pfmmedical
expert

European Authorized Representative

www.pfmmedical.com

EC REP

Regulation (EU) 2017/745, MDR, Article 11
Regulation (EU) 2017/746, IVDR, Article 11
European Authorized Representative (EAR)

pfm medical expert as Authorized Representative

According to the current EU regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) manufacturers of medical devices outside the EU must appoint an EAR (European Authorized Representative) based in the EU in order to be able to sell the medical device in the EU.

pfm medical expert gmbh is a service provider based in Germany offering consulting services in the field of Quality Management and Regulatory Affairs. The company also acts as European Authorized Representative, employing staff with extensive experience in the medical device industry.

European Authorized Representative

MDR, IVDR, Article 11 (1)

Where the manufacturer of a medical device is not established in a Member State, medical devices may only be placed on the Union market, if the manufacturer designates a sole Authorized Representative.

Services of European Authorized Representative

According to MDR and IVDR, Article 11(3):

- Verification of the EU Declaration of Conformity and Technical Documentation and, if appropriate, conformity assessment procedure
- Keeping available a copy of the Technical Documentation, the EU Declaration of Conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements
- Verification of compliance with the registration obligations laid down in Article 27, 29 and 31
- Provision of all requested information and documents to the Competent Authorities to demonstrate the conformity of the medical device
- Linking the manufacturer with the Competent Authority
- Cooperation with the Competent Authorities on any preventive or corrective action taken to eliminate or mitigate the risks posed by medical devices
- Information to the manufacturer on complaints and reports from healthcare professionals, patients and users about suspected incidents related to the designated medical device

Checklist

Please check out before placing medical devices on the European Market (example of MDR):

- ☐ Check, that provision of all requirements under Article 10 of MDR are met
- ☐ Draw up an EU Declaration of Conformity (Article 10(6))
- ☐ Create or update the Technical Documentation (Annexes II and III, MDR) (Article 10(4))
- ☐ Designate an EAR in writing (Article 11(2))
- ☐ Register the medical devices in EUDAMED

Contact

Should you have any questions our team will be glad to advise you.

info@pfmmedical-expert.de
+49 (0)2236 9641-800

pfm medical expert gmbh
Wankelstraße 60
50996 Cologne, Germany

Use the contact form on our website
www.pfmmedical-expert.com

Rev. 2024-09-11_EN