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Medical Device Trade

CE Mark

A guide for medical device companies

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Introduction

Companies expanding into the European Economic Area (EEA) need to conform to the EU regulatory requirements (CE Mark) before they can start selling their products in the territory. However many people are misled about what the CE mark truly represents and often assume that it is equivalent to FDA approval or clearance, which is not quite accurate.

Understanding the similarities and differences between what FDA and CE certification mean will allow you to develop a more efficient and effective overall company strategy. It will also help reduce unnecessary duplication of efforts, cost and time.

This paper will explain in details what the CE Mark is all about and show you some of the similarities and differences with the FDA certification.

“CE Mark classification depends on a set of rules and FDA depends on other approved products’ equivalency”, this is how Klaas Besseling, BesTech Consulting of Laguna Niguel, CA, a regulatory expert, summed up the main difference between CE Mark and FDA approval.

The European regulations are defined in the Council Directive 93/42/EEC of June 14 1993 concerning medical devices, usually referred to as the Medical Device Directive (MDD).

A few highlights about CE Mark:

- CE Mark is not equivalent to FDA approval / clearance
- CE Mark confirms the safety of a product
- CE Mark does not confirm effectiveness of a product
- The CE marking affixed to a product is a declaration by the person responsible that:
 - the product conforms to all applicable Community provisions
 - the appropriate conformity assessment procedures have been completed

CE Mark classification:

How easy or difficult it is to get CE mark depends on the classification of your product.

There are four classes of products - Class I, IIa, IIb and III.

There is an extensive set of rules in Annex IX of the MDD to enable a company to determine the classification of their product.

Note that the company must determine the classification, but a notified body has the authority to challenge and/or change this classification.

Class I {Annex VII MDD – EC Declaration of Conformity} is used for products with the least amount of risk, i.e. products that are not sterile or do not measure anything. You can self-certify these products by making your own declaration in compliance with the Medical Device Directive (MDD) and you can place the CE mark on your product yourself. See [Diagram A](#) (1)

- No ISO is required
- No involvement of notified body

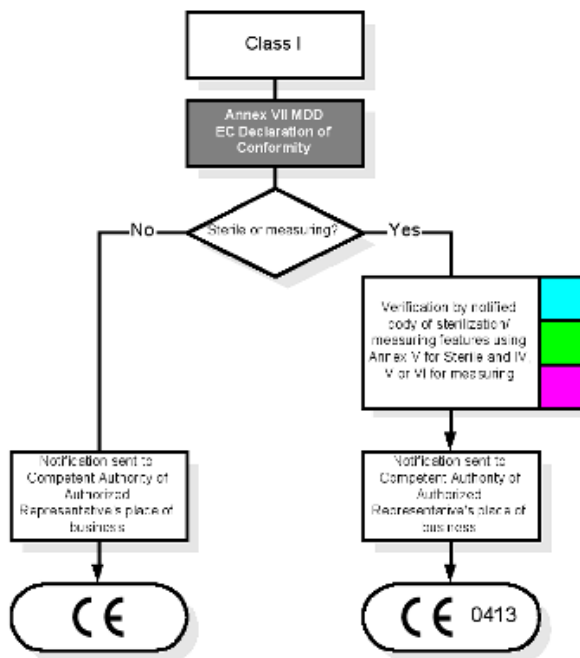


Diagram A

Self-certification means that you declare that the product you are selling in Europe complies with MDD and a company representative signs the document – always file a copy with your Authorized Representative as this is your product's technical file

If the product is either sterile or measures something, then you need to get a notified body involved for those operations that require certification such as sterility and measurements. The CE mark logo displayed on your product will then need to include the ID number of the notified body used (i.e. CE 0413).

In this case you still do not require ISO certification, however the easiest on a long term basis is to go through a full QA process and get ISO 13485, a full quality system that is certified by a notified body.

ISO 13485 is similar to the quality system that FDA requires plus a few additional requirements needed in Europe.

Class IIa – four different avenues to get your CE Mark – all of them include the involvement of a notified body (The notified body confirms that your company complies with Medical Device Directive) [See Diagram B \(1\)](#)

- 1- {Annex II MDD} is a full QA process, less S4 (Design Controls). It includes EC Verification {Annex IV MDD}, Production QA {Annex V MDD}, Product QA {Annex VI MDD} and more
- 2- EC Verification {Annex IV MDD} – Every product must be tested by a notified body or such tests must be carried out on a statistical basis
- 3- Production QA {Annex V MDD} – You get the production facility to be certified
- 4- Product QA {Annex VI MDD} – You get the product itself to get certified

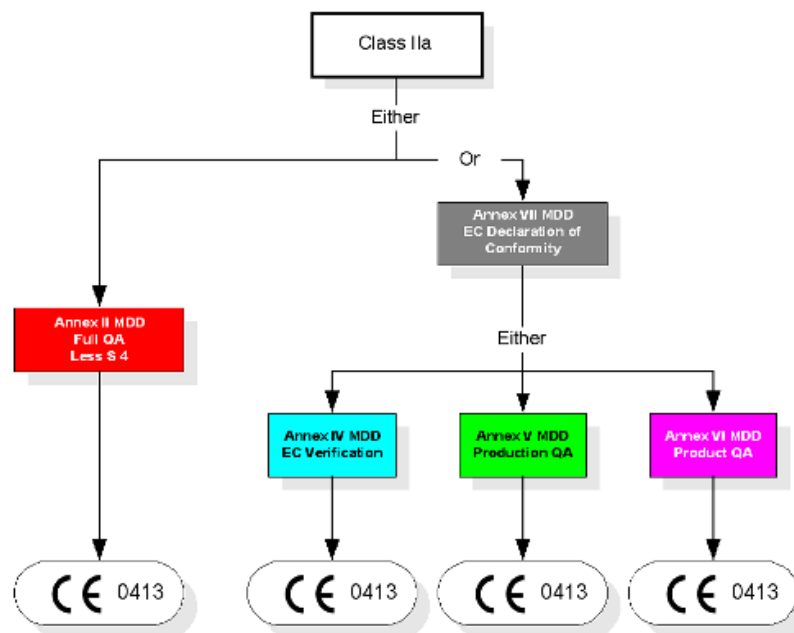


Diagram B

A company can choose to comply with either one of Annex IV, V or VI in order to get certified. You can therefore have an EC Verification, or get either your Production or your Product certified.

In essence, by choosing one of the Annexes you are in effect fulfilling part of the ISO certification.

Note that either one of those Annex certifications will allow you to have your product CE certified.

Full QA process is always easier in the long run, although it might be more involved and costly in the short-term.

Class IIb – essentially it is the same as Class IIa except that you have to comply with Annex III (EC Type Examination) v/s Annex VII (EC Declaration of Conformity) for the partial certifications. You may also need to have Clinical data for this classification group to support your file. [See Diagram C \(1\)](#)

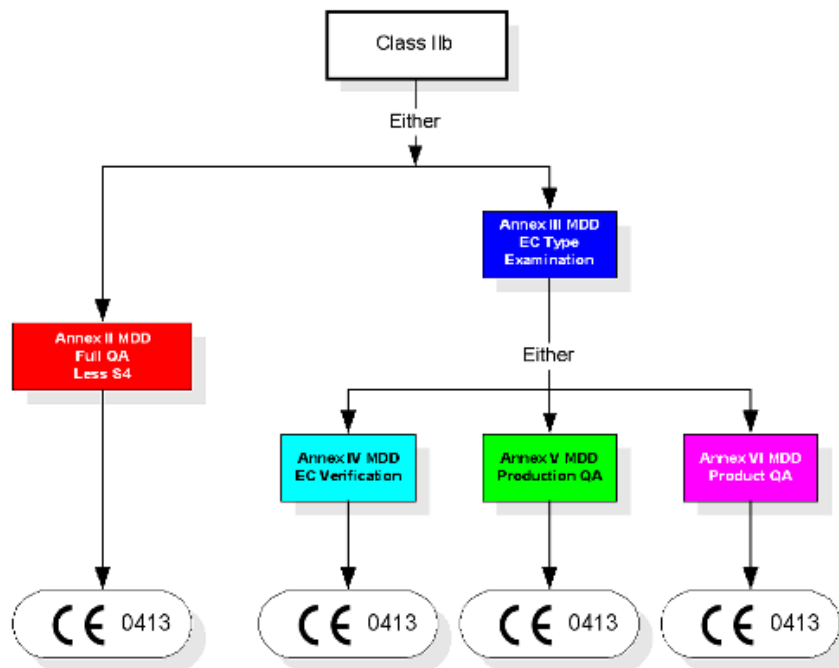


Diagram C

Class III – definitely needs Clinical Data – If your Clinical Studies were performed in the US and you want to use the data for your CE Mark application, you need to insure that the studies comply with the Helsinki accords for Clinical Studies. Please note that the US did not ratify these accords, which means that some of the additional steps included in the Helsinki accords are not being performed in your regular US Clinical Trials. See [Diagram D \(1\)](#)

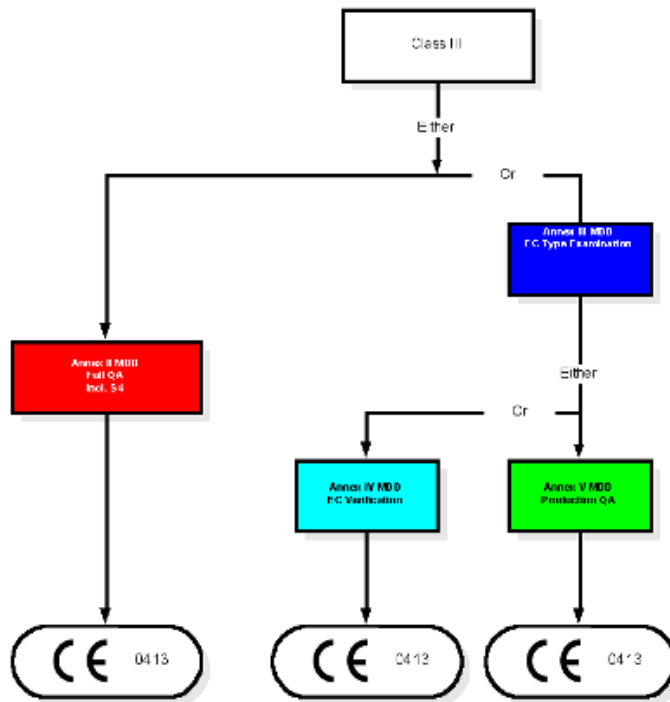


Diagram D

Clinical Data:

Performing Clinical Trials in Europe may be faster and cheaper, due to the fact that it is less litigious and patients who are asked by their doctor to participate usually comply quite readily. This (clinical trial) however will be the topic of a separate paper.

It is however suggested to incorporate the Helsinki Declaration requirements to your US studies in order to insure that you are able to use the data in Europe. Advantages are that you will have access to the second largest medical device market in the world (\$97 billion / year) and when you do it will help you save time, effort and cost as you will not need to have new costly and timely consuming trials performed again in Europe.

Please note that additional safeguards and paperwork need to be completed to meet the Helsinki Declaration requirements. Ask more clarification about this to either your notified body or your IRB contacts.

Beware that classification of products between the US and Europe may differ. Therefore a product may be classified as IIa in the US but is actually classified as a IIb product in Europe

Different classifications between the US and the EU:

Classification groups are set up by FDA whereby you need to determine if the classification of your device is closer to one group (of products) or another. The European Community on the other hand has devised rules that you need to determine for your products such as: Is it sterile, does it measure anything, does it do this, does it do that, etc. For example, a derma abrasion product that takes a substance away from the body (i.e. collects skin cells) is classified as Class I in the US and Class IIa in Europe.

In the US, manufacturers try very hard to justify the classification of their product to an already existing technology because requesting a brand new classification is almost a nightmare.

Time it takes to get approval:

- FDA – 510(k) takes 5-6 months
- CE Mark –
 - Self-certification is often possible
 - If you need to go through a notified body then it depends on whether your company is already ISO certified. If it is, then it becomes just a matter of having the product in question certified by building and presenting your technical file to the notified body.

The technical files that you submit for a 510(k) in the US and for CE Mark in Europe are somewhat similar. We estimate that there is about a 60% overlap between the two.

On the other hand, QSR (Quality Systems Regulation) and ISO 13485, the quality systems required in the US and in Europe respectively, have about an 80% overlap.

It is not possible to have a comparative chart between FDA requirements and CE Mark requirements as it does depend on your product and your company's quality system.

“You have to look at each situation individually, it is very hard to generalize” – Klaas Besseling

Notified Bodies:

Partial list of European notified bodies:

- BSI – UK, <http://www.bsi-global.com/CEMark/MedicalDevices/index.xalter>
- CERMET – Italy <http://www.cermet.it/>
- Det Norske Veritas – Norway www.dnv.com
- G-MED – France www.gmed.fr
- Intertek Semko – Sweden www.medtechinfo.com
- Kema Medical Quality – The Netherlands
- NSAI – Ireland www.nsai.ie
- ORKI – Hungary www.orki.hu
- TUV Product Services GmbH – Germany www.tuv.com

Selection of a notified body:

Selection of notified bodies is important:

- Not all are allowed to perform every procedure
- Uniformity of assessment is debatable between the various bodies

The notified body can not represent the company that it is verifying and validating. The notified body can not either be involved in assisting in the design, construction, marketing or maintenance of the devices. A company needs therefore to hire an independent Regulatory Consultant to help with these and assist the company in being compliant and getting them ready for a notified body inspection.

The notified body can not either be the company's authorized representative. A company will need to look for an independent regulatory consultant for that.

Notified bodies are for-profit companies and will charge their clients for their services. Costs will depend on the size of the company, i.e. all the steps, processes that need to be certified therefore the number of days that the notified body will need to spend on the premise to audit your company. Price usually starts around \$10,000 for ISO certification and \$5,000 per technical file (per product).

The notified body (that certifies your product) needs to come on an annual basis to recertify your Quality System as well as the technical file of each certified product. So both the quality system and the product need to be reviewed on an annual basis. Also, note that there is a fee for recertifying annually both the Quality System as well as each product file that needs to be maintained.

Selecting a notified body is important because it is a long-term relationship, as you can see from the above. Apart from direct costs, one should pay attention to hidden costs (such as the distance of the notified body's office to your plant; you will have to pay for travel) and intangibles (such as the experience the individual auditors have with your particular devices, the personal rapport with the auditor).

Definitions:

Authorized Representative:

- Your primary contact with Competent authorities
- Needs to be located in the EU
- Insures that you comply with the Community Directives
- Keeps full technical file and documentation
- Is readily available to any inquiries from the Competent Authorities

Directive: A directive is a legislative act of the EU which requires members' states to achieve a particular result without dictating the means of achieving that result (source: Wikipedia)

European Economic Area (EEA) = EU countries + Iceland, Liechtenstein and Norway.

IRB: Institutional Review Board – a committee that approves, monitor and review clinical trials

MDD: The European regulations are defined in the Council Directive 93/42/EEC of June 14 1993 concerning medical devices, usually referred to as the Medical Device Directive (MDD).

Notified Body: They are nationally accredited bodies that examine the conformity of the production process completed on behalf of the manufacturers and whose correctness is certified according to uniform assessment factors – (source: DIMDI – German Institute of Medical Documentation and Information).

NOTE:

(1) Diagrams A, B, C & D courtesy of BestTech Consulting, Laguna Niguel, CA

About the author

Christian Chahine is an experienced international executive leader in the medical device industry. He is currently President of MDT International, a Business Consultancy, Commercial Agents, Sales & Marketing Support and Seminars / Training company, helping medical device manufacturers achieve profitable growth in Europe.

For any additional information and /or assistance on CE Mark you can send an e-mail to Christian B. Chahine at cchahine@mdtinternational.eu Also, please contact Christian should you wish to receive a free list of European Authorized Representative and/or a full list of European Notified Bodies.