

# SGS ELECTRO MEDICAL DEVICE SERVICES

DURHAM  
UK



## INTRODUCING SGS DURHAM LAB

- Established: 1992
- Employees: 30

SGS's Durham lab was founded in 1992 and serves the following key competences for electro medical devices:

- Product safety testing requirements of over 52 countries
- US NRTL (UL standards) and standards council of Canada
- Electromagnetic compatibility (EMC) testing
- Wireless testing/telemedicine
- Battery testing
- Restricted substance testing, including testing to RoHS II requirements
- Packaging testing

## LABORATORY FEATURES

Facilitating access to global markets, SGS UK is accredited by EU's certification schemes, as well as international bodies. This means we can provide technical support, pretesting, compliance testing, debugging, certification and production surveillance whatever the destination of our clients' products.

- Dedicated test areas specific to Environmental
- Mechanical & Performance Testing
- Endurance Rooms
- Metrology Testing
- Anechoic Chambers
- Medical, FFU, Material Testing
- Radio, Shock and EMC Testing

SGS



## KEY SERVICES

- ISO 13485:2003
- ISO 9001:2008 (for Medical Devices) in combination with ISO 13485:2003
- 93/42/EEC as amended by 2007/47/EC (Medical Devices Directive, CE marking for the EU)
- CMDCAS (Canadian Medical Devices Regulations)
- 510(k) support services for test data, advisory and factory follow-up
- US Food and Drug Administration (FDA) site inspections
- JPAL (japanese regulations for Medical Devices)
- Other EC directives (CE marking of PPE, pressure vessels, NAWI)
- Other regulatory certifications: including third-party certifications for Taiwan, Australia, Hong Kong and Brazil (INMETRO)

Other services related to Medical Devices include:

- Biocompatibility and Biological Evaluation of Medical Devices according to ISO 10993
- Audits – Supplier Audits, Gap Analysis Audits, Pharmaceutical and Cosmetic GMP Audits
- Clinical trials
- Hygienic qualification of production facilities
- Microbiological Tests of products before and after sterilisation
- Product Control for possible toxic residues from the sterilisation process
- Training including QMS/Auditing (ISO 13485:2003; Internal Auditing), Global Regulations (CE marking, FDA, JPAL), sterilisation (radiation, ethylene oxide, steam), Risk Management (ISO 14971:2007), Product Safety and EMC (the IEC 60601 Series)

## QUALITY MARKS

The SGS Durham lab offers a wide range of marks to help you gain access to the global marketplace:

- USA NRTL (AAMI & UL Standards), SGS US/C certification mark
- USA Test Reports as part of a FDA 510(k) or PMA, FCC
- Canada (CSA Standards)
- Europe (CE, EN Standards)
- Brazil (INMETRO)
- CB (Global, IEC Standards)
- SGS Fimko, SGS CEBEC



## CONTACT US

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**WHEN YOU NEED TO BE SURE**

**SGS**