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Medical Devices certification

Regulation (EU) 2017/745

What is a Medical Device

A Medical Device is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred above.

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.

Manufacturer obligations

In order to legally CE mark and sell their products in EU market, Manufacturers must comply with the **Medical Device Regulation (EU) 2017/745** (MDR) and updated and Common Specification.

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

Class I	Low/medium risk - Class *Im: Measuring devices* - Class I_S: *Sterile devices* - *Class* I_R: *Reusable 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 Regulation (EU) 2017/745 and update for:

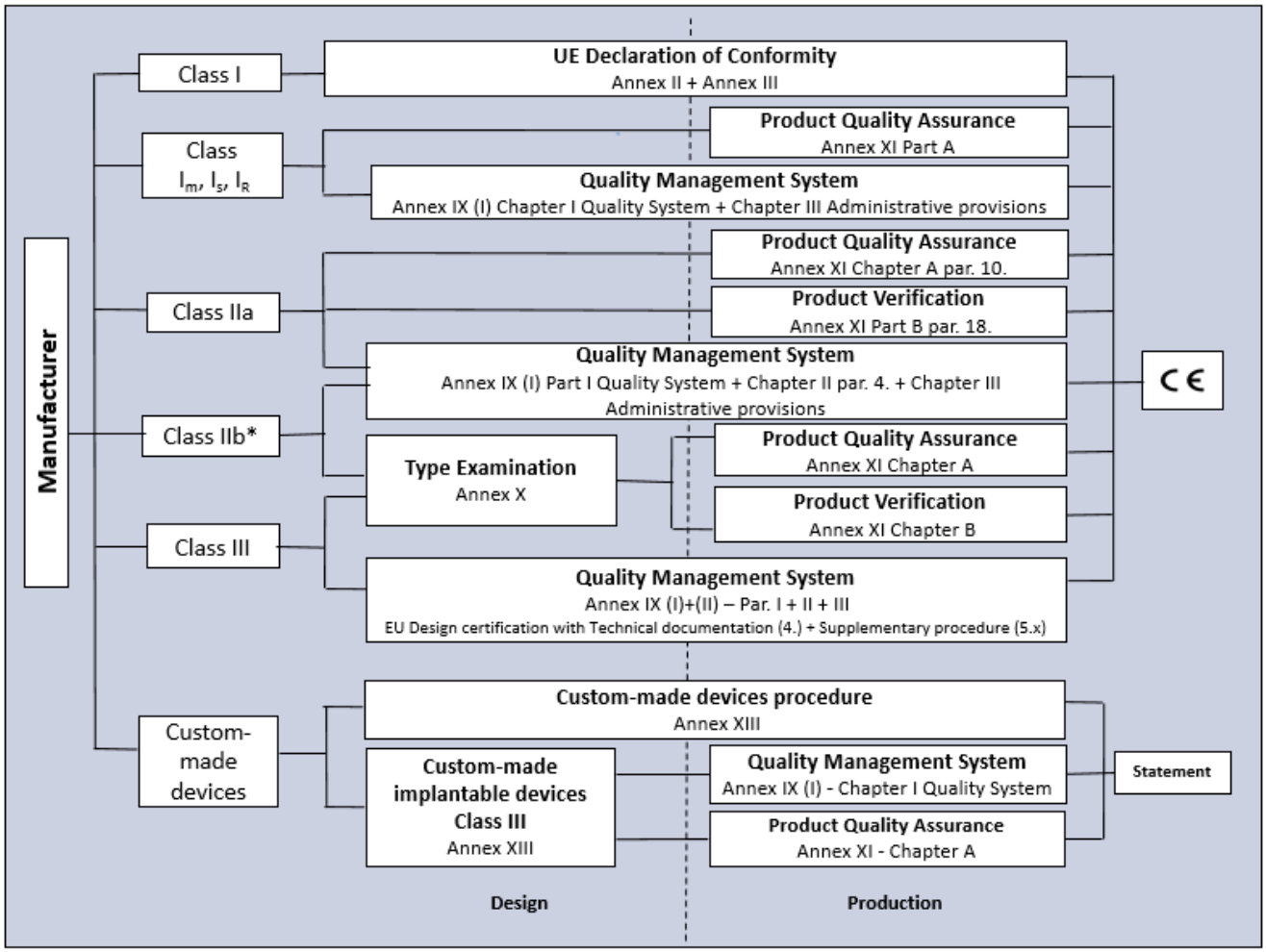
- **Active** (**MDA**) and **Non Active** (**MDN**), horizontal competence **(MDS)** and technologies **(MDT)**.
- specific device listed in Annex XVI of the Regulation (EU) 2017/745 (product of the group 1, 3, 4 and 5).

Certification Body n° 133A

- according to **ISO 13485** Scheme (Quality Management System for Medical Devices).

For more details about the specific MDR code that Eurofins Product Testing Italy is notified, please see the NANDO web site:
https://ec.europa.eu/growth/tools-databases/nando

Medical Devices Directive Conformity Assessment Procedure



* Class IIb Active medical devices intended to deliver to and/or take from the body a medicinal product must follow the Quality Management System evaluation procedure, according to Annex IX (I) + (II) - Chapter I + II + III, EU Design Certification with Technical Documentation (4) + Additional Procedure (5.1).

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** (measuring, sterile and reusable medical devices)
- **Class IIa and IIb**
- **Class III** (medical devices containing medicinal substances, using tissues or cells of animal origin or their derivatives - including those of Regulation No. 722/2012 - and certain medical devices consisting of substances or combinations of substances that are absorbed or locally dispersed).

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