Regulations for distributors to implement the Medical Device Regulation (EU) 2017/745

The following Regulation for distributors to implement the Medical Device Regulation (EU) 2017/745 ("MDR") applies for all legal relations between the company VBM Medizintechnik GmbH ("VBM") and the purchasers of its products wherever the purchaser acts as a distributor ("distributor") according to Regulation (EU) 2017/745 for medical devices. Further the requirements of the General Terms and Conditions of Sale of VBM apply in addition. This Regulation will apply in priority in case of conflicts or contradictions compared to the General Terms and Conditions of Sale. If there is a specific Supply - / Quality – or Distribution Agreement with the distributor, this shall take precedence.

1. The distributors are obliged to meet the requirements and duties of MDR article 14. To make a product available on the market, the distributors shall carefully consider the applicable requirements as part of their activities.
2. The distributors ensure traceability of the products to the customer at any time (REF and serial or LOT number). Where applicable, the distributors verify whether a UDI has been assigned.
3. The distributors ascertain CE marking and the EU Declaration of Conformity of the products.
4. The distributors must adhere to the storage and transport conditions of the products set by VBM to ascertain their integrity.
5. The distributors may not make any modifications to the products of VBM, the associated packaging and labeling (i.a. instructions for use).
6. The distributors shall keep a register of and shall adequately treat non-conforming devices (which may be observed by the distributors e.g. during incoming inspection). The distributors immediately provide detailed information on the non-conformities to VBM.
7. The distributors shall immediately forward all kinds of complaints on the products (received by customers in writing, electronically or verbally) to VBM immediately and in writing via service@vbm-medical.de. The distributors are not entitled to perform any repairs or service procedures. This is the sole responsibility of VBM and authorized VBM service partners.
8. The distributors who have received information about incidents related to a device where patients, users or third parties have been harmed or may have been harmed, shall immediately forward this information by e-mail to fieldsafetynotice@vbm-medical.de. The distributors will support VBM in evaluation and assessment of the incident. VBM decides whether an incident is reported to the competent authority.
9. The distributors will send all kinds of customer feedback regarding the devices to service@vbm-medical.de.
10. If VBM decides on a product recall, Field Safety Corrective Action (FSCA) or Field Safety Notice (FSN), the distributors will support VBM with their resources.
11. All relevant documentation and records related to the sale of the devices (e.g. for traceability, quality management, etc.) shall be kept by the distributors for at least 10 years from the shipping date or for the lifetime of the corresponding product.