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Obligations for importers and distributors

Medical Device Regulation (MDR)

The term **IMPORTER** refers to any natural or legal person in the supply chain who places a product from a third country on the Union market. He verifies the information provided by the exporter of medical devices imported into the European Union from countries outside the European Union (EU).

The term **DISTRIBUTOR** refers to 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;.

YOU ARE AN IMPORTER *(ARTICLE 13)*
if you obtain goods from outside the EU,

as well as
- being a subsidiary of Erbe Elektromedizin GmbH in the EU
- being an authorized specialist distributor in the EU

YOU ARE A DISTRIBUTOR *(ARTICLE 14)*
if you obtain goods from Erbe Elektromedizin GmbH or a manufacturer or importer within the EU,

as well as
- being a subsidiary of Erbe Elektromedizin GmbH in the EU
- being an authorized specialist distributor in the EU

MANUFACTURER
Erbe Elektromedizin GmbH

Please read Articles 13, 14 and 16 in Section 2 of the MDR.

Joint obligations for distributors and importers

Various obligations are defined in the MDR for the verification, storage and documentation of products. These apply as long as the product lies within your area of responsibility.

This includes the obligation to participate in market surveillance, vigilance as well as the traceability of medical devices.

VERIFICATION

You are to verify whether the product has a CE marking and a declaration of conformity.
Article 13.2 a resp. 14.2 a

You are to verify whether the manufacturer can be clearly identified.
Article 13.2 b resp. 14.2 c

You are to verify whether the product is correctly labeled according to the MDR and whether user manuals in an official Union language determined by the Member State in which the product is made available are included.
Article 13.2 c resp. 14.2 b

You are to verify whether a UDI has been assigned.
Article 13.2 d resp. 14.2 d

When verifying the products, a sampling method which is representative for the delivered products may be applied.
Article 14.2

MARKET SURVEILLANCE

Should you notice any defects during the inspection of the medical device, you may not place it on the market until conformity has been established. You shall contact the manufacturer or his authorized representative to discuss the necessary measures such as corrections or a recall. The medical device must not be made available on the market until corrective action has been taken.
Articles 13.2, 13.7 and 14.4

You shall keep a register of complaints, of non-conforming products as well as of recalls and withdrawals. You shall provide all the information necessary to enable the complaints to be reconstructed. In case of serious hazards, you shall inform the competent authorities.
Articles 13.6, 13.7 resp. 14.4, 14.5

You are to inform the manufacturer or importer immediately if health professionals, patients or users report suspected adverse events relating to a product that you have placed on the market.
Article 13.8 resp. 14.5

STORAGE

You shall ensure that the manufacturer's specifications regarding storage or transport conditions are complied with and that the general safety and performance requirements are not compromised.
Article 13.5 resp. 14.3

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Additional obligations for importers

Indicate your name and address on the product.
Article 13.3

Keep a copy of the EU Declaration of Conformity including all amendments and additions.
Article 13.9

As soon as the European Medical Device Database EUDAMED is launched (most likely not until 2021), you will need to check that the products are entered in the system.
Article 13.4

Cases where the manufacturer's more extensive obligations also apply to importers and distributors

You will be deemed to be a manufacturer when you make a product available on the market under your name, your registered trade name or your registered trademark. This also applies if you change the intended purpose of a product already placed on the market or modify the product itself.
Article 16

If you prepare translations or adapt external packaging, you must control these processes via a quality management system. You must inform the manufacturer of this.
Articles 16.2 and 16.3

STRICTER REPORTING OBLIGATIONS FOR MANUFACTURERS APPLY TO YOU IF YOU MAKE THE FOLLOWING CHANGES:

a) own name/brand
b) change of intended purpose
c) modifications to product

It is essential that you contact Erbe Elektromedizin GmbH in a timely manner before becoming active here.

This is because then you are a manufacturer according to *Article 16.1*

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