ELECTRO-MEDICAL DEVICES
IN TRUSTED HANDS

SGS IS THE WORLD'S LEADING
TESTING AND CERTIFICATION COMPANY

SGS

SGS MEDICAL NETWORK: THE

As a medical devices manufacturer your focus is to create products that improve the quality of medical services provided around the world. However, between your devices and the medical professionals who should use them, stand a host of market-specific regulatory requirements, a long list of competitors, various client-defined quality standards and a need to spend time and resources beyond reasonable investment. SGS is the right global partner to help you overcome these hurdles fast and put your products in the hands of medical professionals worldwide today.

KNOW ALL APPLICABLE REGULATORY REQUIREMENTS

To ensure the success of your medical devices, you need to know and comply with all the regulations applicable to all the markets you are targeting. These include directives and statutory requirements specific to medical devices, and the overlapping regulations that cover your product.

When these variables are integrated into your product development process, they will reduce the time and resources required to get your products to market. In an industry where staying one step ahead of competitors is essential, this will help ensure your products get in the hands of medical professionals before those of your competition.

SGS has the right industry knowledge and market experience to help you stay on top of all regulatory requirements. Thanks to its global network of medical devices specialists, SGS can dispatch an expert located near you to assist in identifying the relevant regulations and integrating compliance indicators in your product development process.

ENSURE A FAST GLOBAL REACH FOR YOUR MEDICAL DEVICES

As you intend to target customers located in various parts of the world you need a local partner who will help ensure your products gain quick access to a variety of markets.

Our network of medical devices experts spans all continents, covering all major markets. This means that through your local SGS technical team you can streamline the market access process. One product submission will enable you to gain complete regulatory solutions.

You can receive certifications for multiple global markets, while working with SGS experts locally, in your own language. This will further reduce the resources that you spend on project management processes.

Regardless of where you are located and where you want to send your products, your local SGS medical devices team will manage all your 3rd party testing, technical file assessments, audits and training needs, truly bringing a world of expertise to your door.

PARTNER YOU NEED

PROVIDE QUALITY AND ADDED VALUE TO YOUR CUSTOMERS

Beside proving that your products are better than those of your competition, you also need to be able to prove that you meet industry and client-specific standards for quality and safety. Partnering with SGS, your business will be backed by a global network with a proven track record for raising quality levels throughout entire operations, from products and supply chains, to employee and sustainability programmes.
Thanks to our global reputation and comprehensive range of accreditations, SGS test reports increase the value and quality of your products in the eyes of both regulatory bodies and global players in the medical industry.

When your products fulfil our own quality and safety requirements they are granted SGS certification marks, which are recognised by customers around the world as signs of trusted, quality products.

ACCESS THE COMPLETE SERV

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 Standards) and STANDARDS COUNCIL OF CANADA
- 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

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 Device Directive, 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

ICE OFFERING

Regardless of the project size and number of markets targeted, SGS can improve the efficiency and value of your operation by combining in one global package the advantages of our worldwide reach, wide range of accreditations, resources and global expertise.

OUR ACCREDITATIONS

Our wide range of accreditations includes, among others:

- NOTIFIED BODY for CE marking, both under 93/42/EC as amended by 2007/47/EC for Medical Devices and 98/79/EC for In-vitro Diagnostic Medical Devices

- NATIONAL ACCREDITATIONS including: UKAS ISO 13485, CMDCAS for Canada; JPAL for Japan; FDA site inspections for USA; INMETRO for Brazil, KFDA technical document accredited body in Korea and the schemes for Taiwan, Australia and Hong Kong

- NCB (National Certification Body) AND CBTL's ALL AROUND THE WORLD within the CB Scheme

- All our laboratories are ISO 17025 ACCREDITED.

OUR CERTIFICATION MARKS

Thanks to the wide range of accreditations gained, SGS can offer you complete testing and certification services for nearly all regulatory criteria and markets. You can also access SGS's own global certification marks. Here are a few examples of such marks:

SGS System Certification Mark

SGS Electrical & Electronics Certification Marks

YOUR BENEFITS

Our entire network and medical devices portfolio has been developed to bring added value to your business and fast track your market access. We offer:

- FLEXIBILE SOLUTIONS that keep your business in mind, putting test data to work, to grant you access to multiple approvals, including: CB, CE, NRTL, FDA, etc.

- CONVENIENT CUSTOMER INTERFACE with an option of a local key account manager, to handle all your testing, certification and any other service needs uniquely suited to your business

- COMPLETE TESTING OF YOUR PRODUCTS IN OUR LABS in accordance with the commonly used harmonised standards and your specific requirements

- SUPPORT WITH COMPLEX REGULATORY COMPLIANCE such as risk management requirements for the Medical Devices Directive (MDD) and the In-vitro Diagnostic Medical Devices Directive (IVD) or addressing risk management requirements per ISO 14971

YOU ARE FULLY COVERED

For an industry where timing is everything, SGS offers medical device manufacturers a globally integrated solution to get their new devices to market faster. We have a presence in virtually any market that you are planning to enter.

THE SGS NETWORK

SGS is the world's leading inspection, verification, testing and certification company. Recognised as the global benchmark for quality and integrity, we employ 75,000 people and operate a network of more than 1,500 offices and laboratories around the world.

Supporting organisations large and small, from every step of the supply chain, we ensure that medical device projects achieve quick regulatory compliance that translates into faster market access and faster realisation of profits.

As a leading service provider for the medical devices and IVD industries, SGS has developed a network of medical devices experts located all over the world.

With knowledge of local regulations and markets and instant access to our global capabilities, the SGS medical device expert in your region has the one-stop-solution for your medical devices business.

GET YOUR PRODUCT TO MARKET FASTER. WE KNOW THE WAY

WITH YOUR SGS MARKET ACCESS PASSPORT

SGS offers complete global solutions for medical devices and IVD market access.

COUNTRY	SGS ACCREDITATION	SGS MEDICAL DEVICE SERVICE
GLOBAL	• UKAS Accreditation for ISO 13485:2003, ISO 9001:2008 and ISO 14001:2004 (FINAS) • NCB under the IECEE CB Scheme with CBTLs around the world • All our laboratories are ISO 17025 accredited	• Audits by local SGS staff • CB test results can be integrated to gain access to over 52 countries • Product Testing for Safety and EMC to IEC (IEC 60601 and IEC 61010 series)
EU	• Notified Body for MDD and IVD Directives for all devices	• Audits and technical file reviews by SGS auditors and product experts • Product Testing for Safety and EMC to EN Standards (EN 60601 and EN 61010 series)
US	• FDA Accredited Person Program • NRTL	• FDA Site Inspections • 3rd party data report review for FDA 510(K) • Product Safety and EMC Testing (UL 61010 series)
CANADA	• CMDCAS Recognised Registrar • Standards Council of Canada accreditation	• Audits by local SGS staff • Product Safety and EMC Testing (CSA 60601 and CSA 61010 series)
JAPAN	• JPAL 3rd Party Recognised Certification Body	• Audits and technical file reviews • Product Safety and EMC Testing
BRAZIL	• INMETRO Recognised Certification Body	• Audits and Testing to IEC and NBR standards resulting in INMETRO certification and mark • Product Safety and EMC Testing
TAIWAN	• Technical Co-operation Programme (TCP) partner	• ISO 13485 Audits to include ROC Taiwan requirements • Product Safety and EMC Testing
CHINA	• SFDA Registration	• Pre-evaluation with Product Safety, Performance Test and EMC Testing • Administrative Procedures
HONG KONG	• Conformity assessment body under the Medical Device Administrative Control System (MDACS)	• Audits and Technical File Reviews • Product Safety and EMC Testing
KOREA	• KFDA Designated Technical File Review Body • KFDA Designated Training Body for GMP	• Testing to IEC standard (CB & KOLAS report) for KFDA • Training Services on Medical Device Technical File and GMP Requirements • Product Safety and EMC Testing
SINGAPORE	• SAB accreditation for GDPMDS	• Audits of Singapore Importers and Distributors • Product Safety and EMC Testing
AUSTRALIA	• Listed in Mutual Recognition Agreement with TGA	• Acceptance of SGS Certification • Product Safety and EMC Testing

CONTACT US

For more information on SGS medical device services visit: www.sgs.com/consumermedicaldevices or contact us at: ee.global@sgs.com

WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS