Erbe Elektromedizin GmbH Postfach 14 20 72004 Tübingen Deutschland

To whom it may concern

December 2023

Transition rule MDD to MDR

The entry into force of Regulation (EU) 2017/745 on medical devices (Medical Device Regulation - MDR) replaced the previously applicable directive (MDD Medical Device Directive 93/42/EEC) on May 26, 2021. Before the transition period of the MDR regulation was updated, MDD products (Class III, IIa, IIb, Ir, Is, Im) were only allowed to be placed on the market until May 26, 2024. After updating of transition period of the MDR-Regulation see “REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL” MDD products may now be placed on the market for longer under certain conditions.
Furthermore, MDD products, after having been placed on the market, can now also be sold to the end customer without any restrictions.

Our quality management system is already certified according to MDR-Regulation (EU) 2017/745.

The valid MDR certificate issued by the notified body applies to products that are already MDR-certified.

Our MDD certificate applies to all MDD products without restrictions until May 26, 2024.

The following applies after May 26, 2024:
MDD products that have not yet been updated to MDR until May 26, 2024 may still be delivered as we have registered them with our notified body to update from MDD to MDR (a confirmation letter from the notified body will be available accordingly). In addition, we will have a written agreement between us and our notified body by September 26, 2024, as required by the regulation.

You have already been informed separately about any discontinued products.

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Basic information about registering for MDR products:

According to MDR-Regulation Article 29 and MDCG 2021-1, the following applies:

1. Registration in the EUDAMED database (“UDI database”) is only necessary for economic actors (manufacturers, importers and authorized representatives). This does not apply to distributors.

2. Erbe GmbH (manufacturer) is already registered as an economic operator in EUDAMED.

3. However, EUDAMED is not yet fully functional, so MDR products do not yet have to be registered (see also MDCG 2021-1).

4. MDCG 2021-1 states that the manufacturer (including the importer and authorized representative) must already meet the registration requirements applicable to his country as long as the EUDAMED database is not fully functional. Distributors are also excluded from this. Erbe GmbH, as a manufacturer, has already registered in the DMIDS database in accordance with MPDG §86.

5. The requirements and obligations for distributors are defined in Article 14 of the MDR-Regulation.
   Before making a device available on the market, distributors shall verify that all of the following requirements are met:
   a. the device has been CE marked and that the EU declaration of conformity of the device has been drawn up
   b. the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11)
   c. for imported devices, the importer has complied with the requirements set out in Article 13(3)
   d. that, where applicable, a UDI has been assigned by the manufacturer.

According to the MDR-Regulation and MDCG 2021-1, distributors do not need to additionally register MDR products in a local country-specific database.

Your Erbe contact person will be happy to answer any questions you may have.

Best regards

Erbe Elektromedizin GmbH
i.V Peter Stein
Vice President Global Quality Assurance & Regulatory Affairs (PRRC)

Important information

We have prepared this document with care. Nonetheless, we cannot completely rule out errors in this document.

The information, recommendations and other data ("Information") contained in this document reflect our state of knowledge and the state of science and technology at the time of preparing the document. The information is of a general nature, non-binding and serves solely for general information purposes and does not represent instructions for use or notes on application.

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The information on setting values, application sites, duration of application and the use of the respective Erbe product is based on the clinical experience of physicians independent from Erbe. They represent guidelines which need to be checked by the user for their suitability for the actual planned application. Depending on the circumstances of an actual application case, it may be necessary to deviate from the information provided. The user has to check this on his/her own responsibility in each case when using an Erbe product. We wish to point out that science and technology is constantly subject to new developments arising from research and clinical experience. For this reason it may be necessary for the user to deviate from the information provided in this document.

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