

# Active Implantable Medical Devices

## Compliance with European Directive 90/385/CEE

### Standards applied

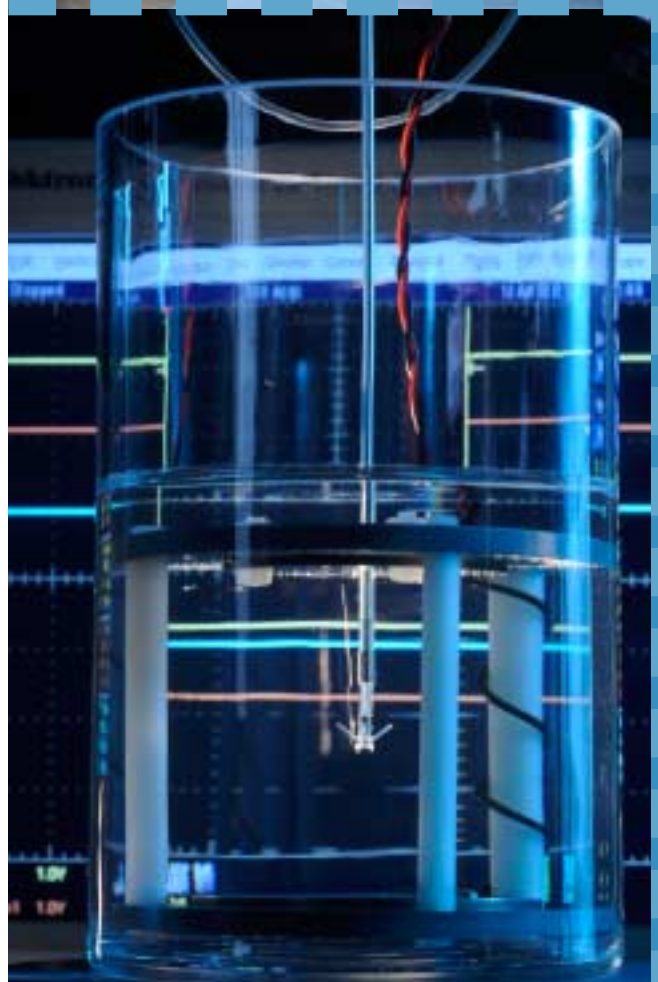
- > General requirements for active implantable medical devices (AIMDs) (EN 45502-1)
- > Cardiac pacemakers and pacing leads (EN 45502-2-1)
- > Implantable pacemakers and pacing leads (EN 45502-2-2)

### Test objectives

- > **Protection of patient**
  - Measurement of electrical characteristics
  - Measurement of patient leakage currents
  - Verification of absence of danger from electromagnetic fields and DC/AC magnetic fields
- > **Protection and immunity of device**
  - Elongation, flexion
  - Extraction of connectors
  - Climatic tests
  - Shock (EN 60068-2-27)
  - Vibration (EN 60068-2-47)
  - External defibrillation shock
- > **Protection provided by packaging of device**
  - Climatic tests
  - Simulation of transport (NF H 00-060, ISTA procedure D4169)
  - Vibrations sur emballage (EN 60068-2-64)
  - Sterility of packaging (EN 868-5, ASTM F 1929)

### Specific assistance at every stage

- > Pre-test of AIMD prototypes according to specifications or a particular standard
- > Validation of AIMD before it is placed on the market



# Advantages of working with LNE

## > One-stop service

LNE is the only laboratory in France with all the required test resources on one site:

- Tests on electromedical devices (NF EN 60601-1 and specific standards such as NF EN 60601-2-47 for Holter monitors)
- Electromagnetic compatibility tests (NF EN 60601-1-2)

## > LNE's expertise is recognized worldwide

- At international level, LNE is ISTA-approved for transport packaging
- At European level, LNE is a notified body for:
  - the Directives on Low Voltage and EMC
  - The Directives on Active Implantable Devices (90/385/CEE) and Medical Devices 93/42/CEE (dispositifs médicaux)

## > Additional services

- Inter-company and in-company training
- Certification of products
- Certification of company management systems
- Technical assistance for compliance with REACH regulations



### Contact

Tel.: +33 1 40 43 37 52  
 Fax: +33 1 40 43 37 37  
 E-mail: info@lne.fr

### Laboratoire national de métrologie et d'essais

1, rue Gaston Boissier - 75724 Paris Cedex 15 (France)  
 Tel.: +33 1 40 43 37 00

[www.lne.fr](http://www.lne.fr)