Placing your medical devices on the european and international market

RADIO · ELECTRICAL SAFETY · EMC · ACOUSTICS · CLIMATIC & MECANICAL · RELIABILITY · HYDRAULIC

Anticipating clients requirements and securing your time to market

Emitech Group is a major player of the tests applicable to equipment. In the medical sector, we are working for **manufacturer**, **importers and distributors of medical devices (MD)**, of laboratories devices and of paramedical equipments.
MD are subject to specific regulations worldwide.
We provide you an overview of **your MD classification**, of what follows in terms of **procedures**, **of testing requirements**, **of files to build** and we guide you step by step until the marketing of your product.

CE Marking of medical devices

- Directive 93/42/CEE modified by 2007/47/CE
- Directive RED 2014/53/UE for radio equipments

CB scheme, your key to exportation

- CB scheme allows testing reports to be recognized in more than 50 member States
- Emitech is CBTL (Certification Body and Testing Laboratory)

Regulatory studies and approval

- Checking analysis of national requirements for 127 countries
- Constitution and transmission of approval files

Expertise
Tests
Assistance

NOTIFIED BODY NB 0536

Accredited

cofrac
TESTING
EN 17025
ACCREDITED
N° 1-0107, 1-0744, 1-0826, 1-0827, 1-1245, 1-1925, 1-2043, 1-2069, 1-2070, 1-2376, 1-2472 & 1-6086
ESSAIS
LIST OF SITES AND SCOPE AVAILABLE ON WWW.COFRAC.FR

CBTL
CB Scheme

EMITECH GROUPE

EMITECH EUROCEM ADETESTS ENVIRONNE'TECH DIRAC PIEME

Anticipating clients requirements and securing your time to market

We intervene during the key phases of your projects thanks to:

- our knowledge of the regulatory framework,
- our laboratories skills on all tests and documentary analysis that can be required,
- the global approach we offer for placing your products on international markets.

Expertise

- **Characterization of the MD**
  - Validation of the applicable directives (medical directives + possible additional directives)
  - MD classification according to 18 rules defining the risk levels (I, IIa, IIb et III)
- **Implementation of the regulatory strategy**
  - Consistence of the classification between the risk analysis study/software reliability and applicable standards
  - List of compliance elements to collect

Tests

- **Progress of the testing program arising from standards to be applied for medical directives**
  - Basic standards IEC 60 601-1
  - Collateral standards 60 601-1-X
    2 – electromagnetic compatibility,
    6 – usability,
    9 – environmentally conscious design,
    10 – physiologic closed-loop controllers,
    11 – home healthcare environment
    ...
  - Specific standards 60601-2-X
    10 – stimulator,
    18 – endoscopic equipment,
    52 – medical beds,
    49 – multifunctions
    ...
- **for additional directives**
  - Radio standards, notably for RED directive

Assistance

- **CE Marking**
  - Direct use of testing reports for MD of class I
    Self certification approach
  - Presentation of testing report to Notified Body from class II
    Certification process
- **CB scheme**
  Validated by the Certification Body of Emitech, reports give you access to more than 50 countries
- **Approvals on a range of destinations**
  Tailored support for worldwide sales

Testing compliance determines the placing on the market

To be approved in Europe and in the world, MD will have to comply with tests covering multiple domains: **electromagnetic compatibility (EMC), radio, EMF (waves & health), safety, climatic or mechanical**.

Leader in environmental testing, Emitech Group offers you its expertise in all these fields.

From our first exchange, according to the markets you wish to place your products on and to the classification of your MD, we can identify the tests to which you will be subjected as well as their severity.

We can then support your teams in their technological choices, identify the required documentary elements, assess your prototypes.

By anticipating the requirements for the approval of your products, we give you the keys for a marketing corresponding to your schedule.

We transform your tests into real success !

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