Your certification process explained

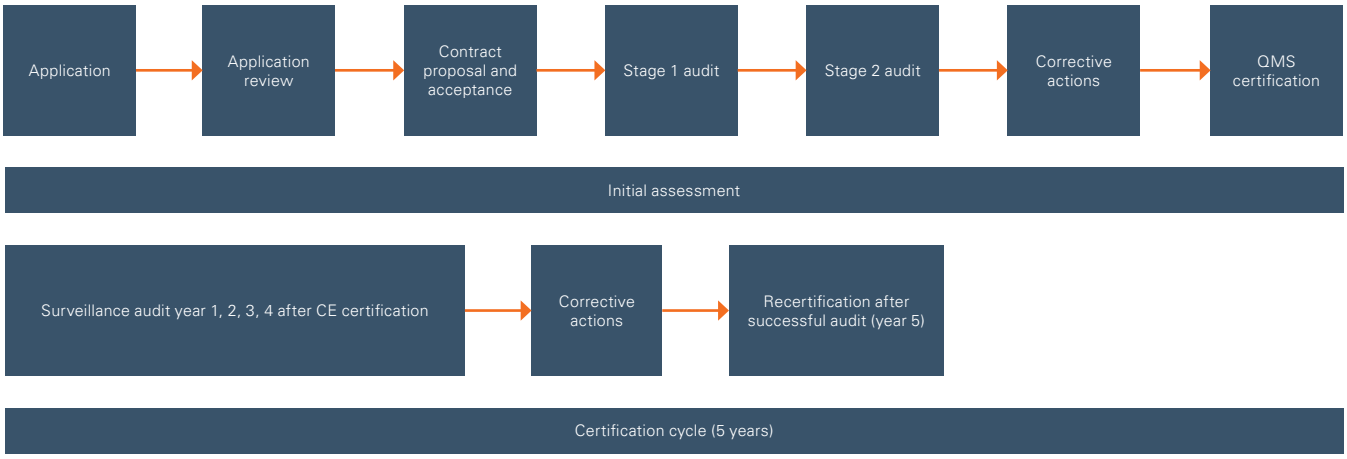
MEDICAL DEVICE REGULATION (EU) 2017/745 ARTICLE 16

This document outlines each stage of the assessment process for the above regulation and gives essential guidance to organizations seeking certification.You must read and understand it to minimize nonconformities and delays in certification.

SGS DESIGNATION AND APPROVAL STATUS

SGS Belgium NV is a Notified Body for your products and certification will be undertaken to attest that your quality management system as the distributor or importer carrying out any activities mentioned in points (a) and (b) of Article 16(2) complies with the relevant requirements.

OVERVIEW OF OUR CERTIFICATION PROCESS



The certification cycle is usually based on 5 years, with at least one surveillance audit every 12 months.

APPLICATION

WHAT YOU NEED TO SEND US:

You do not need to make any payments on application unless payment is referenced in the proposal. SGS requires the following:

- A completed and signed Medical Device Questionnaire, which is available on our website (https://www.sgs.com/en/health-and-nutrition/health-science/solutions/medical-devices/eu-medical-devices-regulations-information-center)
- The documentation on your quality management system
- A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under MDR, and the undertaking by the distributor/importer in question to apply those procedures
- A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures
- A copy of your quality manual, procedures and any work instructions that ensure compliance with Medical Device Regulation (EU) 2017/745

- All elements listed in MDR 2017/745 Section 2.1 of Annex IX
- A copy of the MDR certificates for the products that would be subject to importer/distributor rework
- Your application must be submitted in English. We can accept that your quality management system is in your local language (if accepted during the proposal stage by the Notified Body) or in English. Please note that the acceptable language for any related correspondence with NB 1639 is English

APPLICATION REVIEW

A review of your application is conducted off-site. During this step, the Notified Body will:

- Review the completeness of the application concerning the relevant conformity assessment procedure requirements, as referred to in the corresponding Annex in MDR, under which approval has been sought
- Review the verification of the qualification of products covered by the application as devices and their respective classifications
- Confirm that the devices and the conformity assessment procedures chosen are within the designation of the Notified Body SGS
- Confirm the availability of sufficient and appropriate Notified Body assessment resources for the timely performance of all tasks

Based on the application review, a contract proposal is created. The outcome of the review of the application may be (exceptionally) the refusal of the application (e.g. if incomplete applications, nonconformities or problems in the application documents are detected).

CONTRACT PROPOSAL

A proposal is submitted by SGS for consideration. If this does not adequately include all your requirements or you have questions, please contact your local SGS office to discuss any queries and next steps. This proposal is valid for 60 days. Once the 60 days end, we will review the contract again and issue a new quote, if necessary. SGS Notified Body can only issue and agree a contract with the medical device distributor or importer directly, no intermediate company shall be involved.

Application: To apply for certification and to start the assessment process, the contract proposal must be completed, signed and returned to your local SGS office. We recommend that this is done as soon as your decision to proceed has been taken to allow the maximum time for planning.

Special conditions: In addition to conditions set out in the SGS Codes of Practice, General Conditions for Certification and Regulations Governing the Use of SGS Certification Marks, the following applies:

APPLICANT (OR CERTIFIED CLIENT)

The applicant retains full product liability for registered products or services, and full responsibility for correct categorization, classification and adherence to standards.

The applicant undertakes that no other application to a different Notified Body for this scope is outstanding. The circumstances of any previous Notified Body application will be documented by the applicant and sent to SGS before an application is accepted.

The applicant undertakes to carry out all obligations arising from a certified quality control system and applicable regulations, and maintain its adequacy and efficiency.

The application is valid for up to one year after the effective date of the contract. If the assessment has not been scheduled after this period, then the contract proposal becomes void and the applicant needs to reconfirm all submitted information to get a new contract proposal.

The applicant undertakes to inform SGS in advance of implementation, of any change that could impact the compliance of the device with Medical Device Regulation (EU) 2017/745, or affect the risk-benefit ratio or clinical evaluation of the device.

The applicant undertakes to institute and maintain a post-production monitoring system, in accordance with Medical Device Regulation and any relevant national legislation, and to send SGS copies of any vigilance reports on certified devices. The VIGILANCE section below gives more details.

The applicant is responsible for all fees and costs associated with any activity that SGS considers necessary to grant or maintain certification, or which is required by a European Competent Authority.

The applicant is responsible for informing SGS of all information necessary to ensure that audits, and communications can be efficiently and effectively undertaken, and that certification accurately reflects the current activities and product ranges, and that SGS is aware of all significant proposed changes. The changes section below gives more information.

The applicant is responsible for the right of access of SGS to each of its sites covered by the certification scope, including defined suppliers and subcontractors, both for unannounced audits and scheduled audits (initial, surveillance and recertification). This must be included in your contract with relevant suppliers and subcontractors. Therefore, the applicant must communicate annually the period during which unannounced audits cannot be conducted for each of its relevant suppliers and/or subcontractors.

Certification and control of outsourced activities has not been assessed at the contract proposal stage, therefore, if certification and control of relevant subcontractors and suppliers are found to be inadequate after application, an additional audit may be required at additional cost.

The applicant will facilitate, as far as is legally possible, the obtaining of visas for auditors to undertake audits.

The applicant takes full responsibility for the safety and security of the audit team while on-site and for scheduled audits, including advising on safe travel and accommodation arrangements when necessary.

SGS

SGS undertakes that no information will be disclosed to a third party, except a regulatory or enforcement authority, where they are entitled to be informed under Medical Device Regulation (EU) 2017/745. This excludes information publicly available in EUDAMED, according to Medical Device Regulation (EU) 2017/745, as this cannot be considered confidential.

Competent authorities, including EU experts and the joint assessment team, may access all information gathered during the assessment of the applicant, to verify that the conformity assessment has been conducted by SGS, in accordance with MDR requirements.

SGS retains the absolute right to suspend, withdraw or amend the scope of registration by informing the organization and giving the reasons in writing. This includes suspension following a refusal to accept a scheduled or unannounced audit at your location or that of a defined relevant supplier or subcontractor, or following undue restrictions or pressure during the audit.

SGS retains the right to take photographs of devices and manufacturing sites, to take samples from the audit site and the market, and to take copies of documents and electronic data.

SGS retains the right to undertake any audit, assessment or regulatory action deemed necessary to grant or maintain certification, or to check compliance, including visits to suppliers, subcontractors and distributors, and testing of products without a further application and to charge for such work. When requested SGS will provide a written explanation for the need for any additional audit, assessment, test or regulatory action, but SGS is not obliged to inform the client before such action is undertaken.

Unless stated in the proposal, it is assumed that no further audits to suppliers, subcontractors or additional sites are required. However, during the audit process, if further information indicates a different situation, you will be informed, and additional visits agreed at additional cost.

STAGE 1 AUDIT

The stage 1 audit is conducted on-site as default, but could be off-site if specific circumstances are met. Application review includes an appraisal of your quality management system documentation and intended scope of certification, including products, processes and locations, and related statutory and regulatory aspects.

This stage will include:

- A review of all documents and elements listed in Annex IX section 2.1
- An evaluation of your location and site-specific conditions, and discussions with you to determine your preparedness for the stage 2 audit
- A review of your status and understanding regarding the requirements of the standard(s) and regulations, with respect to identifying key performance or significant aspects, processes, objectives and operation of the management system
- A review to ensure that internal audits and management reviews are being planned and performed, and that the implementation level of the management system confirms that you are ready for the stage 2 audit
- Determining compliance with the documentation requirements of Medical Device Regulation (EU) 2017/745 and the allocation of resources and working documentation for the stage 2 audit

An audit plan for the stage 2 on-site audit will be forwarded to you after this stage. You will receive a stage 1 audit report outlining any deficiencies (findings) to enable immediate action to be taken before moving forward through the process. Serious deficiencies detected at stage 1 within the quality management system, existing certification or certification of a relevant subcontractor and/or supplier could result in you being advised of additional costs and/or delays to the stage 2 quality management system audit.

STAGE 2 AUDIT

This step is usually conducted several weeks after the stage 1 audit to ensure that you have time to implement the stage 1 audit findings. We are led by you regarding the time between stage 1 and 2 activities, but 4 weeks minimum would be recommended and both stages should be planned well in advance.

The stage 2 audit is performed on-site or as a hybrid audit (partially on-site and partially remote) and determines compliance against your documented system, Medical Device Regulation (EU) 2017/745. This audit will also confirm the status of relevant suppliers and subcontractors, your critical processes and the eligibility for MDR (EU) 2017/745 Article 16 certification.

All assessment conclusions are based on a sampling of audit evidence to demonstrate effective implementation of the management system, control over the processes and progress made toward achieving your stated quality objectives and compliance with Medical Device Regulation (EU) 2017/745.

After the audit, the audit team will make a recommendation depending on the findings and subject to the submission of corrective action plans for any nonconformances (corrective action requests). The auditor will talk through the findings that may comprise major and minor nonconformances. The auditor will also agree with you on the name, address and proposed scope details that will appear on your certificate.

CORRECTIVE ACTIONS AND PLANS

Any major nonconformances will have a corrective action plan and date agreed upon during the audit. The certification decision will be deferred until corrective action has been taken and verified by SGS, either on-site or by document review, as appropriate. For new clients, if a major CAR is not closed within one year, the contract will be closed and the entire audit process must start again from the proposal stage. For other clients, major CARs have a 90 day deadline, which may be extended if there is justification, and at SGS discretion. If unclosed at six months, the certification will be suspended and withdrawn after one year, if still open.

All minor nonconformances will have a corrective action plan and date agreed upon during the audit or immediately after, and the corrective actions must be completed by the next on-site audit. Failure to address the root cause and take effective corrective action for major nonconformances, or to submit effective corrective action plans and dates for minor nonconformances, will prevent final review and certification.

Additional time to review and close the nonconformities will be invoiced in addition to the audit.

CERTIFICATION REVIEW

CE 1639

At the end of stage 2, the report is compiled off-site and reviewed with other audit documentation, root-cause analysis, corrective action plans and any corrective actions taken, and a certification decision is made.

SURVEILLANCE VISITS AFTER CE CERTIFICATION

Once issued, certificates are valid subject to regular audits, to check the satisfactory maintenance of your quality management system. Ongoing scheduled audits (surveillance visits) must be conducted annually to verify the continued implementation of your quality management system, in accordance with planned arrangements and the requirements of the standard(s) and regulations.

The first surveillance audit should be scheduled within 12 months following the certification decision. Subsequent surveillance audits must be completed within 12 months of the previous surveillance audit. Certain mandatory elements will be reviewed at every visit, together with other preselected processes. You will be sent a Medical Devices Client Pre-Audit Questionnaire, which is also downloadable from our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center), before every scheduled audit, which will remind you to check recent and gradual changes. You must complete and return this to the SGS office well before the audit, but it must not be used to replace the Medical Devices Notification of Changes or Regulatory Action reporting.

An audit plan will be forwarded in advance of the agreed audit date. Please note that the flexibility in the timing of ongoing visits is strictly limited by accreditation requirements.

RECERTIFICATION

SGS operates a system of continuous certification. As part of this program, it is not necessary to conduct a new full application review, stage 1 and 2 audits, rather we conduct a recertification visit that is more in-depth than a surveillance visit, and which may include an off-site document review, and will ensure that we review all aspects of your system.

You will be sent a Medical Devices Client Pre-Audit Questionnaire before the scheduled recertification audit, which will remind you to check recent and gradual changes. You must complete and return this to the SGS office well before the audit, but it must not be used to replace the Medical Devices Notification of Changes or Regulatory Action reporting.

The recertification audit must be carried out and major nonconformances closed before the expiry of your current certificate. The recertification audit is the first visit of your new certification cycle.

NOTIFICATION OF CHANGES

You shall inform SGS of any plans for significant changes to the quality management system, or the device range covered using the Medical Devices Notification of Changes or Regulatory Action form available on our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center). Significant changes are described in MDCG 2020-3, guidance on significant changes regarding the transitional provision under article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

In the event of any developments that will alter your scope of current certification, e.g. change of site or product range, reductions in scope, company name change, etc., you must inform us as soon as possible and in advance of the change implementation.

Certification does not usually extend to these changes until SGS undertakes the appropriate actions. Changes and additions to the scope or significant changes in the quality management system, or changes to relevant subcontractors and/or suppliers, can be included at any time during the certification cycle, but SGS must be informed in advance so that a revised contract can be issued. An SGS form Medical Devices Notification of Changes or Regulatory Action is available from your local SGS office (or SGS website) and must be used for this purpose.

The SGS Notified Body shall assess the changes proposed, determine the need for additional on-site audits and verify whether, after those changes, the quality management system still meets the requirements referred to in Section 2.2 of Annex IX of MDR. The SGS Notified Body shall notify the manufacturer of its decision which will contain the conclusions of the assessment and, where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device range covered shall take the form of a supplement to the EU quality management system certificate.

Planned changes are not allowed to be implemented before the conclusions of the assessment by the SGS Notified Body and, where applicable, conclusions of additional audits or review by the Notified Body.

The scheduling of any extension to the audit scope can take place at the same time as surveillance/recertification visits, or can be carried out between visits, depending on the nature and timing of the change.

NOTIFICATION OF OTHER CHANGES

Other changes to the operation of your company and important regulatory events also need to be explained to SGS using the Medical Devices Notification of Changes or Regulatory Action form, available on our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center), in advance of the change implementation.

This information is required by SGS to successfully plan scheduled and unannounced audits, and answer queries from regulatory authorities. Examples of changes that need to be included: the number of employees, changes in shift patterns, new processes, changes to relevant subcontractors and/or suppliers and manufacturing sites, and incidents outside of the EU triggering FSCA impacting devices sold in Europe.

GENERAL

SGS RANGE OF ADDITIONAL MEDICAL DEVICE CERTIFICATION SERVICES

For many organizations, the potential market for medical devices and services is worldwide, and additional certification and approvals may be required in the future. It is SGS Group's policy to obtain all possible global approvals to support you. Therefore, we have auditors with knowledge of a wide range of regulatory requirements.

These include:

- 3P510k
- ISO 13485
- MDSAP
- UKCA

USEFUL REFERENCES

- ISO 14971 medical devices – application of risk management to medical devices should be used in constructing your quality management system and technical documentation
- The EU Commission has many documents available on its website (https://health.ec.europa.eu/medical-devices-sector/new-regulations_en)
  - Common Specifications are provided by the Medical Device Coordination group and represent a set of technical and/or clinical requirements, other than a standard, that provide a means of complying with the legal obligations applicable to a device, process or system
  - Guidance (MDCG guidance)
- European Harmonised Standards while not mandatory are used by most manufacturers to demonstrate compliance with Medical Device Regulation (EU) 2017/745 (MDR), so are recommended. Please check the applicable standards from the website https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

ABOUT SGS

SGS is the world's leading testing, inspection and certification company. SGS is recognized as the global benchmark for sustainability, quality and integrity.

With more than 98,000 employees, SGS operates a network of over 2,650 offices and laboratories around the world. We offer the following:

- Inspection services – we inspect and check the quantity, weight and quality of traded goods. Inspection usually takes place when goods are moved from one type of transport to another
- Testing services – we test the quality and performance of products against various health, safety and regulatory standards. We use state-of-the-art laboratories on or close to customers' premises
- Certification services – we confirm that systems or services meet the standards set by governments, standardization bodies (e.g., ISO 9001) or our customers' products. We also develop our own standards to meet our clients' needs. SGS, as an accredited certification body, can provide confidence to clients that professional, experienced auditors are used, and standards are consistently applied
- Verification services – SGS verification services ensure that products and services comply with global standards and local regulations. Combining global coverage with local knowledge, unrivaled experience and expertise in virtually every industry, SGS covers the entire supply chain, from raw materials to final consumption
- Training services – we offer a wide range of training solutions, in a variety of management systems, complemented by many other specialized courses. These are offered publicly or via e-learning, or can be delivered in-house to suit your needs

Our certification section provides independent certification and audits to a range of standards, including:

- ISO 9001 – quality management systems
- ISO 14001, BS 8555 and EMAS – environmental management
- ISO/IEC 27001 – information security management
- Public sector customer service excellence
- ISO 45001 – occupational health and safety
- Corporate Responsibility (SRA)
- EC directives (CE Mark) and other regulations
- ISO 13485 and MDSAP – medical device certification
- ISO 22000 – food safety management systems

For more information, visit www.sgs.com.