Europe

The regulatory process for medical devices

EU

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**
	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.*
Appoint an Authorized Representative (EC REP) located 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				
	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, but are generally reviewed annually at the same time as the ISO 13485 surveillance audit.			
All Class I devices must be registered with the Competent Authority where your EC REP is based.	Most EU member states do not require registration of Class IIa, IIb or III devices.			
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				
The self-certified CE Marking certificate does not expire as long as you remain in compliance with 93/42/EEC.	You will be audited by a Notified Body each year to ensure ongoing compliance with 93/42/EEC or 90/385/EEC. Failure to pass the audit will invalidate your CE Marking certificate.			

* Class III/AIMD devices will likely require clinical study data. 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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Device classification in Europe	How long you should expect to wait after submission until approval is granted. (See note 1)	Validity period for CE Marking certificate. (See note 2)	Registration renewal should be started this far in advance. (See note 3)	Complexity of the registration process for this classification. (See note 4)	Overall cost of gaining regulatory approval. (See note 5)
CLASS I * Non-sterile, non-measuring	<1 month	Does not expire	Not applicable	Simple – Complex	Low – High
CLASS I Sterile, measuring	3-5 months	3 years	2 months	Simple – Complex	Low – High
CLASS IIa	3-5 months	3 years	2 months	Simple – Complex	Low – High
CLASS IIb	3-6 months	3 years	2 months	Simple – Complex	Low – High
CLASS III	6-9 months	3 years	2 months	Simple – Complex	Low – High

NOTE 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.

NOTE 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.

NOTE 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.

NOTE 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 in January 2014. The European CE Marking process is considered the mid-point to which all other markets are compared.

NOTE 5: Low = Less than US$5000; Midpoint = US$15000-$30000: High = More than US$50000. Overall cost includes registration application fees, product testing, in-country representation, submission preparation consulting and translation of registration documents but not IFU. Costs assume you already have approval for your device in the United States, Canada or Japan. Does not include cost of product testing, nor implementing, auditing, or updating a quality management system compliant with ISO 13485, if applicable.

* Class I devices which are not provided sterile and which do not have a measuring function can be self-certified (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.