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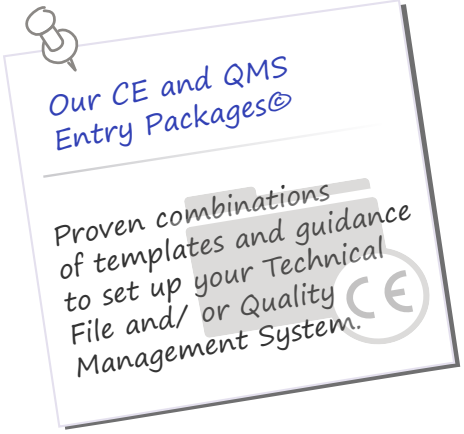
CEpartner4U serves as consultant and Authorized Representative under the European medical devices directives.

Regulatory Affairs and Quality Management

Our experts have a practical approach to assist you with the regulatory requirements. Our services range from Authorized Representative to vigilance reporting, from self-supporting tools to extensive consultancy.

CEpartner4U assists hundreds of manufacturers from all over the world. We support you and your stakeholders with the interpretation and application of the European regulations for medical devices.



Training & workshops

CEpartner4U provides for a global network of offices and affiliates in the Benelux, the Americas, Israel, Russia and Asia. CEpartner4U organizes seminars and training, addressing a variety of topics, including regulatory- and legal affairs, marketing and operations.

For example, we can organize interactive workshops to support you with your regulatory and market access strategy, device classification, risk management and usability.

Frequently Asked Questions about the Authorized Representative

All non-EU manufacturers must appoint an Authorized Representative (AR or EC rep) in the European Community Market. As Authorized Representative, CEpartner4U is your interface with the EU Competent Authorities.

EC REP

1. Why choose an independent AR?
An independent AR deals with regulatory affairs only and does not distribute or sell devices. If you select a master-distributor to fulfill the position of Authorized Representative, his commercial interests may conflict with your regulatory obligations. (e.g. warehouse conditions, information supply to customers etc.) Next to that, other distributors might be reluctant to handle devices with the name of the master-distributor printed on the label (as AR).

2. How to select an AR?
Per definition, the Authorized Representative is a natural or legal person established in the EU who has received and accepted a written mandate from a manufacturer to act on his behalf with regard to the obligations under the medical devices directives.
Hence, choose an experienced Authorized Representative who is well versed in both the medical device industry and regulatory compliance. CEpartner4U has sample agreements clearly outlining the essential duties of an Authorized Representative.

3. What are the manufacturer's main duties?
- Guaranteeing device safety and performance
- Providing the technical file to the AR
- Printing the AR's name and address on the product label
- Notifying the AR of any incidents with the devices
- Cooperating with the requests of Competent Authorities
- Indemnifying the AR from product liability

4. What are the essential duties of the AR?
- An AR acts and can be addressed by the EU authorities instead of the manufacturer with regard to his regulatory obligations
- Registration of risk class I and IVD devices
- Keeping the technical documentation available to the Competent Authorities
- Reporting vigilance cases

5. What is the reason for placing part of the technical documents on file in the EU?
An AR must be able to provide all documentation and information that an authority may require for the purpose of market surveillance.

6. Is the technical information confidential?
Confidentiality is secured by the AR-agreement. The regulations require that all parties, Competent Authorities included, are bound to observe confidentiality with regard to all information.

Committed • Expertise • Global network • Since 1998

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