Regulatory requirements for distributors outside the EU

1. All distributors must comply with applicable national requirements.

2. All distributors are responsible for ensuring that the sales personnel who appear on the market with the Medicon product, whether in the form of active promotion, sample or catalogue reviews, have the appropriate advisory capacity and expertise to place the products responsibly on the market. If this expert competence is not available, take the necessary information, e.g. in the field of equipment, from the operating instructions.

3. All advertising material for Medicon products that is not Medicon's own must be authorised by Medicon in advance before distribution.

4. The distributor shall in any case ensure that the identification and traceability of Medicon products is guaranteed at all times and is sustainably ensured within the framework of the legal obligation.

5. The distributor shall ensure that the Medicon products are stored and transported correctly. We expressly point out that the products may not be modified. This applies in particular to packaging or additional labelling.

6. Should the sales partner discover non-conforming Medicon products during the incoming goods inspection, it must be reported directly to the Medicon company. These products may not be placed on the market. All distributors are obliged to forward all complaints in writing to Medicon.

7. If distribution partners become aware of suspected incidents in which patients have been harmed by the use of Medicon products or in which there is a possibility of harm, this must be reported to Medicon immediately by e-mail in German or English.
   Reporting address: md.vigilance@medicon.de
   In any case, the sales partner supports Medicon in providing information and evaluating the respective incident. Medicon shall decide whether an incident is to be reported to the competent authority.

8. The distributor undertakes to maintain continuous market observation for our products.

9. In the event of a product recall, Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN), the distributor will support Medicon with its resources to the best of its ability.

10. Medicon shall have the right to audit compliance with the requirements herein in case of doubt. Distributors shall ensure that competent personnel are available at all times during regular business hours,

11. Distributors shall promptly notify Medicon upon receipt of any notice or occurrence of an inspection by a regulatory authority concerning Medicon products.

12. All relevant documents and records related to the distribution of Medicon products (especially for quality control and traceability purposes) shall be kept by the distributor at least in accordance with national legal requirements.