Certification

MEDICAL DEVICES

Medical devices, being intended for diagnostic or therapeutic uses, must meet strict safety and efficiency requirements.
Specifically, **Legislative Decree 46/97** - in accordance with Directive 93/42/EEC - sets out the **CE marking** of medical devices for placing on the market and putting into service in the European Union.
The CE marking process involves a series of obligations for the Manufacturer and the assistance of a Notified Body to define the risk classes.

MTIC INTERCERT Srl is Notified Body no. **CE 0068** since **1996** by the European Commission and operates in the field of certification of many types of medical devices subjected to Directive 93/42/EEC and subsequent amendments and integrations.

Within the scope of these authorizations, all the necessary activities to verify compliance with the "**essential safety requirements**" of Medical Devices are carried out within the scope of these authorizations.

Depending on the conformity assessment method chosen by the company, the activities may relate to:

- Laboratory tests with reference to the harmonized standards applicable to the specific products.
- Conformity assessments of the medical device technical files.
- Evaluation and surveillance of the Company Quality Management Systems, design and manufacturing processes required by the Directive.