eurofins | Medical Device Testing



Notified Body Services

In order to legally sell products in the EU market, medical device manufacturers must earn a CE mark to confirm compliance with the Medical Device Directive 93/42/EEC and supplementary Directive 2007/47/EC (MDD) to be classified according to potential risks associated (Class I, II and III products).

Eurofins Medical Device Testing operates a Notified Body authorized to award EC certification (NB n.0477) for active and non-active medical devices in accordance with Directive 93/42/EEC to help clients obtain products that are safe and highly functional, offering reproducible and controlled quality. We work with product designers and manufacturers to perform risk evaluations and necessary assays in order to certify the product.

Choose Eurofins Medical Device Testing to help you:

- Develop products that are both very safe and highly functional, offering reproducible and controlled quality.
- Ensure that product innovations are permitted as long as they do not prejudice its safety.
- Ensure that the product designer and the manufacturer can contact qualified experts and laboratories to make correct risk evaluation and do the assays necessary to certify the product.

Certifications Available

- **Type examination certificates (annex III):** EC certificate showing conformity of the Medical Device examined (type) with the essential requirements established in the directive.
- **EC verification certificates (annex IV):** the EC certificate that guarantees and declares that the production batch(statistical verification) or each product (individual verification) conforms to the type certified and to the applicable requirements of the directive.
- **EC declaration of conformity -** guarantee of quality of the manufacturing process or of the product (annexes V-VI), limited solely to performance factors designed to secure and maintain sterility, the certificate that guarantees and declares that the quality system, with regard to sterility, is applied and complies with the requirements of the directive.

Eurofins Medical Device Testnig's certification authority covers the following products (except Class III products):

- Annex III and Annex IV
  - non-absorbable surgical implants
  - devices for infusion, transfusion, injection, taking samples, extracorporal
  - circuits ophthalmic devices
  - disinfectants and antiseptics
  - products for the care and maintenance of contact lenses
  - non-absorbable materials for suture and clamps
  - single-use products
  - medication materials
  - devices, materials and equipment for use in the dental sector
  - surgical equipment
  - gloves for medical use
  - contraceptive devices
  - devices for anaesthesia and ventilation
  - catheters, drains and probes
  - reusable devices
  - devices for enteral and parenteral nutrition

To achieve these goals with the greatest possible impartiality, Eurofins Medical Device Testing commits itself to:

- maintain strict confidentiality and impartiality.
- make a careful selection of inspectors and experts.
- maximum openness and clarity in the decision-making process, involving the members of the Certification Committee in the decisions of the Notified Body.