CMF SURGICAL NEURO+SPINE medicon®

MDR - Requirements for distributors in the EU

1. All distributors must meet the requirements of Article 14 of the MDR. The applicable requirements must be complied with for the distribution of our products.

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 advertising, sample or catalog 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 non-Medicon promotional materials for Medicon products must be authorized by Medicon in advance, prior to distribution.

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

5. The distributor ensures 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 labeling.

6. If the distributor finds non-conforming Medicon products during the incoming inspection, it must be reported directly to Medicon. These products must not be placed on the market. All distributors are obliged to forward all complaints in writing to the company Medicon.

7. If distributors become aware of suspected incidents in which patients have been harmed or are likely to be harmed by the use of Medicon products, this must be reported immediately to Medicon by e-mail in German or English. We have set up a central e-mail address for the transmission of your reports: md.vigilance@medicon.de.
   The sales partner supports the company Medicon in any case to bring in information as well as the evaluation of the corresponding incident. The company Medicon decides whether an incident is reported to the competent authority. Your obligation to report to the competent authorities remains unaffected. Please note that you must still inform other relevant authorities independently, as this system only serves to notify Medicon eG.

8. The Distributor agrees to maintain continuous market monitoring 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. In case of doubt, Medicon has the right to monitor compliance with the MDR requirements by means of an audit. 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 the occurrence of any inspection by a regulatory authority insofar as it relates to Medicon products.

12. All relevant documents and records related to the distribution of Medicon products (in particular for quality control and traceability purposes) shall be retained by the distributor for at least 10 years, or 15 years in the case of implants, from the date of shipment of the relevant product.