1. The following Requirements for Distributors concerning the implementation of Regulation (EU) 2017/745 on medical devices ("Requirements") applies to all legal relationships between Bionmed Technologies GmbH ("Bionmed") 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 Bionmed'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 Bionmed Products ("Products") Distributors will only use approved marketing claims which can be found in the respective current marketing materials of Bionmed (current leaflets, brochures, website). Distributors will not revise or alter images or create new images. Bionmed reserves the right to veto any marketing material created by the Distributors which may infringe Bionmed'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 Bionmed's website. It is also possible to participate in online training courses.

5. The **installation** of and the **instruction** for Bionmed devices sold by the Distributors is done by trained employees. This will be documented in Bionmed'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 sterile **packaging** or the Bionmed **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 Bionmed 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 Bionmed by sending an email to service@bionmed.de.

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 MedicalDeviceReporting@bionmed.de Distributors will assist Bionmed with assessing and evaluating the incident. Bionmed 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: service@bionmed.de.

12. If Bionmed decides to implement a **product recall, Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN)**, Distributors will assist Bionmed 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.

Bionmed Technologies GmbH, Saarbrücken

03/2021

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