EUREPforMedicalDevice

产品名称	EUREPforMedicalDevice
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价格	.00/个
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产品详情

ANSWERED ON THIS PAGE:

- What are the responsibilities of an EU Authorized Representative (EC REP)?
- Can I appoint a distributor as my representative?
- What happens if I want to change my EC REP?

Interested in obtaining CE certification to sell your medical devices in Europe? If your company does not have a physical location in the EU, you are required to appoint an Authorized Representative, also referred to as an EC REP, to represent your company to European authorities. You must retain an EC REP as long as you sell your devices in Europe.

What is the role of an EU Authorized Representative?

Your European Authorized Representative serves as a liaison between you and the national Competent Authorities (Ministries of Health). Additionally, your appointed representative will:

- Assist with certain device registrations, as required
- Be identified on your product labeling throughout Europe

· Make a current copy of your Technical File or CE Declaration of Conformity available for inspection by a Competent Authority, upon request

· Assist with Incident and Field Safety Corrective Action (FSCA) reporting, in cooperation with you and your distributors

It is possible to appoint a distributor as your Authorized Representative in Europe, but it is not recommended because most distributors are not prepared to fulfill the mandatory responsibilities of the EC REP. Instead, select an independent representative that will focus on regulatory affairs, rather than sales and marketing. Read more about the benefits of hiring an independent firm to act as your EC REP in Europe.

Why choose SUNGO as your European Authorized Representative?

SUNGO is the largest Authorized Representative for medical devices and IVDs, representing more than 1,000 device companies worldwide.

· Our experienced consultants will review your Technical File, register your medical device or IVD, as required, and respond to any questions or concerns from the Competent Authorities.

· You will have secure online access to all of your documentation and regulatory information, including technical files, labeling information and symbols, language requirements, directives, guidelines, and more.

· Our vast expertise with European regulations, registering thousands of devices, facilitates a smooth and efficient registration process.

· We send frequent updates to all of our Authorized Representation clients with important regulatory updates focused on Europe.

· In addition to our European offices, we maintain offices in the US, Canada, Japan, Korea, Brazil, and many other places worldwide. We can serve you efficiently regardless of your time zone.

Ask us about our special 3-year and "deferred payment" packages for new European representation clients.

Common Questions

What happens if we do not appoint an EC REP Authorized Representative?

Your Notified Body requires appointment of an EC REP before they will issue a CE certificate. Compliance with the applicable Directive is mandatory for any device placed in the EU market; therefore, engaging and identifying your chosen representative is essential. If you do not appoint a rep, your products may be stopped at the border.

Do we have to put the name of the Authorized Representative on our labeling, packaging and IFUs?

Yes. You must list the name and address of the Authorized Rep on the product label, outer packaging and/or Instructions for Use. The name and address of the Authorized Representative should be shown next to the official EC REP logo.

Can a Competent Authority inspect my Authorized Representative?

Yes. A Competent Authority can inspect an Authorized Representative at any time to determine if they understand their role, have direct access to client documentation such as the Technical File/Design Dossier and have processes in place to ensure it can fulfill its role as an Authorized Representative.

Can I change Authorized Representatives after I appoint one?

Yes. You may switch your EC REP without invalidating your product approvals in Europe. However, keep in mind that because your EC REP must be printed on your labeling, switching can be somewhat costly as you will need to change labeling and deal with the issue of products that are already on the market.

What is the role of the Authorized Representative under the MDR?

Authorized Representatives will take on more risk and liability under Europe's new Medical Device Regulation (MDR). The EC REP will be held jointly and severally liable for defective medical devices so you can expect that your representative will monitor your compliance more thoroughly. Download our 15-page white paper to learn more about the MDR changes.

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