Your certification process explained

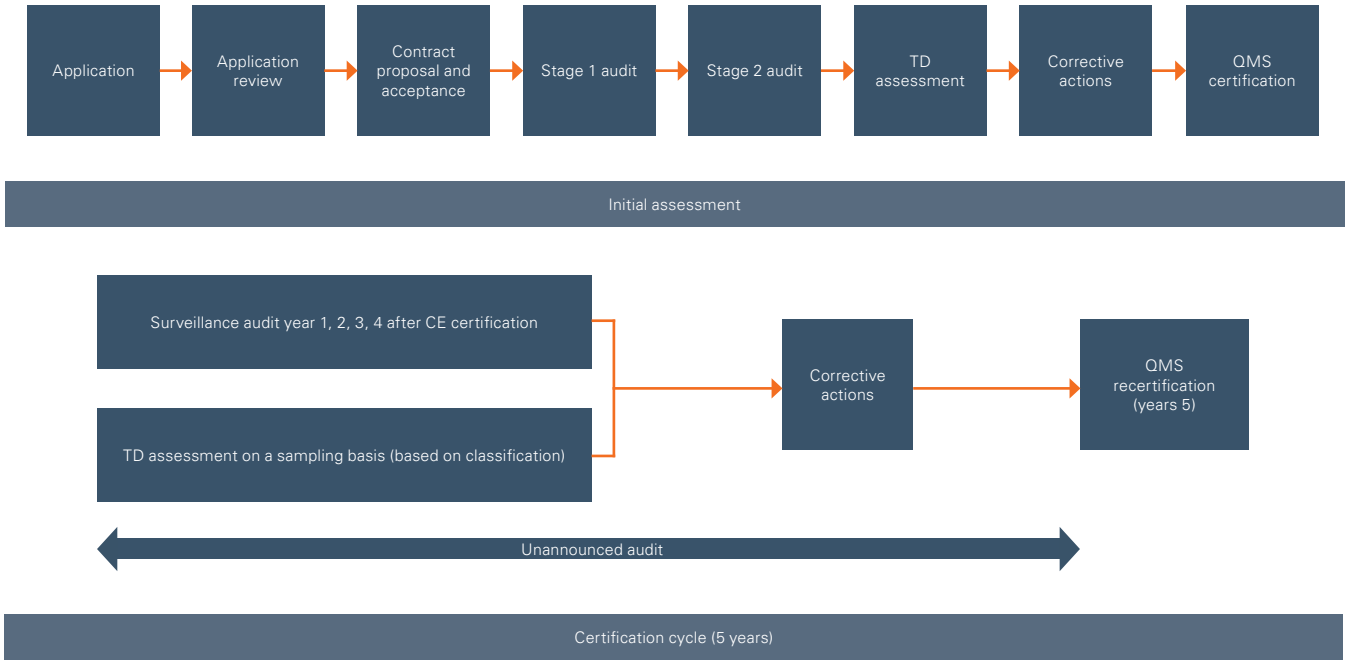
MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX IX OR XI PART A

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 range of products and certification will be undertaken as Notified Body 1639. This means you are entitled to use CE 1639 on devices within your scope, on the completion of a successful audit and technical documentation assessment. Class III and implantable Class IIb[1] devices must additionally have an EU technical documentation assessment certificate before using CE 1639.

OVERVIEW OF THE CERTIFICATION PROCESS



The certification cycle is usually based on five years. However, SGS may, based on documented evidence, decide to reduce the cycle to four years or less, depending on the results of initial, surveillance and recertification conformity assessment, as authorized by MDR (EU) 2017/745.

[1]*Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.*

APPLICATION

WHAT YOU NEED TO SEND TO US:

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

- 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)
- Completed and signed Product Information Questionnaire(s), 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). Preferably, one per technical documentation to be certified, but minimal one per device for Class III and specific[2] Class IIb devices, one per generic device group for Class IIb and one per device category for Class IIa and specific[3] Class I devices
- A draft of an EU declaration of conformity, in accordance with MDR 2017/745 Article 19 and Annex IV, for the device model covered by the conformity assessment procedure
- The documentation on the manufacturer's 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 manufacturer 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
- The documentation on the manufacturer's post-market surveillance system and, where applicable, the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance, set out in MDR 2017/745 Articles 87 to 92
- A description of the procedures in place to keep the post-market surveillance system up to date and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance, set out in MDR 2017/745 Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures
- Documentation on the clinical evaluation plan
- A description of the procedures in place to keep the clinical evaluation plan up to date, considering state-of-the-art
- A copy of your quality manual, procedures and any work instructions that ensure compliance with MDR 2017/745, appropriate common specifications and the harmonized standard for quality management systems (including sterilization and other critical processes). These should be controlled and sent to the assessment team in electronic format
- All elements listed in MDR 2017/745 Section 2.1 of Annex IX
- A copy of the EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X, if relevant, and issued by another Notified Body other than SGS Belgium NV, if you need a certificate Annex XI Section A
- A copy of the current internal audit schedule, the last internal audit report and the minutes of the last management review, to demonstrate that your internal audit and management review processes are functioning
- A list of your sets of technical documentation for the devices you wish to CE mark, as you may be requested to send a copy of selected technical documentation to this office before the audit
- When requested, technical documentation, as well as any further evidence in response to corrective action requests, should be submitted in English and electronically through a secured web-based application with prior agreement from SGS (preferably SGS-secured server ShareFiles). Documents should be presented in text-searchable format (i.e. text-recognition PDF or Microsoft Word). All information should be appropriately indexed to allow easy access to the relevant information and follow the requirements of MDR Annex II and Annex III
- Your application needs to 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
- If any critical processes are subcontracted or outsourced, copies of any relevant subcontractor/supplier certification should also be sent

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
- Review whether the conformity assessment procedures chosen apply to the device in question under MDR
- Confirm that the devices and conformity assessment procedures chosen are within the designation of NB 1639
- Confirm the availability of sufficient and appropriate Notified Body assessment resources for the timely performance of all tasks

[2]Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, and class IIb active devices intended to administer and/or remove a medicinal product.

[3]Class I devices placed on the market in sterile condition, have a measuring function or are reusable surgical instruments.

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 application, nonconformities or problems in the application documents are detected).

CONTRACT PROPOSAL

A contract proposal is submitted by SGS for consideration. If this does not adequately include all of your requirements, or you have questions, please contact your local SGS office to discuss any queries and the next steps. The contract 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 legal manufacturer.

Application: To apply for certification and 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 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 the 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 post-market surveillance, in accordance with Annex XIV of the Regulation (EU) 2017/745 and to inform SGS Belgium in writing of any substantiated EC Vigilance Reports on certificated devices.

The applicant undertakes only to affix the CE Mark when all requirements of the Medical Device Regulation (EU) 2017/745 are met, including a valid technical documentation assessment certificate for Class III and implantable Class IIb[4] devices.

The applicant is responsible for all the 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. If the proposal includes device certification with technical documentation under specific additional procedures required by MDR (EU) 2017/745 Section 5, external scientific opinion has to be requested by the Notified Body to complete certification, and associated fees not depending on the Notified Body will be invoiced additionally.

The applicant is responsible for informing SGS of all information necessary to ensure that audits, unannounced audits, assessments 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, a further 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.

[4]Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

SGS retains the right to take photographs of devices and manufacturing sites, to take samples from the audit site and 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 the 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.

When requested, SGS will provide documentary proof of the identity of their unannounced audit team members and will provide a telephone contact point for clients to confirm the authenticity of the unannounced audit team.

Unless stated in the proposal, it is assumed that no further audits of 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 and 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, evaluation of codes, and working documentation for the stage 2 audit

An audit plan for the stage 2 on-site audit will also be forwarded to you after this stage. During the stage 1 audit, the technical documentation is checked for preparedness to be sure it is up to date for technical documentation assessment. 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, technical documentation, preparedness, existing certification or certification of a relevant subcontractor and/or supplier could result in you being advised of additional costs and/or delay to the stage 2 quality management system audit or technical documentation assessment.

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.

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 of your products for medical device 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.

TECHNICAL DOCUMENTATION ASSESSMENT

The assessment of your medical device technical documentation is done in parallel with the on-site audit, and is performed on a sampling basis[5] for Class IIa and Class IIb. Class III, implantable Class IIb[6] and Class IIb active devices intended to administer and/or remove a medicinal product are not subject to sampling and the technical documentation of each product is assessed.

WHAT YOU NEED TO SEND TO US:

- A complete copy of your technical documentation. Technical documentation should be submitted in English and electronically through a secured web-based application with prior agreement from SGS (preferably SGS-secured server ShareFiles). Documents should be presented in text-searchable format (i.e. text-recognition PDF or Microsoft Word). All information should be appropriately indexed to allow easy access to the relevant information. Please note that the acceptable language for any related correspondence with NB 1639 is English
- If any relevant processes are subcontracted or outsourced, copies of any current subcontractor/supplier certification should also be sent

[5]*Devices are sampled in accordance with MDCG 2019-13.*

[6]*Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.*

If the assessment of your technical documentation leads to a high number of nonconformities, SGS may reject the technical documentation and ask you to provide fully updated technical documentation and restart the assessment. The review will be charged, even if the review has been stopped early as the technical documentation is not compliant.

CORRECTIVE ACTIONS AND PLANS

Any major nonconformances will have a corrective action plan and date agreed 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 existing clients who hold a valid MDR certificate, 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.

All minor nonconformances will have a corrective action plan and date agreed upon during the audit or immediately after. Verification and closure of minor nonconformances will take place at the next routine surveillance visit for quality management system on-site audits and can be done on- or off-site for technical documentation assessment. For new clients, minor nonconformance will not prevent recommendation for certification, but may delay it, as planned action must be submitted to and reviewed by SGS, prior to the certification decision taking place.

Additional time to review and close the nonconformities will be invoiced in addition to the audit or technical documentation assessment.

CERTIFICATION REVIEW

CE 1639

At the end of stage 2 and technical documentation assessment, the report is compiled off-site and reviewed together with other audit documentation, root-cause analysis, corrective action plans and any corrective action plans and any corrective actions taken, and a certification decision is made. This step can sometimes lead to limited changes in scope about which you will be informed. Once the certification decision has been made, the certificate is processed. You must be informed that certificate validity may be reduced to four years or less during the certification decision process, based on multiple aspects that would be justified to you, if relevant.

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 (including device testing and technical documentation review based on sampling) 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 your local SGS office well before the audit, but it must not be used to replace the Medical Devices Notification of Changes or Regulatory Action reporting.

During the surveillance audit, one or more devices should be tested (witnessing test), according to the defined sampling plan, but if this cannot be achieved on-site, devices will be sampled and tested outside of the manufacturer's site and the cost will be invoiced in addition to the audit cost.

Surveillance activities cover the review of technical documentation, based on the established sampling plan. When requested by your local SGS office, you will need to submit the required technical documentation, similar to initial certification, within four weeks following the demand to allow technical documentation assessment.

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.

UNANNOUNCED AUDIT AFTER CE CERTIFICATION

Unannounced audits can be undertaken at any time within the certification cycle, excluding prior agreed periods of unavailability. The unannounced audit cycle is associated with your certificate, so, if you have multiple conformity assessment procedures leading to multiple certificates, you will have one unannounced audit cycle per certificate. Your period of unavailability and the ones from your relevant subcontractors and suppliers must be sent to your local SGS office for the upcoming year and no later than the end of each calendar year using the Unannounced Audit Questionnaire, which can be downloaded from our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center). In the absence of this questionnaire, SGS will consider that there is no period of unavailability. No notice will be given, so you must always be ready to facilitate these audits. Unannounced audits to investigate product compliance may be undertaken by SGS at any defined locations other than your site, so you are obliged to help define these locations and facilitate these audits. If the unannounced audit cannot be performed, this could lead to SGS suspending your certificate.

Unannounced audits will focus on checking the production and traceability aspects of one of the more recent batches of devices, witnessing the final testing and inspecting processes, and auditing two processes that are critical to the safety and regulatory compliance of the devices. Samples may be taken for subsequent testing. It is a requirement that the technical documentation is available at the audit site, so that it can be compared with actual or recent production.

The frequency of unannounced audits will be once every five-year cycle. However, frequency can be increased at the discretion of SGS, following information received during audits or from other sources that devices may be nonconforming. The minimum duration of an unannounced audit is one day for two auditors at the same time.

RECERTIFICATION

SGS operates a system of continuous certification. As part of this program, it is not necessary to conduct a new full application review and stage 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 and technical documentation.

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 audit or technical documentation assessment, 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. This can be carried out by an on-site audit or, in some cases, an off-site technical documentation assessment. The appropriate method will be shown in the approved change form and proposal.

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 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: number of employees, periods of unavailability (including relevant subcontractors and relevant suppliers), 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.

VIGILANCE

REPORTING OF VIGILANCE

It is a requirement of Medical Device Regulation (EU) 2017/745 to report vigilance cases to the appropriate European competent authority, either on the European electronic system (EUDAMED) on vigilance and post-market surveillance when fully functional or using the relevant form, by you or your European authorized representative. A copy of the report submitted to the competent authority must also be sent to SGS with a completed SGS form, Reporting on EC Vigilance to SGS, which can be obtained from your local SGS office.

Documents that must be copied with a completed Reporting of EC Vigilance to SGS form are one of the following:

- Manufacturer's incident report (initial, final and combined, not follow-up reports)
- Manufacturer's field safety corrective action report with attachments (e.g. a copy of a field safety notice)
- Manufacturer's periodic summary report (PSR)
- Manufacturer's trend report

Details of the format of these documents and how to send them are included in the Reporting of EC Vigilance to SGS form.

After review by SGS, SGS will either file the information as input for the audit team at the next scheduled audit (in this instance, there will be no communication from SGS) or inform you of actions that must be taken as soon as possible. This could include the provision of additional information to SGS, a review by SGS of technical documentation or information received, or an unannounced audit. Work undertaken by SGS will be invoiced.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

It is a requirement of Medical Device Regulation (EU) 2017/745 for implantable devices[7] and Class III medical device manufacturers to draft a summary of safety and clinical performance, as part of their technical documentation. This summary must be validated by SGS and uploaded to the European database on medical devices (Article 33, Medical Device Regulation (EU) 2017/745).

After review by SGS, SGS will either upload in the European database on medical devices (Article 33, Medical Device Regulation (EU) 2017/745), in this instance, there will be no communication from SGS, or inform you of further requested action.

Note that annual reviews of your summary of safety and clinical performance documentation follow the same process as the initial assessment, with a review that can be followed by rounds of nonconformities and responses, until all nonconformities are closed. The costs in the proposal assume that there are no nonconformities raised, a review of responses to correct nonconformities is at extra cost.

PERIODIC SAFETY UPDATE REPORT

It is a requirement of Medical Device Regulation (EU) 2017/745 (MDR) for Class II (Class IIa and IIb) and Class III medical device manufacturers to:

- Prepare the periodic safety update report (PSUR), as part of their post-market surveillance activities
- Update at least annually for Class IIb and Class III devices, and at least every two years for Class IIa devices
- Upload it annually into the electronic system on vigilance and post-market surveillance (Article 92 of MDR) for Class IIb implantable and Class III only
- Make PSURs available to the Notified Body involved in the conformity assessment and, upon request, to competent authorities for devices, other than Class III or implantable devices

This summary must be assessed by SGS and an evaluation report by SGS must be uploaded in the electronic system on vigilance and post-market surveillance (Article 92 of MDR).

After assessment and uploading of the assessment by SGS, SGS will or inform you of any actions that must be taken. This could include the provision of additional information to SGS, review by SGS of a technical documentation or information received, or an unscheduled audit. Work undertaken by SGS will be invoiced.

Manufacturers of Class I devices shall prepare a post-market surveillance report and update it, when relevant. This report may be requested by the competent authority.

This activity is undertaken off-site and will be identified in your proposal as an activity. If there is any appropriate action to be taken resulting from PSUR assessment, you will be notified in writing by SGS.

GENERAL

TRANSFER OF CERTIFICATION

If you have other current MDR certifications assessed by a designated Notified Body and this certification is up to date and in good standing, you can transfer to SGS at any time during the certification cycle. We will conduct a review of your current certification for which you will need to send us a copy of the relevant certificate(s), audit reports from the previous cycle, including the status of any outstanding corrective actions, and the approximate due date of your next visit. Following a review, we will provide you with a proposal to take over this certification within the existing cycle or start a new cycle, as preferred.

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

[7]Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

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.