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P R E S S R E L E A S E

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Medical electrical equipment: LNE tests and certificates recognized under the CB Scheme

The International Electrical Commission System for Conformity Testing and Certification of Electrical Equipment (IECEE) has recognized LNE as a National Certification Body (NCB) and a Certification Body and Testing Laboratory (CBTL) in the context of the international CB Scheme covering electromedical devices.

For manufacturers of medical electrical equipment, the admission of LNE to the CB Scheme means that its test and certification services will be recognized by all 49 countries participating in the programme (Argentina, Australia, Brazil, Canada, China, India, Japan, Korea, Russia, the United States, etc.).

Manufacturers may now apply to LNE for a wide range of certificates of conformity to the following IEC standards:

- IEC 60601-1 ed 2 General safety and performance requirements
- IEC 60601-1-1 Safety of medical electrical systems
- IEC 60601-1-2 Electromagnetic compatibility
- IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7 Safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-18 Safety of endoscopic equipment
- IEC 60601-2-32 Safety of associated equipment of X-ray equipment
- IEC 60601-2-38 Safety of electrically operated hospital beds
- IEC 60601-2-43 Safety of X-ray equipment for interventional procedures

This recognition also means that manufacturers wishing to obtain the French NF-Medical mark or CE marking for their products may ask LNE to take into account test reports and certificates they have obtained from other member bodies of the CB Scheme.

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