1. The following Requirements for Distributors concerning the implementation of Regulation (EU) 2017/745 on medical devices ("Requirements") applies to all legal relationships between Erbe Elektromedizin GmbH ("Erbe") and buyers of its Products if the buyer is a Distributor ("Distributor") within the meaning of Regulation (EU) 2017/745 on medical devices ("MDR"). The provisions set out in Erbe's General Terms and Conditions of Sale and Supply continue to apply in addition to these Requirements. In case of conflicts or inconsistencies between the Requirements and the General Terms and Conditions of Sale and Supply, these Requirements will take precedence.
2. Distributors will meet the requirements and comply with the obligations set out in **Article 14** MDR. When making a Product available on the market, Distributors will act with due care in relation to the requirements applicable in the context of their activities.
3. When creating own **marketing materials** for Erbe Products ("Products") Distributors will only use approved marketing claims which can be found in the respective current marketing materials of Erbe (current leaflets, brochures, website). Distributors will not revise or alter images or create new images. Erbe reserves the right to veto any marketing material created by the Distributors which may infringe Erbe's marketing materials.
4. Distributors are responsible for ensuring that all of the staff dealing with and handling the Products have the necessary **expertise**. This expertise can be acquired by using the information available in instruction manuals and instructions for use as well as the information on Erbe's website. It is also possible to participate in online training courses (www.erbe-med.com).
5. Erbe employees will perform the **installation** of and the **instruction** for Erbe devices sold by the Distributors. This will be documented in Erbe's CRM system.
6. Distributors will ensure that the Products can be **traced** (article number and series or batch number) back to the customer at all times.
7. Distributors will **handle, store and transport** the Products in a controlled manner (in accordance with the product-specific labelling) so that the integrity is maintained and all specified requirements are met. Distributors will not modify the Erbe **packaging** or the Erbe **labelling**.
8. Distributors will document **non-conformities** of the Products (e.g. which are discovered during the incoming goods inspection and examination by Distributors) and handle these appropriately. Distributors will inform Erbe about the non-conformities without undue delay providing detailed information.
9. Distributors will forward all **complaints** concerning the Products (which are communicated in writing, electronically or orally by the end customer) without undue delay in writing to Erbe by sending an email to TechService@erbe-med.com.
10. If Distributors receive knowledge of **incidents** where patients were harmed or could have been harmed when using Products, Distributors will report these without undue delay by email to Medical.DeviceReporting@erbe-med.com. Distributors will assist Erbe with assessing and evaluating the incident. Erbe will decide whether to report an incident to the competent authority.
11. Distributors will send all types of customer feedback concerning the Products to the following address: https://erbeelektromedizin.eu.qualtrics.com/jfe/form/SV_5nVNiLUijl9US8t.
12. If Erbe decides to implement a **product recall, Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN)**, Distributors will assist Erbe with their resources.
13. All of the relevant **documents and recordings** (e.g. for the purpose of traceability, quality management, etc.) relating to the distribution of the Products will be retained by Distributors from the time when the Product concerned is dispatched for at least 10 years or the Product lifetime.

Erbe Elektromedizin GmbH, Tübingen

08/2020

Requirements for Distributors concerning the implementation of Regulation (EU) 2017/745 on Medical Devices