



# HOW DO YOU FIND THE FASTEST AND MOST RELIABLE ROUTE TO THE MARKET?

## MEDICAL DEVICES AUDIT, CERTIFICATION & TRAINING SERVICES FROM SGS

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 whilst meeting the highest quality standards and all relevant global regulations.

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 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes is now the basis for regulatory compliance in your local market and for all export markets and shows that you are committed to meeting your customers' requirements. For many markets ISO 13485:2012 is not sufficient on its own 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 13485:2012 certification will often be the only certificate required. Medical device certification is equally appropriate for own brand labellers, very small manufacturers and multi-national 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.

### **CERTIFICATION OPTIONS**

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 options are subject to change depending on regulatory updates, but the main current certification 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 13485:2012*

Now the global basis for regulatory compliance, ISO 13485:2012 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 13485:2012 will help 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. Although UKAS accredited ISO 13485:2012 certification is voluntary, we can use it as the basis for regulatory approvals such as ROC Taiwan and Australia. In addition, customers will often find it a contractual requirement for certain countries.

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

EC Directive 93/42/EEC as amended by 2007/47/EC for medical devices 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 UK is Notified Body 0120 under directive 93/42/EEC for all devices, including drug/device combinations and associated directives 2003/32/EC and 2005/50/EC. The certification options under this directive offered globally by SGS affiliates include Annex II, V and VI comprising site audits and/or assessments of technical documentation. Our site audits will assess compliance to ISO 13485:2012 and directive 93/42/EEC.

#### *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 UK is Notified Body 0120 under directive 98/79/EC. SGS UK has a full scope of designation under Directive 98/79/EC for all IVD medical devices, including List A, List B and self test. The certification options under this directive offered globally by SGS affiliates include Annex III, IV and VII comprising site audits and/or assessments of technical documentation. Our site audits will assess compliance to ISO 13485:2012 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 from a CMDCAS Recognised Registrar before applying for a licence and selling products in Canada. SGS UK is Standards Council of Canada accredited as a CMDCAS Recognised Registrar and our site audits will 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 certain Class II medical devices and IVD reagents to give access to the Japanese market. We offer this service in Japan and globally but it does not follow all the steps of the Medical Device Certification Process below. Differences include the application being made by the Japanese Market Authorisation Holder (MAH) not the manufacturer.

#### *Others*

A number of other countries have medical device regulations that require audits or certification, all based to some extent on ISO 13485:2012. These include ROC Taiwan, Hong Kong, Brazil (INMETRO), for which SGS also offers certification.

#### **HOW DOES THE CERTIFICATION PROCESS WORK?**

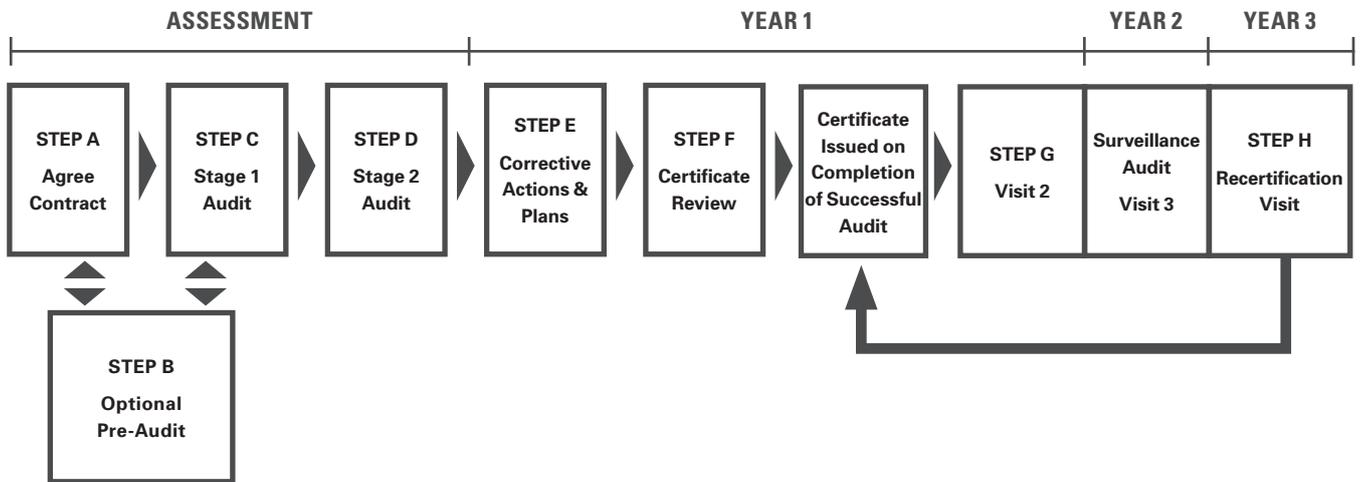
The SGS medical devices certification service starts at the inquiry and proposal stage where our experts discuss with you in detail your products, activities, current certification, regulatory compliance requirements, auditing and documentation assessments. This allows us to offer less experienced organisations the best approach for market approvals and larger organisations the optimum audit and assessment schedule taking into account existing certificates. Subsequent steps are transparent and logical and provide added value and risk reduction to our customers at every stage. The initial certification process involving site audits normally consists of Steps A to Step H. However extensions to scope, technical documentation assessments and certification for own brand labelling follow simpler routes often not requiring a site visit.

- Step A – SGS provides you with a proposal based on the size and nature of your organisation and activities. You can then proceed with the audit by accepting and signing the proposal.
- Step B – You may ask SGS to perform a 'pre-audit' to give an indication of the readiness of your organisation for the audit. This stage is optional, yet it

is often found useful in identifying any weaknesses in your systems and in building confidence before the formal audit. This step can often reduce the time to certification.

- Step C – The first part of the formal audit is the 'Stage 1 – Preparedness or Readiness Review'. This lets us evaluate the compliance of your documentation, your understanding of the regulatory aspects, whether certain processes are operational and your preparedness for a Stage II site audit. You will receive a report after this stage identifying any concerns or deficiencies so that you can take immediate action if required along with an audit plan.
- Step D – This is 'Stage 2' of the initial audit process. This on-site audit determines compliance against your documented system, the appropriate parts of ISO 13485:2012 and the regulations. This is a standard audit process of interviews, sampling of documentation and records and sometimes of technical files. On conclusion of the audit the audit team will make a recommendation dependent on the findings and subject to the submission of corrective action plans for any non-conformances
- Step E – Any major non-conformances will have a corrective action plan and date agreed during the audit. Certification will be deferred until corrective action has been taken and verified by SGS either on-site or by document review as appropriate. Minor non-conformances will have a corrective action plan and date agreed, which must be completed by the next audit.

## MEDICAL DEVICE CERTIFICATION PROCESS (SITE AUDITS)



- Step F – SGS will review the audit report and other audit documentation and a certification decision will be made. You will then receive the certificate and formal report.
- Step G – By the end of the first year, SGS will conduct its first surveillance audit, a process which will also be repeated at the end of the second year.
- Step H – At the end of the third year, SGS will conduct a recertification audit to ensure conformity with the standards and regulations. After successful completion of this step, the certificate will be reissued.

Certification under EC Directives 93/42/EEC and 98/79/EC and JPAL require assessment by SGS of technical documentation (technical files) to determine that the device is safe and performs as intended. These are undertaken in addition to the site audits described above. The details of the appropriate certification process will be discussed at the proposal stage and in most cases you will receive a detailed annex with your proposal, which describes the steps appropriate to your chosen certification options.

### **MEDICAL DEVICES RELATED TRAINING**

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 or as public courses.

Courses include:

- Quality Management Systems/Auditing (ISO 13485:2012, internal auditing);
- Global Regulations (CE Marking, FDA, Japanese Regulations);
- Sterilisation (radiation, ethylene oxide, steam); and
- Risk Management (ISO 14971:2007).

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

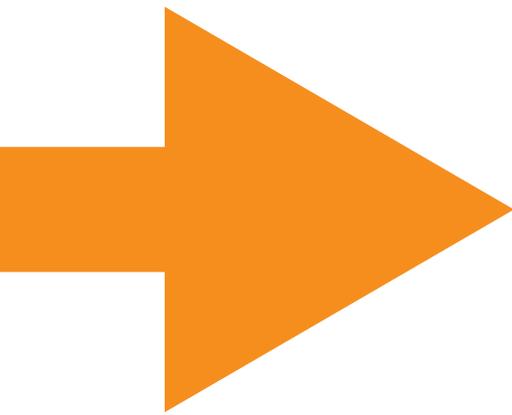
### **OTHER SERVICES RELATED TO MEDICAL DEVICES**

We also 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; and
- Good Distribution Practice (for medical device)

In addition, we also offer services that include:

- Supplier Audits (using the SGS global network to outsource auditing);
- Gap Analysis Audits (to check compliance); and
- Testing Services (electro-medical, biocompatibility and sterility).



## **WHY SGS?**

SGS is the world's leading inspection, verification, testing and certification company. Recognised as the global benchmark for quality and integrity, we employ over 75 000 people and operate a network of more than 1 500 offices and laboratories around the world. SGS have medical devices experts in over 35 countries with local language working in an internationally consistent manner. SGS count their medical device customers in the thousands and are experienced at working with large and multi site organisations offering Global Key Account Management and with smaller organisations where more technical support may be needed.

SGS is constantly looking beyond customers' and society's expectations in order to deliver market leading services wherever they are needed and it is our policy to obtain all new medical devices approvals when available.

Partnering with SGS opens the door to better performing processes, increasingly skilful talent, consistent and compliant supply chains and more sustainable customer relationships delivering profitable competitive advantage. Work with the global leader and take your commitment to the next level.

We have a history of undertaking and successfully executing large-scale, complex international projects. With a presence in every single region around

the globe, our people speak the language and understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

**TO LEARN HOW SGS CAN HELP YOU  
MANAGE YOUR TECHNICAL AND  
BUSINESS RISKS AND MAXIMISE  
THE POTENTIAL OF YOUR PRODUCTS  
AND SERVICES IN THE MEDICAL  
DEVICES MARKET VISIT**

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