Quality assurance information for distributors

We ask you to observe our regulatory requirements when handling our products. You are thereby fulfilling the binding obligations for your activity as a distributor according to MDR (EU) 2017/745.

For administrative reasons, it is not possible for us to conclude an individual contract with each of our trading partners with regard to these requirements.

Inspection obligations of a trader

According to Article 14(2) MDR (EU) 2017/ 745, a distributor has to check on a random basis whether the CE marking is present on the medical devices purchased and whether a declaration of conformity has been issued for the product.

Information on the product, product data sheets and the declarations of conformity are provided under the respective product on our website. Certificates and product data sheets supplement the information in the declaration of conformity and belong together. The declaration of conformity is limited and refers to the term of the certificates or, in the case of changes, the specification of a batch in the product data sheet.

The Declaration of Conformity according to MDR contains the manufacturer identification number (SRN) and the so-called basic UDI (unique device identification). The products are reported by NOBAMED Paul Danz AG in the European database EUDAMED. The UDI code of the products labelled according to MDR is applied in a staggered manner.

Risk class	Prescribed date of implementation
MD Class III (MDR Art. 123 3f)	26 May 2021
MD Class II (MDR Art. 123 3f)	26 May 2023
MD Class I (MDR Art. 123 3f)	26 May 2025

Non-compliant products

If a distributor is of the opinion that a product supplied by NOBAMED Paul Danz AG does not comply with the requirements of the MDR or other legal requirements, he must not pass this product on to third parties. The distributor has to inform NOBAMED Paul Danz AG immediately and to justify this measure.

The distributor is obliged to store separately and temporarily products from complaints, claims and recalls or products that are considered non-compliant. The distributor and NOBAMED Paul Danz AG shall then agree on the further procedure.

Storage and transport

The distributorr has to handle our products carefully to avoid damage. They must be stored in a dry and clean place and protected from access by unauthorised persons. The storage conditions indicated on the labelling must be observed. This also applies to further transport.

Reports from the market

If the distributor becomes aware of complaints or reports from the distributor's customers about suspected incidents involving users or patients, the distributor shall immediately forward this information to NOBAMED Paul Danz AG.

The distributor shall cooperate with NOBAMED Paul Danz AG in the implementation of corrective measures. He shall keep a record of complaints of suspected non-compliant products, of recalls or withdrawals. The corresponding information shall be made available to NOBAMED Paul Danz AG upon request. Official reporting obligations remain unaffected. The distributor and NOBAMED Paul Danz AG shall support each other in the fulfilment of these reporting obligations.

Product knowledge

We provide certificates, declarations of conformity and product information on our website. Our medical device advisors also provide support. The distributor shall also provide sufficient personnel to advise its customers and shall ensure that its employees have appropriate product knowledge.

Modifications to the product

Products may not be marketed under the distributor's own name without a special and express written agreement.

Changes of the intended purpose or other changes relevant for the conformity such as changes of the directions for use, changes of the labelling, translations changes of the package size, require the express consent of NOBAMED Paul Danz AG. If the distributor makes such changes on his own responsibility, the tasks and duties of the manufacturer are transferred to the distributor and the CE-mark applied by NOBAMED Paul Danz AG loses its validity.

Traceability

The distributor shall keep records of the article number (REF), batch (LOT) and quantity of the products, from whom (name, address) he has obtained them and to whom (name, address) he has supplied them. The records shall be kept for at least 10 years.

Products in the trade chain according to MDD 93/42 (EEC)

Please note that products according to MDD 93/42 (EEC) may continue to be in the trade chain. A sales deadline does not apply ((EU) 2023/607, 2023-03-20).