



# ELECTRO-MEDICAL DEVICES IN TRUSTED HANDS

## ACCESS THE COMPLETE SERVICE OFFERING

Achieving a fast time to market requires comprehensive regulatory knowledge and a flexible approach in establishing the most suited assessment procedure. With specific combinations of tests and audits you can ensure compliance with requirements of multiple certifications at the same time.

### TESTING

Our testing portfolio includes:

- **EU/INTERNATIONAL PRODUCT SAFETY**, including testing to the IEC/EN 60601 and IEC/EN 61010 series and the CB scheme that covers testing requirements of over 52 countries
- **US NRTL** (UL & AAMI Standards and **STANDARDS COUNCIL OF CANADA** (CSA Standards)
- **EMC TESTING** (IEC/EN 60601-1-2, and IEC/EN 61326 series including CB Scheme)
- Approval for **OVERLAPPING EC DIRECTIVES**: Machinery Directive, Personal Protective Equipment; Pressure Equipment; Non Automatic Weighing Equipment; R&TTE
- **FUNCTIONAL SAFETY**
- **WIRELESS TESTING/TELEMEDICINE**
- **BATTERIES**, testing to IEC 62133 for secondary cells and batteries containing alkaline or other non-acid electrolytes, and to IEC 60086-4 for lithium primary batteries
- **RESTRICTED SUBSTANCE TESTING**, including testing to RoHS2 requirements for Medical Devices
- **PACKAGING TESTING**
- **USABILITY**

## CERTIFICATION

Our range of regulatory and quality audit and certification services cover the following requirements:

- **ISO 13485**
- **ISO 9001** and **ISO 14001**
- **93/42/EEC** as amended by 2007/47/EC (Medical Devices Directive, CE Marking for Europe)
- **98/79/EC** (In Vitro Diagnostic Medical Devices, CE Marking for Europe)
- **CMDCAS** (Canadian Medical Devices Regulations)
- **510(k) SUPPORT SERVICES** for test data, advisory, and factory follow-up
- U.S Food & Drug Administration (**FDA SITE INSPECTIONS**)
- **JPAL** (Japanese Regulations for Medical Devices)
- **OTHER EC DIRECTIVES** (CE marking of PPE, Pressure Vessels, NAWI, and more)
- **GLOBAL REGULATORY CERTIFICATIONS**, including third party certifications for Taiwan, Australia, Hong Kong and Brazil (INMETRO)



## AND MUCH MORE

Other services related to medical devices include:

- **BIOCOMPATIBILITY EVALUATION**. Biological evaluation of medical devices according to ISO 10993
- **AUDITS** - Supplier Audits, Gap Analysis Audits and Pharmaceutical and Cosmetic GMP Audits
- **CLINICAL TRIALS**
- **HYGIENIC QUALIFICATION** of production facilities
- **MICROBIOLOGICAL TESTS OF PRODUCTS** before and after sterilization
- **PRODUCT CONTROL FOR POSSIBLE TOXIC RESIDUES** from the sterilization process
- **TRAINING** including QMS/Auditing (ISO 13485; internal auditing), Global Regulations (CE Marking, FDA, JPAL), Sterilization (Radiation, Ethylene Oxide, Steam), Risk Management (ISO 14971) and Product Safety & EMC (the IEC 60601 series), including Functional Safety
- **SOFTWARE** and **CYBERSECURITY ANALYSIS**
- **MULTIFUNCTIONALITY** and **SIMULATION EVALUATIONS**

## WHY CHOOSE SGS?

SGS is the world's leading inspection, verification, testing and certification company. We are recognised as the global benchmark for quality and integrity. With more than 85,000 employees, we operate a network of more than 1,800 offices and laboratories around the world.

Independent and innovative, our Electrical & Electronics experts use state-of-the-art facilities and technology to deliver tailor made added value services that support to improve your business.

We strive to deliver outstanding value at every step in your project by providing:

- Rapid turnaround
- Value-based pricing
- Technical assistance
- Key account management

Our expertise in compliance management will support you to make the right choices for different national markets, while carrying out the necessary testing and certification quickly and professionally.

## A GLOBAL REACH WITH A LOCAL TOUCH

With a presence in nearly every single region around the globe, our experts speak the local language, understand the culture of the local market and operate globally in a consistent, reliable and cost-effective manner.

## CONTACT US

To learn more about SGS's certification services, please contact your local SGS representative, or contact our global team at

[ee.global@sgs.com](mailto:ee.global@sgs.com)

**SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.**

**WHEN YOU NEED TO BE SURE**

**SGS**