ISRAEL TESTING LABORATORIES
Global Certifications You Can Trust

ITL can help you quickly and safely introduce your medical electrical products in global markets, satisfying the required regulatory demands.
As an active member of the key committees and organizations that develop standards for medical products, ITL offers manufacturers of Medical Electrical Equipment the fastest and most professional services available in Israel.

GLOBAL REACH FOR MEDICAL DEVICES CERTIFICATION

Safety and EMC: Design **Guidance** (which standards apply, implementation of all applicable standards, etc.), full testing, check-up pre-testing (for Helsinki Committee) according to the following standards:

- IEC/EN/UL 60601-1, CSA 22.2 No. 601.1, IEC/EN 60601-2-x, IEC/EN 60601-1-x;
- Risk Management and Usability Engineering File elaboration and evaluation according to the ISO 14971 standard and IEC 60601-1-6 (IEC 62366) standards.
- Guidance and design support for Home Care Medical Electrical Equipment (IEC 60601-1-11);
  Experienced consultation and guidance to small companies in licensing or selling products they have developed to large organizations. Our expertise allows us to act as impartial experts in device safety during litigation;
- Monitoring and reporting on the content of selected standards, revisions and amendments for impacts to specific products and processes;
- Development of standards compliance strategies for new products (tactical) or for the entire organization (strategic);
- Guidance in the application of Medical Device and Process Standards (IEC, ISO, CEN, CENELEC, AAMI, ASTM, etc. for worldwide Regulatory and Global Harmonization aspects;

For European Union, ITL provides a complete turnkey package, working with leading European Notified Bodies:

- Complete assistance in obtaining CE Marking according to the Medical Devices Directive 93/42/EEC.
- Project Management for CE Mark MDD and Technical File Management;
- Quality System Certification according to ISO 13485;

For North and South America, ITL provides a complete turnkey package including:

- NRTL (ETL, CSA, UL, TUVR, MET or other – per client request) Mark according to the UL 60601-1 and CSA 22.2 No. 601.1standards;
- Project Management for FDA 510 (k) submission and Technical Documentation Management;
- Quality System implementation according to the ISO 13485 and 21CFR820 (and other relevant CFR documents).
- Project Management for Brazil (ANVISA) and Argentina

For Far East and Australia, ITL provides a complete turnkey package including:

- Complete assistance in obtaining registration in China, South Korea, Japan, Australia, New Zealand, etc.

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