

How to obtain CE-marking for a medical device

Step I: Classification

The applicable EU Directive 2007/47/EC / 93/42/EEC foresees three different classification categories for medical devices according to the potential risk involved:

Class I	low risk
Class IIa/IIb	medium risk
Class III	high risk

In order to define the correct classification rationale for the device in question, Article 9 of the above-mentioned article should be read, as well as Annex IX.

In addition, the European Commission offers guidance documents to explain in more detail the rules laid down in the Directive.

Concurrent documents:

- Directive 2007/47/EC
- MEDDEV 2.4 – Classification of MD

Step II: Conformity Assessment Routes

Depending on the classification of the device, the Directive offers different routes to CE-marking.

Class I devices are entitled for self-certification. In this case, the manufacturer only has to fulfill Annex I – Essential Requirements and Annex VII – EC Declaration of Conformity.

Checklists and templates are available on request from mdi Europa.

For Class IIa devices and higher, Notified Body certification is necessary. The manufacturer has to choose between one of the additional routes, such as:

Annex II - Full quality assurance system

The manufacturer must ensure application of the quality system approved for the **design, manufacture and final inspection** of the products concerned.

Annex III –EC TYPE-EXAMINATION

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of the Directive.

Annex IV - EC VERIFICATION

EC verification is the procedure whereby the manufacturer ensures and declares that the products which have been subject to Notified Body testing conform to the type described in the EC type-examination certificate. The Notified Body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product or by examining and testing products on a statistical basis, as the manufacturer decides.

Annex V – PRODUCTION QUALITY ASSURANCE

The manufacturer must ensure application of the quality system approved for the **manufacture** of the products concerned and carry out a **final inspection** as specified by the Directive.

Annex VI – PRODUCT QUALITY ASSURANCE

The manufacturer must ensure application of a quality system approved for **the final inspection and testing** of the product.

Application for CE-marking for Class IIa and higher products is not possible unless one of the above Annexes has been fulfilled and an applicable Notified Body certificate has been issued.

Concurrent documents:

- *List of Notified Bodies*

Step III: Documentation

The following documents are necessary before the devices can be registered for CE-marking:

- Technical File

For description of the contents see Annex VII, § 3.

Checklist is also available from mdi Europa

- Declaration of Conformity

The DoFC must list so-called UMDNS codes for each product group to be registered.

The DoFC Template and the complete list of codes is available from mdi Europa.

- Notified Body certificate (only for Class IIa and higher)

All these documents must be forwarded to the Authorized Representative for registration of the device with the EU authorities.

Step IV: Additional requirements

Labeling: The labeling should reflect certain symbols in accordance with the European Standard EN 980, available via www.beuth.de

Languages: Most member states require the labeling and instructions for use to be available in their national language. Some, however, still accept instructions for devices for “professional use only” to be just in English.

Miscellaneous: There are a number of different EU standards available that might be applicable to the device, for example on sterilization or biocompatibility.

Concurrent documents:

List of harmonized standards

Step V: Role of the Authorized Representative

All the above-mentioned documents must be forwarded to the Authorized Representative located in the European Union.

He will initiate registration of the device upon verification and check of the documents against the requirements laid down in the Directive. Registration is done via an online database. Within 10-14 days, the Authorized Representative will receive confirmation of registration from the authorities.

He will then countersign the manufacturers DoFC and issue a Certificate of CE-Registration, which will list the applicable registration numbers. Those documents will be airmailed to the manufacturer.

Step VI: Maintenance of the CE-mark

Post Market Surveillance is an important issue when it comes to CE-marking. Manufacturers have to keep a close eye on comments, complaints, etc. about their products from the market.

They have to make sure to report all incidents or near incidents to the Authorized Representative who will forward the report to the responsible authority. This needs to be done by standardized procedures, as close time frames are involved.

On the other hand, the manufacturer must ensure to always be aware on regulatory changes in Europe in order to be able to comply with them. This continuous updating service is normally covered by the Authorized Representatives duties and responsibilities, who will keep the manufacturer informed.

Concurrent documents:

MEDDEV 2.12 on Market Surveillance