LNE/G-MED services

Comprehensive service

LNE/G-MED will provide you with certificates for all conformity procedures: product design examination, EC type examination, approval and monitoring of the production quality system, and batch release testing for products referred to in Annex II list A.

Key advantages

LNE/G-MED offers you six genuine advantages:

- The technical file is meticulously examined. Data on clinical assessments and analytical performances is submitted to internationally recognized biologists for their approval, and studies already performed by the manufacturer are assessed for their pertinence.
- Regulatory precedence is systematically recognized. All reagents already registered in France (under Decree no. 96-351 of 19 April 1996) will not need to be reassessed.
- The most appropriate formula is applied for batch control tests.
- EMC and electrical safety tests can be performed on the analysis equipment sold with reagents to ensure that it complies with the corresponding regulations.
- All services are planned to ensure you meet both your production schedule and your time to market.
- Quality system audits are performed anywhere in the world.

Three-in-one certification

ISO 9001:2000, ISO 13485:2003 or EN ISO 13485:2004 certification will enhance the quality of your products on markets worldwide.

Certification to harmonized European standard EN ISO 13485 is particularly useful, as it guarantees compliance with the requirements of Directive 98/79/EC concerning design, production and product release.

With LNE/G-MED you can obtain all three types of certification through one sole audit.

LNE/G-MED's expertise is widely recognized. It is accredited by French accreditation body COFRAC for all voluntary certification, by Health Canada (CMDCAS programme) for CAN/CSA ISO 13485/8 certification, and by Taiwan's Ministry of Health for audits to standard ISO 13485.

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In vitro diagnostic medical devices

SUCCESSFUL CERTIFICATION WITH LNE/G-MED

G MED
CE 0459

LNE
Sharing a passion for progress
Laboratoire national de métrologie et d'essais

LNE/G-MED OFFERS

- **a team of highly qualified experts**
- **extensive experience of multi-site audits**
- **a tailor-made service and agreed schedule**
- **four centres, in Paris, Trappes (Paris region), Saint-Etienne and Washington DC**

What you need to know about the Directive

A wide scope

European Directive 98/79/EC on in vitro diagnostic medical devices covers reagents, calibration and control materials, and instruments and appliances used by health professionals or individuals.

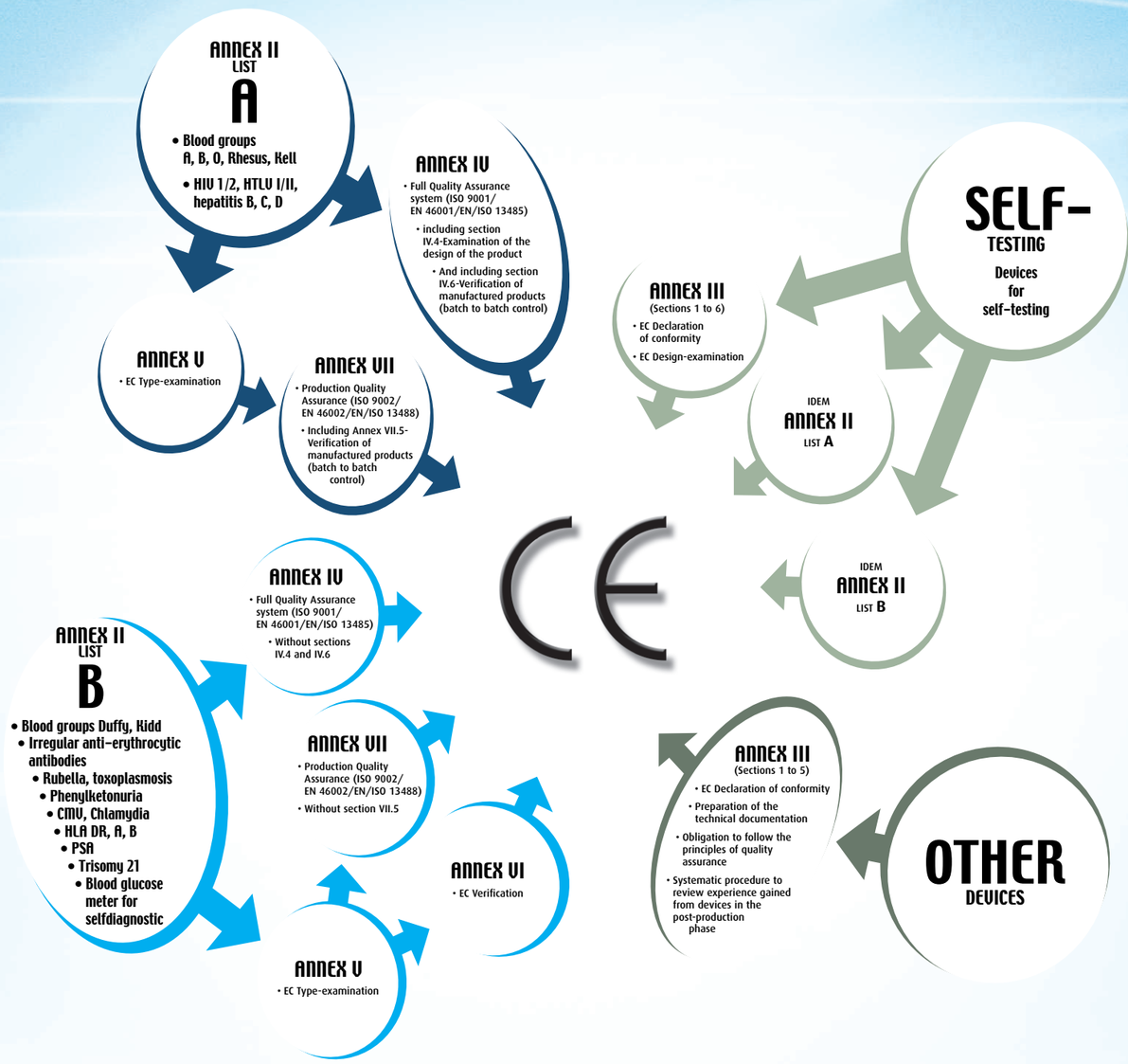
Key dates

The Directive came into force on 7 June 2000. CE marking of devices became mandatory on 7 December 2003.

Assessment procedures

The Directive includes five annexes (III to VII) describing possible procedure(s) for each type of device.
All devices which may have a significant impact on the safety of the patient must be assessed by a notified body. These include products used for blood or tissue donation, detection of infectious diseases (particularly in the foetus), self-monitoring of blood glucose by diabetics, diagnosis of phenylketonuria, dosage of prostatic hormones, and screening for trisomy 21, plus self-testing devices intended for the general public.
Products must be reassessed every five years.

Conformity assessment procedures to CE marking



New features of the regulations

- Existing documentation must be very thoroughly examined and additional assessments may be required.
- Your quality system must be set up or reassessed according to the requirements of the Directive for the device concerned.
- Statutory requirements are revised according to the adaptation of the Directive to national law in each European country.

CE marking step-by-step

You must:

- check that the device is covered by the Directive
- establish who is responsible for the CE marking
- determine which requirements apply to the device
- choose the conformity assessment route
- compile all required data
- obtain product and quality system certification
- complete a declaration of conformity
- affix CE marking to the product
- inform the authorities that the product is being placed on the market.