



**QUALITY**



**RISK MANAGEMENT**



**COMPETITIVE ADVANTAGE**



**EXPERTISE**



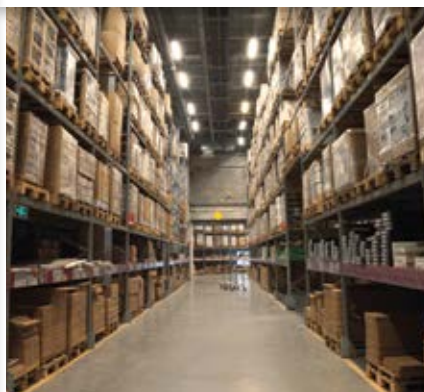
**FURTHER EXCELLENCE**



**MARKET INTELLIGENCE**



**REGULATORY COMPLIANCE**



**SPEED TO MARKET**



**PATIENT SAFETY**

## **MEDICAL DEVICES – FIND THE FASTEST AND MOST RELIABLE ROUTE TO MARKET**

**AUDITS, CERTIFICATION AND TRAINING**

**SGS**

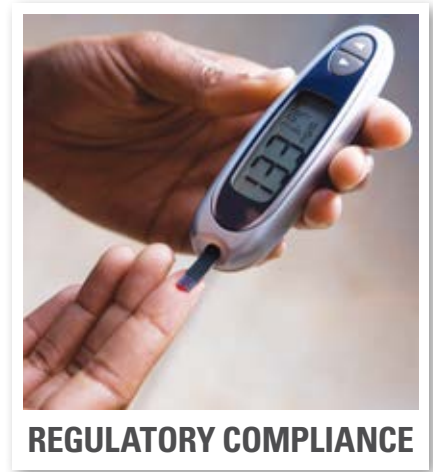
# ENSURE YOUR MEDICAL DEVICES MEET REGULATORY REQUIREMENTS

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**SGS CAN AUDIT AGAINST A RANGE OF STANDARDS AND REGULATIONS IN ONE COMBINED ANNUAL AUDIT.**

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Regulatory requirements and customer needs are becoming more onerous and complex for manufacturers and providers of medical products, devices, components and services. So the challenge is to bring new and improved products to the market quickly while meeting the highest quality standards and all relevant global regulations.



## **INDEPENDENT CERTIFICATION**

One essential part of this process is the independent certification of your products, processes and quality management systems. The correct certification can open markets and the correct choice of certification body can differentiate your organisation from competitors.

Certification to ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes is now the basis for regulatory compliance in most markets and shows that you are committed to meeting your customers' requirements. For many markets ISO 13485:2003 is not sufficient for the legal manufacturer of medical devices and the appropriate regulatory certification issued by a regulatory approved body is also needed. For contract manufacturers, component manufacturers, service providers and distributors of medical devices accredited ISO 13485:2003 certification will often be the only certificate required. Medical device certification is equally appropriate for own brand labellers, very small manufacturers and multinational corporations.

## **THE BENEFITS**

The right medical device certification at the right time is the key to winning new contracts, launching new products and entering new markets. With a strong reputation for technically correct advice and certification, we have the expert knowledge and a global network of auditors which can help you achieve these objectives. We work with you to plan activities, undertake audits and assessments and deliver reports and certificates quickly allowing you to enter markets sooner and with confidence. It is also likely that now or in the future most customers will wish to have a range of medical device certifications and SGS can usually provide these in one combined annual site visit. It is our wide range of regulatory approvals, UKAS accreditation and our close links with medical devices authorities that guarantee that you have chosen a certification partner that can meet your current and future needs.



## COMPETITIVE ADVANTAGE

### OUR RANGE OF APPROVALS

There are a large number of certification options depending on whether you are the legal manufacturer or a contractor, the device risks and where you wish to sell the product. These are subject to change depending on regulatory updates, but the main current options are described below. It is often the case that customers will select a range of certifications that can be conducted in a single audit and assessment.

### ISO 13485:2003

ISO 13485:2003 is applicable to all manufacturers and providers of medical devices, components, contract services and distributors of medical devices. We offer certification against this standard with our globally respected UKAS accreditation. ISO 13485:2003 helps you achieve regulatory approval, sell your devices, manage your risks, and reduce the number of regulatory and supplier audits you undergo. It is often requested in combination with regulatory certification and/or ISO 9001:2008.

### EC Directive 93/42/EEC Medical Devices Directive

EC Directive 93/42/EEC requires manufacturers of Class I (sterile/measuring), IIa, IIb and III devices to obtain certification from a Notified Body before using the CE mark and placing the product on the market. SGS United Kingdom Limited is Notified Body 0120 under Directive 93/42/EEC for all devices including electro-medical, sterile, implants and other high risk products. SGS specialises in providing a fast turnaround review process for implants and high risk (class III) devices, including drug device combination products. We also provide clinical strategy reviews to give manufacturers greater confidence in their regulatory pathway.

### EC Directive 98/79/EC In Vitro Diagnostic Medical Devices Directive

EC Directive 98/79/EC for in vitro diagnostic medical devices requires manufacturers of medium and high risk devices (List A, List B and self test devices) to obtain certification from a Notified Body before using the CE mark and placing product on the market. SGS United Kingdom Limited is Notified Body 0120 under Directive 98/79/EC. SGS has a scope of designation under Directive 98/79/EC for all List A, B and Self-Test IVD devices. The certification options under this directive offered globally by SGS include Annex III, IV and VII comprising site audits and/or assessments of technical documentation. Our site audits assess compliance to ISO 13485:2003 and Directive 98/79/EC.

### ISO 13485:2003 CMDCAS

The Canadian medical devices regulations require all manufacturers of Class II, III and IV devices to obtain ISO 13485:2003 certification under the CMDCAS scheme. SGS United Kingdom Limited is Standards Council of Canada accredited as a CMDCAS Recognised Registrar and our site audits assess compliance to ISO 13485:2003 and parts of the Canadian regulations as necessary.

### JPAL (Japanese Pharmaceutical Affairs Law)

The Japanese medical devices regulation allows approved bodies, such as SGS Japan Inc. to review the technical documentation and audit the manufacturing site of designated Class II medical devices and IVD reagents to give access to the Japanese market. We offer this service in Japan and globally but the application is made by the Japanese Market Authorisation Holder (MAH) not the manufacturer.

### US Food and Drug Administration (FDA) Site Inspections

FDA medical device regulations require most manufacturers to have a quality management system based on 21CFR Part 820 but no certification is required or issued. Site inspections are required to determine compliance and can be undertaken by the FDA or by certain approved bodies, such as SGS United Kingdom Limited. This service is offered globally, initiated by a communication from the FDA to the manufacturer that an inspection is needed. Alternatively, manufacturers can choose to submit SGS issued ISO 13485 reports to the FDA as part of the Voluntary Audit Report Submission Program, or can opt to participate in the forthcoming pilot Medical Device Single Audit Program (MDSAP).

### Brazil Inmetro Certification

Electro-medical devices must obtain INMETRO (i.e. the National Institute of Metrology, Standardisation and Industrial Quality) certification from a third-party certification body such as SGS prior to being placed on the market in Brazil. In line with the requirements, this requires accredited test reports and a site audit. SGS performs tests and supplies test reports from our Accredited Testing Laboratories and undertakes the annual site audits required by the scheme. Brazil is also taking part in the forthcoming pilot of the Medical Device Single Audit Program (MDSAP), in which SGS can replace ANVISA as the auditing body for all types of device.

### Hong Kong Medical Devices Administrative Control System (MDACS)

Currently, there are no mandatory legislative requirements for the importation and sale of medical devices and IVDs into Hong Kong. However, in preparation for future legislation, the Medical Device Administrative Control System (MDACS) has been set up by the Hong Kong Department of Health. SGS is a recognised conformity assessment body under this scheme, and can perform the assessments and certification required for voluntary listing of higher risk medical devices (Class II, III and IV) and high risk IVD medical devices (Class D), allowing a fast tracked access to market.

### Taiwanese Regulations

SGS supports manufacturers who have EU (MDD or IVDD certification) or US (notification letter for FDA 510 (k)) approvals by providing the necessary documented confirmation on the exact list of devices covered by certifications granted, as is required to support market entry into Taiwan.



## RISK MANAGEMENT

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## SGS MEETS YOUR CURRENT AND FUTURE NEEDS THROUGH OUR WIDE RANGE OF APPROVALS, TECHNICAL EXPERTISE AND CLOSE LINKS WITH REGULATORY BODIES.

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Manufacturers of all devices, except non-sterilised Class I devices listed in annex II of Regulations for Governing the Management of Medical Devices, must also hold a GMP licence from a third party such as SGS for their quality system.

For manufacturers located in the EU and Switzerland, SGS, as a certification body designated under the EU/Taiwan Technical Cooperation Program II undertakes GMP audits. Following these audits we issue the appropriate documentation confirming compliance to Taiwanese regulations, in addition to ISO 13485:2003 certificate.



**QUALITY**



**PATIENT SAFETY**

## **ELECTRO-MEDICAL TESTING SERVICES**

As a manufacturer of electro-medical devices ensuring fast and smooth access to your target markets requires market specific regulatory knowledge and attention to the relevant details during the product development phase. SGS works with you to prove your products meet industry and client-specific standards for quality and safety, ensuring you have the right certifications and accreditations for your products. For example, 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, CE Marking)
- Approval for overlapping EC Directives: Machinery Directive, Personal Protective Equipment; Pressure Equipment; Non Automatic Weighing Equipment; R&TTE
- Wireless Testing/Telemedicine rechargeable batteries are required to meet IEC 62133 for the CB scheme. In the US, UL 2054 applies
- Restricted Substance Testing, including testing to RoHS2 requirements for Medical Devices
- Packaging Testing

These testing services along with our regulatory and quality audit and certification services ensure your products have covered all the necessary requirements for your markets.

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**WORK WITH A CERTIFICATION PARTNER WHO IS CONSTANTLY UP-TO-DATE AND ABLE TO HELP YOU STAY AHEAD OF CHANGING REQUIREMENTS.**

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## **PREPARATION FOR FUTURE REGULATIONS**

The regulatory frameworks guiding access for medical devices into different markets are frequently evolving. The only way to ensure your products continue to meet the necessary requirements is to work with a certification partner who is constantly up-to-date and who is therefore able to help you stay ahead of the changing requirements. With our support you are aware of future changes and as an original signatory of the Notified Body Code of Conduct, SGS enables you to stay close to the future requirements of CE marking. Through the assessment and certification services that we provide you can be sure to have all the documented evidence to support your market applications in line with the regulatory developments.



## EXPERTISE



## MARKET INTELLIGENCE

### TRAINING SOLUTIONS

We offer a wide variety of training courses for all levels of ability and awareness. Our Medical Devices training course portfolio is designed to meet the requirements of any organisation, and can be undertaken as an in-house training tailored to your organisation as public courses.

Our courses include:

- Quality Management Systems/ Auditing (ISO 13485:2003, internal auditing)
- Global Regulations (CE Marking, FDA, Japanese Regulations)
- Sterilisation (radiation, ethylene oxide, steam)
- Risk Management (ISO 14971:2007)
- Electrical Safety (IEC 60601, Usability)
- Leading e-learning solutions aimed at the medical device professional in partnership with World Medical Device Organization (WMDO), a leading provider of online training for the industry

Please visit [www.sgs.com/training](http://www.sgs.com/training) to view the Medical Devices course schedules in your region.

### OTHER SERVICES RELATED TO MEDICAL DEVICES

We offer a range of other certification services to complement medical devices certification, and in some cases this could be an additional legal or contractual requirement:

- Other EC Directives such as: Personal Protective Equipment; Pressure Vessels; Non Automatic Weighing Instruments; Machinery; Radio and Telecommunication Terminal Equipment
- Other Management Systems such as: ISO 14001 or OHSAS 18001
- Good Distribution Practices (for medical devices)
- BRC Global Standard – Consumer Products

In addition, we also offer services that include:

- Supplier Audits (using the SGS global network to outsource auditing)
- Gap Analysis Audits (to check compliance)
- Customised Audits on a wide range of relevant subjects
- Pharmaceutical GMP Audits
- Testing Services (biocompatibility and sterility)

## WHY SGS?

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

SGS has a global team dedicated to the specific needs of the medical device market, certifying medical device manufacturers in over 40 countries. As such, our experts can support you in the definition of the optimum audit and testing programme for your organisation, using our experience in the industry and benchmarking to best practices.

Enhancing products, processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your products, services and value chain by increasing performance, managing risks, better meeting stakeholder requirements, and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.



## FURTHER EXCELLENCE

**TO LEARN HOW SGS CAN HELP  
YOU FIND THE FASTEST AND MOST  
RELIABLE ROUTE TO MARKET VISIT  
[WWW.SGS.COM/MEDICALDEVICES](http://WWW.SGS.COM/MEDICALDEVICES)  
OR CONTACT US AT  
[MEDICALDEVICES@SGS.COM](mailto:MEDICALDEVICES@SGS.COM)**

**TO VIEW OUR COMPREHENSIVE  
WHITEPAPERS ON MEDICAL  
DEVICES, SUCH AS 'MEDICAL  
DEVICE REGULATIONS IN THE  
MAIN GLOBAL MARKETS', VISIT  
[WWW.SGS.COM/WHITEPAPERS](http://WWW.SGS.COM/WHITEPAPERS)**

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WHEN YOU NEED TO BE SURE

