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Europe
The Regulatory Process for Medical Devices

Current MDD Process

Determine which Medical Device Directive applies to your device:
93/42/EEC – Medical Devices Directive (MDD)
90/385/EEC - Active Implantable Medical Devices Directive (AIMDD)

Determine classification of your device using Annex IX of the MDD.
Active implantable medical devices are typically subject to the same regulatory requirements as Class III devices.

Non-sterile Class I Non-measuring	Sterile Class I Measuring	Class IIa	Class IIb	Class III
A QMS is not formally required. However, a PMS procedure is required, not to be audited by a NB.	Implement a Quality Management System (QMS) in accordance with Annex II or V of 93/42/EEC. Most companies apply the ISO 13485 standard to achieve QMS compliance.			
Prepare a Technical File which provides detailed information on your medical device, and demonstrates compliance with 93/42/EEC.				Prepare a Design Dossier.*
If you do not have a location in Europe, appoint an Authorized Representative (EC REP) in Europe who is qualified to handle regulatory issues. Place EC REP name and address on Instructions for Use or outer packaging or device label. EC REP				
No Notified Body audit of QMS or Technical File.	Your QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by European authorities to audit medical device companies and products.			
	You will be issued a CE Marking certificate for your device and an ISO 13485 certificate for your facility following successful completion of your Notified Body audit. ISO 13485 certification must be renewed every year. CE Marking certificates are typically valid for 3 years.			
Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable Directive. You may now affix the CE Marking. CE				
Class I devices must be registered with Competent Authority in the country where you, or your EC REP, is based.	Some EU member states require additional registration of Class lla, llb or lll devices that are placed on their markets.			
CE certificates do not expire. You must perform CER updates and PMS activities.	You will be audited each year by a Notified Body to ensure ongoing compliance with 93/42/EEC or 90/385/EEC. Failure to pass the audit will invalidate your CE Marking certificate. You must perform CER updates and PMS activities.			

* All devices require will require clinical data. Most of these data should refer to the subject device. Clinical studies are required for Class IIb and III implants. Existing clinical data may be acceptable. Clinical trials in Europe must be pre-approved by a European Competent Authority.

This is a simplified overview of the process. Your Notified Body may choose to audit your submission and request more documents, which will add time to your approval.

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Europe
Time, Cost, and Complexity of Registration

Current MDD Process

Device classification in Europe	Non-sterile Class I Non-measuring	Sterile Class I Measuring	Class IIa	Class IIb	Class III
How long you should expect to wait after submission until approval is granted.[1]	Not applicable	3-5 month	3-5 month	3-6 month	6-9 month
Validity period for CE Marking certificate.[2]	Not applicable	3 years	3 years	3 years	3 years
Registration renewal should be started this far in advance.[3]	Not applicible	6 months	6 months	6 months	6 months
Complexity of the registration process for this classification.[4]	Simple 1 Complex	Simple 2 Complex	Simple 3 Complex	Simple 3 Complex	Simple 4 Complex
Estimated cost (USD) of gaining regulatory approval .[5]	Low 1 High	Low 3 High	Low 3 High	Low 4 High	Low 4 High

Notes

1. The time frames shown above are typical for the majority of medical device submissions but assume that your device does not contain animal tissue, medicinal substances or employ entirely novel technology. Your length of approval will depend on the quality and completeness of your technical documentation and how much time you take to address additional information requests from authorities after submission. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

2. CE Marking certificates are typically valid for 3 years, but are generally reviewed annually at the same time as the ISO 13485 surveillance audit. They remain valid as long as you do not make changes to the device, intended use or indications for use. Failure to pass your annual audit could invalidate your CE Marking certificate. Once the MDR has entered into force validity of certificates may be expanded to five years.

3. Most CE Marking certificates are valid for 3 years, and you do not need to "re-register" your device in Europe. However, your Notified Body will conduct an annual compliance audit and could invalidate your device CE certificate if you are found to be out of compliance. Your Notified Body will reissue your CE certificate every three years. We recommend starting the preparations for your annual audit no later than the time specified above. Please consult with your regulatory expert well before this suggested time to avoid any lapse in your registration.

4. Our rating of the complexity of the registration process is based on our experience and the opinion of nearly 1,000 QA/RA professionals worldwide who were asked to rate the difficulty of registering a device in each country. The European CE Marking process is considered the mid-point to which all other markets are compared.

5. Prices in US Dollars for a single device. 1 = Less than $5,000; 2 = $10,000 - $15,000; 3 = $15,000 - $30,000; 4 = $30,000 - $50,000; 5 = $50,000 or more. Estimated cost includes registration application fees, in-country representation, Notified Body audit fees, submission preparation consulting and translation of documents, if required. Costs assume you already have approval for your device in the United States, Canada, Australia or Japan. Costs do NOT include product testing, clinical trials or ISO 13485 implementation, if applicable. These costs are generally spread across many markets and thus not specifically attributed to a European CE submission.

* Class I devices which are not provided sterile and which do not have a measuring function can be self-certi ed (self-declared). As such you will be able to sell your product in Europe within one week of submitting the necessary paperwork to the Competent Authority in which your European Authorized Representative is based, once the requirements of the applicable directive have been met.

This is a simplified overview of the process. Your Notified Body may choose to audit your submission and request more documents, which will add time to your approval.

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