medídee®

EUROPEAN AUTHORIZED REPRESENTATIVE

Non-EU based manufacturers of medical devices must mandate a European Authorized Representative in order to market medical devices or IVD in the EU.

Swiss manufacturers must prepare for fulfilling obligations of a manufacturer from a non-member state as the Mutual Recognition Agreement related to medical devices is not covering the applicable medical device regulatory framework from May 26 onwards.

Medidee acts as European Authorised Representative (EAR) for medical device manufacturers. Take advantage of our scientific, technical and clinical expertise to optimize return on investment from the EAR obligations.

Our dedicated EAR office is in the South of Germany, near the Swiss border in the heart of European Union.

Medidee Services (Deutschland) GmbH

EC REP

- Direct contact with EAR experts over our representatives in Switzerland (Olten / Lausanne)
- Review and ensure your product compliance with the general requirements for safety and performance as set out in the applicable European legislation (93/42 EEC, 90/385 EEC, 98/79 EC, Reg.EU 2017/745 MDR, Reg.EU 2017/746 IVDR)
- Propose a mandate agreement tailored to your specific needs supporting setup of liability coverage as required by the regulations.
- Register your device with the national Competent Authority before being placed on the market.
- Maintain a current copy of your Technical Documentation available for inspection by the European Competent Authorities and protect the confidentiality of your documentation.
- Provide you with the European contact details to be placed on your device labels, packaging, and Instructions for Use, thus acting on your behalf as the main contact for European Competent Authorities.
- Support you to implement the necessary adaptations to your packaging, labelling and IFU to comply with national requirements (i.e. support of translation activities).
- Perform audits of your subcontractors located within the EU (Suppliers, distributors, etc.).
- Support vigilance, manage and coordinate any Incident resolution or Field Safety Corrective Action with the Competent Authorities, in cooperation with you and your distributors.
- Notify EU Authorities of all major incidents pertaining to products when necessary.
- Provide regulatory intelligence for EU regulations.

Contact: ecrep@medidee.com

www.medidee.com