LCIE BUREAU VERITAS

ASSESSING THE COMPLIANCE OF ELECTRICAL MEDICAL DEVICES

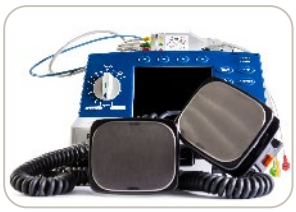
REGULATORY FRAMEWORK

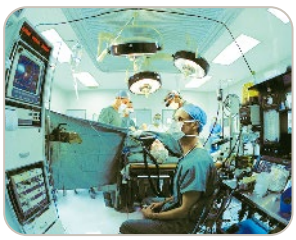
The European market is becoming more regulated and more controlled.
To be sold in Europe, medical devices have to comply with the requirements of the following Directives:

- Directive 93/42/EC (amended in 2007) related to Medical Devices
- Directive 90/385/EC related to Active Implantable Medical Devices (AIMD)
- Directive 98/79/EC related to In Vitro Diagnostic Medical Devices (IVDMD)

Depending on the device's characteristics, other Directives might apply:

- RED 2014/53/UE (previously R&TTE 1999/5/EC)
- RoHS 2011/65/UE





YOUR RESPONSIBILITIES

The company placing the product on the EU market should:

- Create and update the medical device's technical file, including relevant test reports
- Create and update compulsory processes
- If necessary, obtain the ISO 13485 certification for the management of the quality system

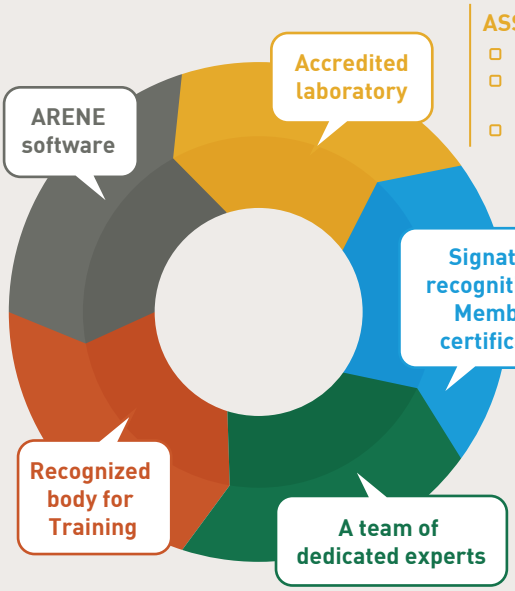
OUR SOLUTIONS

REGULATORY WATCH

- Identification of the applicable regulatory requirements for the target countries
- Database regularly updated

TRAINING

- Testing methods
- Regulatory requirements
- Quality Management



ASSESSMENT AND TESTING

- Electrical safety testing
- Electromagnetic compatibility (EMC) testing
- Radiofrequency testing
- Climatic and mechanical environments testing
- Technical File review
- Environmental impact assessement

INTERNATIONAL CERTIFICATION

- CB Scheme
- NRTL Mark
- SCC
- ...

SUPPORT AND EXPERTISE

- Technical File development support (risk assessment, fitness for use etc.)
- Upgrade of the quality management system to comply with the medical organization standard EN ISO 13485
- Impact analysis of the modifications of the medical device's construction
- Failure analysis
- ...

OUR SERVICES FACILITATING THE INTERNATIONAL MARKET ENTRY OF MEDICAL DEVICES

Recognition, experience and expertise

As an independent and accredited testing laboratory, LCIE Bureau Veritas assesses the compliance of electrical medical devices according to European and international regulations.

Test reports, which can be established by LCIE Bureau Veritas, are a necessary element of your technical file.

As a member of various international certification schemes and having signed numerous mutual recognition agreements, LCIE Bureau Veritas can facilitate the access of your products to international markets.

In this framework, LCIE Bureau Veritas proceeds to electrical safety and electromagnetic compatibility testing, and also establishes test reports to the international CB Scheme format.
These documents are recognized by the international certification bodies that are members of the CB Scheme, and allow you to obtain the certification marks that are necessary for the entry on the target markets.

To access to the North American market, a certification mark covering the electrical safety requirements and delivered by a recognized organization may be required.

In Canada, SCC (Standards Council of Canada) designates the bodies that are authorized to deliver certification marks. Bureau Veritas is an NRTL, through its Curtis Straus subsidiary, and is recognized by SCC.

Bureau Veritas is able to deliver a certification mark to help you access the North American market.

BENEFITS

You benefit from the experience of our team of experts, that provide you guidance on the following topics:

- Technical
- Regulatory (ARENE : regulatory watch software, covering regulations for Europe and worldwide)
- Quality

WHY CHOOSE LCIE BUREAU VERITAS

- LCIE Bureau Veritas is a worldwide recognized testing laboratory and certification body
- Multidisciplinary technical expertise under one roof
- Wide scope of testing capabilities
- Support at all stages of your product life cycle
- Training sessions tailor-made to your needs
- Third Party Laboratory, providing impartiality, consistency and confidentiality
- As a Recognized Training Center, LCIE Bureau Veritas offers training sessions that can be tailor-made to your needs and delivered in-house or at our premises.

PARIS AREA

LCIE Bureau Veritas - Fontenay-aux-Roses (Head Office)
Laboratoire Central des Industries Electriques
33 avenue du Général Leclerc
92260 Fontenay aux Roses
Phone : + 33 1 40 95 60 60

LCIE Bureau Veritas Ecuelles site

LCIE Bureau Veritas Villebon site
Parc d'activité de Courtaboeuf 1
4 avenue de la Baltique - Bât B
91946 COURTABOEUF
Phone : + 33 1 69 07 87 78

contact@lcie.fr - www.lcie.fr

NORTHEAST REGION

LCIE Bureau Veritas Pulversheim site
Aire de la Thur
68840 PULVERSHEIM
Phone : +33 3 89 28 33 70

SOUTHEAST REGION

LCIE Bureau Veritas Moirans site
ZI Centr'alp
170 rue de Chatagnon
38430 MOIRANS
Phone : +33 4 76 07 36 36

OUR LABORATORIES WORLDWIDE

- United Kingdom
- Germany
- USA
- China
- Taiwan
- Hong Kong