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Medical Device
CE mark Certification

Directive 93/42/EEC

What is a Medical Device

Medical Device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

The Medical Device does not achieve its principal intended action in, or on, the human body by pharmacological, immunological or metabolic means.

Medical devices with peculiar features not clearly belonging to a specific sector (biocide, cosmetic, pharmaceutical, supplement) are called "**Borderline**".
Eurofins has long experience in evaluating these particular products.

Manufacturers Obligations

In order to legally CE mark and sell their products in EU market, Manufacturers must comply with the **Medical Device Directive 93/42/EEC** (and supplementary Directive 2007/47/EC MDD).

Medical devices must be classified according to potential risks associated as follow:

Class I Low/medium risk
- Class *Im: Measuring devices*
- Class *Is: Sterile devices*

Class IIa Medium risk

Class IIb Medium/High risk

Class III High risk

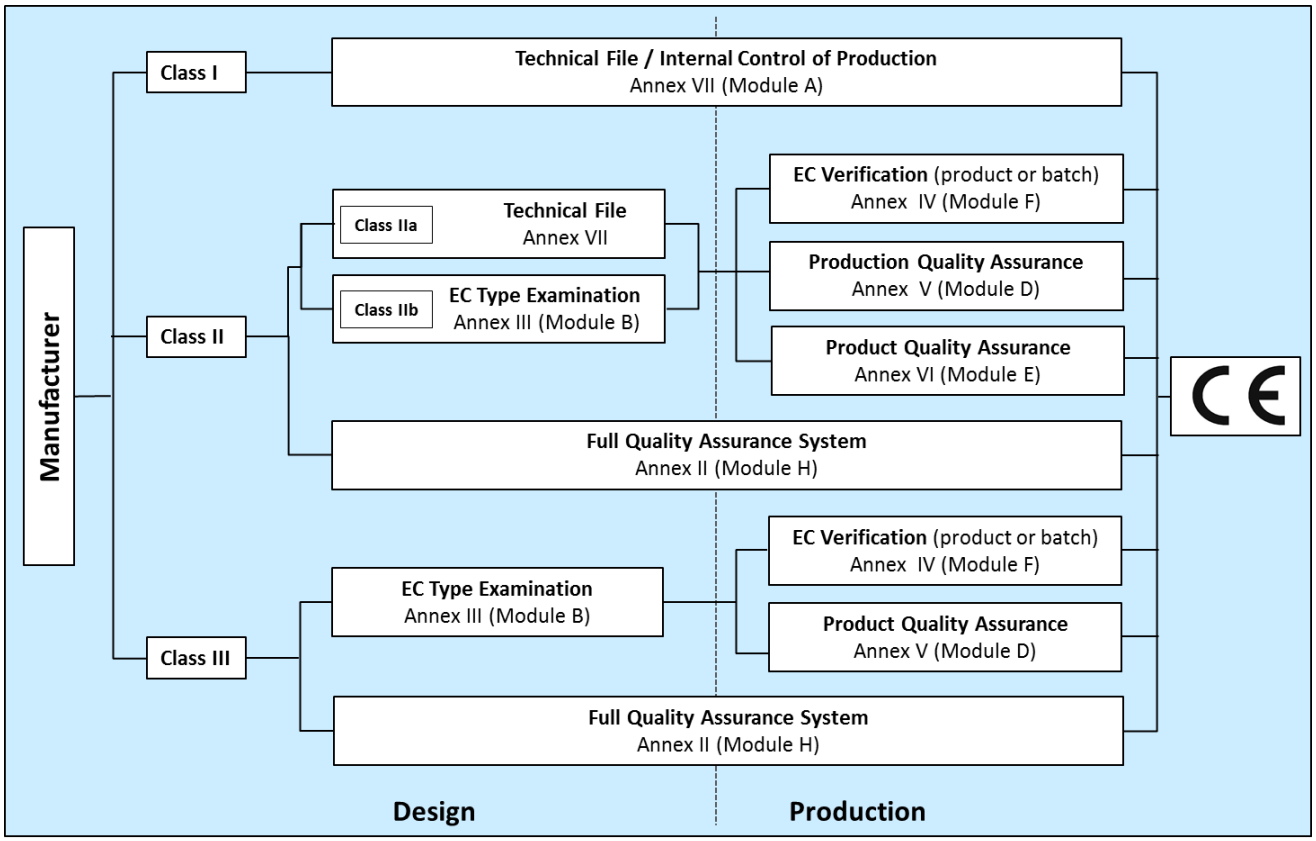
Eurofins Product Testing Italy is

Notified Body n° 0477 for CE certification in accordance with Directive 93/42/EEC, both for Active and Non-Active Medical Devices.

Notification for the new Medical Device Regulation (2017/745) expected within May 2021.

Certification Body n° 133A according to ISO 13485 Scheme (Quality Management System for Medical Devices).

Medical Devices Directive Conformity Assessment Procedure



Eurofins Product Testing Italy, as European Medical Device Notified Body, is able to support Customers in finding the right certification path and in the certification process for Medical Devices (Active and Non-Active), where **the Notify Body assessment is mandatory** for manufacturers, before commercializing the products and, in particular, for medical devices belonging to:

- **Class I** (only measuring and sterile medical devices)
- **Class IIa and IIb**
- **Class III** (incorporating medicinal substances and/or tissue of animal origin).

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