

Product use restriction

Special conditions for medical devices

Terms and conditions of the obligations for distributors to sell medical devices in compliance with European law in accordance with Regulation (EC) 2017/745 (MDR) and in-vitro diagnostics in accordance with Regulation (EC) 2017/746 (IVDR)

These terms and conditions apply to all business deals between the Manufacturer MACHEREY-NAGEL GmbH & Co. KG, Valenciennr Str. 11, 52355 Dueren, Germany and the Distributors of its medical devices and in-vitro diagnostic agents.

§ 1 Subject matter of this terms and conditions

Based on the Medical Devices Regulation (MDR) and the In-Vitro Diagnostic Regulation (IVDR) original Manufacturers and Distributors have obligations to ensure a higher degree of transparency, security and traceability of medical devices. The Distributor's obligations are specified in Art. 14 MDR as well as in Art. 14 IVDR. With this terms and conditions, the Manufacturer wants to ensure that the Distributor knows and fulfills the obligations according to Art. 14 MDR and Art. 14 IVDR.

§ 2 Scope

This Agreement applies to all medical devices and in vitro diagnostic medical devices provided by the Distributor on the Union market within the meaning of Art. 2 No. 27 or Art. 2 No. 20 IVDR.

§ 3 Definitions

(1) "Manufacturer" means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark (cf. Art. 2 No.30 MDR/Art. 2 No. 23 IVDR).

(2) „Distributor“ means any natural or legal person in the supply chain, other than the Manufacturer or the importer, that makes a device available on the market, up until the point of putting into service (cf. Art. 2 No. 34 MDR/Art. 2 No. 27 IVDR).

(3) „Device“ within the meaning of this terms and conditions means both a medical device within the meaning of Art. 2 No. 1 MDR and an „in vitro diagnostic agent“ within the meaning of Art. 2 No. 2 IVDR.

§ 4 Distributor responsibility

(1) In the course of his activities, the Distributor shall take due care of the applicable requirements.

(2) Before the Distributor makes a Manufacturer's product available on the market, Distributor shall verify especially that a) the device has been CE marked, b) the EU declaration of conformity of the device has been drawn up c) the device is accompanied by the information to be supplied by the Manufacturer in accordance with Art. 10 (10) MDR or Art. 10 (10) IVDR, d) that, where applicable, a UDI has been assigned by the Manufacturer.

In order to meet the requirements referred to in Sec. 2 points a) to d) the Distributor may apply a sampling method that is representative of the devices supplied by that Distributor.

(3) Distributor shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the Manufacturer.

(4) If the Distributor considers or has reason to believe that a product does not meet the requirements of the present regulations, he may not make the product available on the market before the conformity of the product has been manufactured. In this case he must inform the Manufacturer immediately.

(5) If the Distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall inform the Manufacturer as well as the competent authority.

(6) If the Distributor considers or has reason to believe that a product which he has made available on the market does not comply with the Regulation, he shall immediately inform the Manufacturer thereof.

(7) Where the Distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities. He is obliged to give details, in particular, of the non-compliance and of any corrective action taken.

(8) The Distributor shall co-operate with the Manufacturer and, where applicable the Manufacturer's authorized representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken.

(9) If the Distributor receives complaints about suspected occurrences in connection with a product that he has provided, he shall immediately forward them to the Manufacturer. He shall keep a register of complaints, non-compliant products, recalls and withdrawals and keep the Manufacturer informed of these monitoring activities. Upon request, the Distributor shall make all information available to the Manufacturer.

(10) Upon request, the Distributor shall provide the competent authority with all information and documentation at his disposal necessary to demonstrate the conformity of a product. This obligation shall be deemed to be fulfilled if the Manufacturer provides the relevant information.

(11) The Distributor shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which he has made available on the market

(12) The Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

(13) This list of obligations is not to be understood as exhaustive. The Distributor must always carry out his activities in accordance with the applicable laws.

(14) In the event that any provision of these terms and conditions is invalid or becomes invalid, the remainder of the terms and conditions shall remain unaffected there by.

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