2 (34) the term **distributor** describes *„ any natural or legal person in the supply chain, other than the manufacturer or the importer, **that makes a device available on the market**, up until the point of putting into service “*.

MDR Article 14 describes the general obligations of distributors. Distributors must check with due diligence (e.g. by random sampling) whether the products they distribute comply with the requirements of the MDR. Before making a product available on the market, they must check whether:

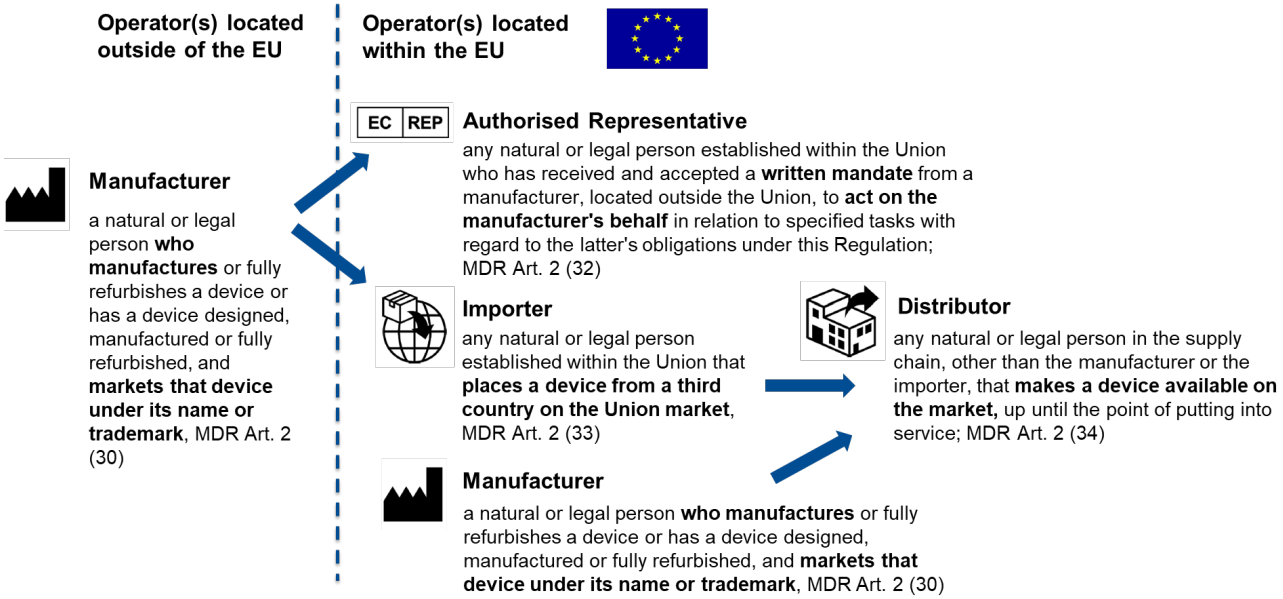
- the device bears the CE marking and an EU declaration of conformity has been issued
- the device is labelled in accordance with the MDR in the applicable national language
- the importer has affixed his name and contact address on the product or on an accompanying document
- the manufacturer has issued a UDI for the device (as soon as applicable).

If there is a suspicion that a product does not comply with the Regulation, the distributor shall not make the product available on the market and shall inform the other economic operators. In case of serious risk or suspicion of counterfeiting, the local authority must also be informed.

Distributors must ensure that the storage and transport conditions while a product is under their responsibility are appropriate and comply with the manufacturer's recommendations | MDR Article 14 (3). Importers are also obliged to keep a register of complaints, non-conforming products, recalls and withdrawals and to provide information on these to the manufacturer, authorised representative and importer | MDR Article 14 (5). Distributors shall cooperate with the authorities and provide them with all information and documentation in their possession.

Overview of relationships between economic operators and implications for medical devices from Sempermed

The chart below summarises the definitions of economic operators and pictures the respective relationships in the supply chain:



The manufacturer for medical devices of the brands **sempermed, sempercare** and **semperguard** is our Singapore-based company **Semperit Investments Asia Pte. Ltd**. **Semperit Technische Produkte GmbH**, based in Austria, is the **Authorised representative** in the EU for **Semperit Investments Asia Pte. Ltd.** for all products.

In order to enable all economic operators in the supply chain to fulfil their obligations as written above, the EU declarations of conformity of the devices are made available for download on our website www.sempermed.com/userinformation. Should you require assistance in defining your role and/or implementing your obligations, please get in touch with your contact at Sempermed.

Time frame

The Medical Devices Regulation (EU) 2017/745 applies from **26 May 2021**, with some provisions (such as UDI and EUDAMED registration obligations) coming into force at a later date.

Devices involving a Notified Body in the conformity assessment procedure may be marketed in accordance with the Medical Device Directive (MDD) until the corresponding EC certificates have expired.

With regard to Sempermed's products, this means the following:

- **Non-sterile examination gloves of class I** are already labelled according to the new MDR
- **Class Is sterile examination gloves** have a current EC certificate with certificate number G2S 18 03 88308 017 and can still be placed on the market under the MDD until **30 April 2023**.
- **Class IIa sterile surgical gloves** have a current EC certificate with certificate number G1 088308 0018 Rev. 00 and can still be placed on the market under the MDD until **26 May 2024**.

We are already working on MDR certification for sterile products and will inform you separately as soon as a changeover to MDR labelling is planned.

Below you will also find helpful links on the topic of MDR and the roles of the economic actors:

- Fact sheets and information material provided by the European Commission: https://ec.europa.eu/health/md_newregulations/publications_en
- Medical device regulation (EU) 2017/745: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

Your Area Sales Manager will be happy to answer any questions you may have!

Your Sempermed Team

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