Special Terms and Conditions for Medical Devices

Insofar as one of our offers according to our prospectus and price list or the information within the safety data sheet concerns the delivery of medical devices or accessories of a medical device within the meaning of Art. 2 No. 1 and 2 of the European Directive (EU) 2017/745 (hereinafter referred to as "MDR"), we are a manufacturer within the meaning of Art. 2 No. 30 MDR.

Due to the increased requirements now to be fulfilled on the part of economic operators with regard to the required certification and the data and contents of the quality and monitoring process to be disclosed to the competent authorities in this context, the following supplementary provisions apply in addition to our Terms and Conditions of Domestic Delivery or our Export Terms and Conditions:

1 Right of Sale

1.1 The customer, as one of those who make our medical products or their accessories available on the market until the time, they are made available to the end user, is entitled to market and sell the medical devices or their accessories (hereinafter referred to as "products").

1.2 The customer's right of sale pursuant to para. 1 above shall extend to the European Economic Area (hereinafter referred to as the "sales territory").

1.3 Marketing and/or sale of the products outside the sales territory shall only be permitted with our prior written consent. In this case, the necessary approval and/or registration of the products shall be carried out by the customer on our behalf. If the consent required in accordance with sentence 1 above has been granted, the customer undertakes to inform us in writing of all documents required for the approval or registration. We undertake to provide the customer or the competent authority with the necessary information and data exchange to the extent provided by law. Any approval or registration costs incurred shall be borne by the customer.

1.4 None of the provisions contained in this agreement shall establish the right of the customer to act as an agent, to represent us in any way or to enter into obligations on our behalf.

2 Obligation catalog

2.1 We point out that the customer is obliged to fulfill the legal duties of a distributor according to art. 14 MDR. Accordingly, before he sells a product to third parties, he must in particular check whether

a) the product bears the CE marking and that an EU declaration of conformity has been issued for the product

b) the product is accompanied by the information provided by the manufacturer in accordance with Article 10 (11) MDR;

c) if applicable, a Unique Device Identification has been assigned by the manufacturer.

The customer shall ensure that the specific storage and transport conditions of the products comply with our specifications.

Should the customer be of the opinion or have reason to believe that a product does not comply with the legal requirements of the MDR, he is in particular obliged to inform us of this in writing without delay, at the latest within 72 hours.

2.2 In addition, the customer shall maintain and update a post-market surveillance and vigilance system in compliance with the relevant legal requirements to support and ensure the taking of preventive and corrective actions as well as the reporting of serious incidents and safety corrective actions in the field to the competent authorities. Within the scope of this, both parties undertake in particular to exchange information and data on incidents (malfunction or deterioration of the properties or performance of a product, which in particular may lead or have led to a permanent serious deterioration of the state of health or even to the death of an end user) in writing without delay and at the latest within 48 hours of becoming aware of them. In addition, the customer is obligated to keep sufficiently detailed documentation on the products sold by him, their purchasers and their use, and to send it to us in writing without delay if necessary. The reasonable costs of the corresponding exchange of information and data shall be borne by us.

2.3 The customer is not entitled to change the product marking provided by us - that is any written, printed or graphically represented information which is either on the product itself or on its packaging. The only excep

tion to this is the affixing of a reference to the customer's sales activity in its own name on the product packaging.

3 Resale of the Products

If the customer does not sell the products to end customers, but also to third parties selling the products (dealers), he shall ensure compliance with the obligations pursuant to Section 2. above, in particular with regard to market surveillance and vigilance, by means of a separate contractual agreement with the respective third party

4 Contact

For notifications and questions regarding medical devices, market surveillance and vigilance, we can be reached at the following e-mail address:
support@elma-ultrasonic.com.

Elma Schmidbauer GmbH
As of 02|2021