EC REP

european authorized representative

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The Medical Device Regulations (MDR (EU) 2017/745 & IVDR (EU) 2017/746) – as the existing Medical Device Directive MDD 93/42/EEC and the IVDD 98/79/EC require the designation of an **Authorized Representative (EAR)** for those legal manufacturers who are based outside the European Union. The EAR must be based within the EU. The relevant legal requirements are described in both regulations in Art. 11.

Art. 2 (32) MDR/Art. 2 (25) IVDR

'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

Art. 11 (1) MDR/IVDR

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

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MT Promedt Consulting GmbH, a Germany based organization is acting since 1995 as a reliable European Representative under the Medical Device Directives 93/42/EEC, IVDD 98/79/EC and AIMDD 90/385/EEC and will also providing qualified and professional EAR services in all EU Member States under the new regulations.

cooperation partner
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The EAR is a registered economic operator. The **EAR services** under the new regulations will include:

/ provision of an authorized European address
/ verification activities regarding EU declaration of conformity, technical documentation and 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, issued by the notified body
/ verification of compliance with all registration obligations for the EAR and manufacturer
/ interaction with competent authorities providing all relevant information and documentation necessary to demonstrate the conformity of a device as well as product samples on demand
/ liaison between competent authorities, manufacturer, importer, distributor in vigilance aspects
/ cooperation with the competent authorities on any preventive or corrective action taken to eliminate or mitigate the risks posed by devices;
/ information of the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected product related incidents

Our **EAR services** include also

/ access to certificate of marketability
/ regulatory support for clinical investigations
/ in-house trainings

All clients have permanent and safe access to our document server system. Make use of our personalized EAR services. Our EAR services meet the requirements of the new regulations and provide you full flexibility in your European distribution network.

Profit from our experience and competence