MEDICAL-HEALTH

Training

The medical sector's highly regulated environment requires constant monitoring in order to anticipate its evolution. Risk management, manufacturing controls, and control or analysis resources: medical device manufacturers or biology laboratories, you will find in our training offers dedicated programs and e-learning courses, technical seminars, and webinars providing updates on the regulatory developments. As intra-company courses, our trainings are scalable to your specific needs.

Offices in **France** and **International**

France

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

1, rue Gaston Boissier • 75724 Paris Cedex 15

Specialized in and dedicated sales team at your service.

Tél. : 01 30 69 10 00 • email : info@lne.fr • www.lne.fr

LNE
Le progrès, une passion à partager

LNE/G-MED Saint-Étienne
19 D rue de la Télématique
42000 SAINT-ETIENNE FRANCE
Tél. : 01 40 43 38 50

LNE Toulouse
Parc Technologique du Canal
2, rue des Satellites
31520 RAMONVILLE-SAINT-AGNE
Tél. : 05 62 17 39 62

LNE Nîmes
Parc Georges Besse
190, rue Georges Besse
30035 NÎMES Cedex 1
Tél. : 04 66 38 14 66

Contact

United States

LNE/G-MED North America

Washington (DC office)
3930 Knowles Ave. Suite 306
Kensington, Maryland, 20895
USA
Tel : (301) 495-0477

Rocklin (California office)
5701 Lonetree Blvd, Suite 318
Rocklin, CA 95765, USA

gmedna@lne-gmed.com
www.lne-america.com

LNE G MED

Réalisation : Esquif Communication - Crédits photos : Philippe Stroppa, LNE, Fotolia - Avril 2014.

Medical Device Manufacturer Audits

LNE/G-MED's Medical-Health teams provide support and a personalized response to many actors intending to increase international growth and reduce time-to-market while complying with European and international regulations.
As medical devices become more sophisticated, their regulatory compliance strategy must also evolve to solve the challenges.

Access International Markets

From our offices in the United States and France, we can certify your quality management system and products for Europe and other international jurisdictions, helping you benefit from our accreditations and regulatory recognition.

CERTIFICATION

LNE / G-MED is the only French notified body for all European medical directives, medical device categories, and all conformity assessment procedures. LNE/G-MED is also recognized by Canada (CMDCAS Program), Brazil (Inmetro Certification), Taiwan, and Australia / New Zealand. Access to these markets is possible by using LNE/G-MED's specialized combination auditing and testing practices, combining many references into one certification audit or test.

With the CB Scheme * program, LNE provides a recognized testing report for over 50 countries. In addition, our partnership with QPS provides access to the North American markets (NRTL).

We also offer certification for the quality standards ISO 9001, ISO 13485, ISO 14001, OHSAS 18001, ISO 15378, ISO 22716, and more. Also, to differentiate yourself from your competitors on the French market, the NF medical mark for medical beds, condoms, microbiological safety workbenches, dental products, and many more products.

1er French Laboratory
Listed in the JCTML * database

*Joint Committee for Traceability in Laboratory Medicine.

* Created by the IECEE (International Commission on the Rules for the Approval of Electrical Equipment), an international agreement between the certification bodies based on the mutual recognition of test results on electro-medical devices).

FIVE MAJOR POINTS

TECHNICAL AND REGULATORY CONFORMITY, SAFETY, INNOVATION, PERFORMANCE, EXPORT ...
Medical device and pharmaceutical manufacturers, healthcare institutions, and medical analysis laboratories, your industry requires that you pay attention to:
- The requirements established by European directives and other regulations (national and international);
- Controlling the design of your product;
- Metrics for controlling your production, measurement, and analysis equipment;
- Globalizing your markets cost-effectively;
- Control over your production processes.

Our teams support your project as a whole, perform assessments, and help you achieve your goals for marketing approval.

R&D : Supporting You in Innovation

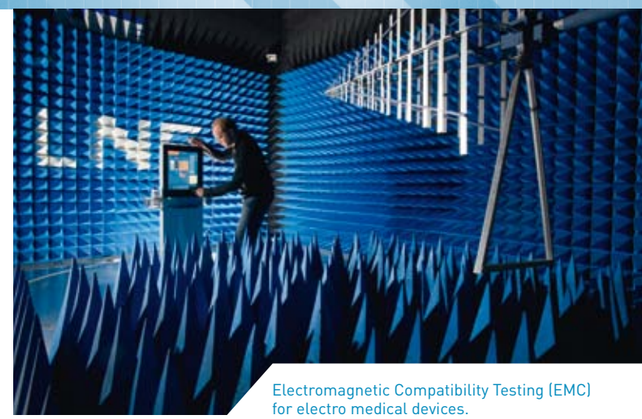
RESEARCH & TRANSFER

Manufacturing partners in applied R & D, we develop methods and tools that allow you to master the latest technologies and integrate them into your medical devices and hospital equipment. Our partnership studies allow us to support you in developing and validating new products. As a source of proposals in the **evolution of references and standards**, LNE devotes its technical expertise to agencies, organizations, and manufacturers concerned with medical device safety.

In the area of **data processing**, our teams define with you how the data automated processing system should perform: creation of protocols, metrics, surveys, and more.

Upstream from **quality control for medical biology laboratories**, we develop analytical methods and certified reference materials for the determination of biomarkers.

Our CARMEN platform is dedicated to the **measurement of nanomaterials and develops in particular characterization methods** for the end use statement of nanoparticles for therapeutic, cosmetics purposes and more.



Electromagnetic Compatibility Testing (EMC) for electro medical devices.

1200
certificates issued per year.

Evaluate your product from design to marketing

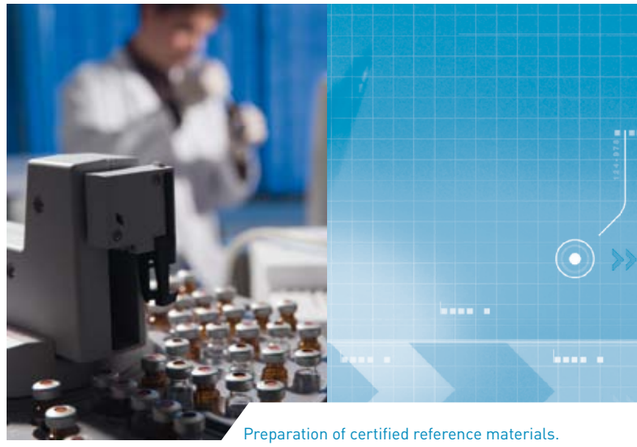
TECHNICAL ASSISTANCE

By identifying and clarifying regulations and applicable references for your project, we provide support throughout the product's entire lifecycle.

- We will help you respond to the security, performance, and reliability challenges your products face. Our multidisciplinary technical platform dedicated to medical devices handles the whole set of problems: mechanical, dynamic / static, climatic and acoustic testing, analysis of aging resistance, physical and chemical analysis, measurement of electromagnetic compatibility (EMC), electrical safety, compliance examinations to the pharmacopoeia, testing in the context of the LPPR procedure, and more.

TESTING AND CALIBRATION

Our full range of testing services adapts to many types of devices and situations, integrating the specific evaluation for the product and its integrity of the impact of transportation.



Preparation of certified reference materials.

- As experts in metrology, we assist the health industry in the control of **calibration chains** in implementing the function and metrological methods within the company and validating prototypes and of protocols tests.

- For health care facilities and testing laboratories, we intervene on site to check the quality of medical air and check or calibrate sensitive equipment (ovens, centrifuges).