Medical Device Regulation (EU) 2017/745 Annex IX section 5 specific procedures

This document outlines the assessment process for the above Regulation (EU) 2017/745 annex IX section 5. It outlines each stage of the audit process and gives essential guidance to organizations seeking certification and the regulatory and commercial conditions that apply. It is essential that it is read and understood to minimize nonconformities and delays in certification.

This document forms part of the overall information and requirements for certification services from SGS, along with the legal contract and SGS terms & Conditions. These are defined in the Special Conditions in this document.

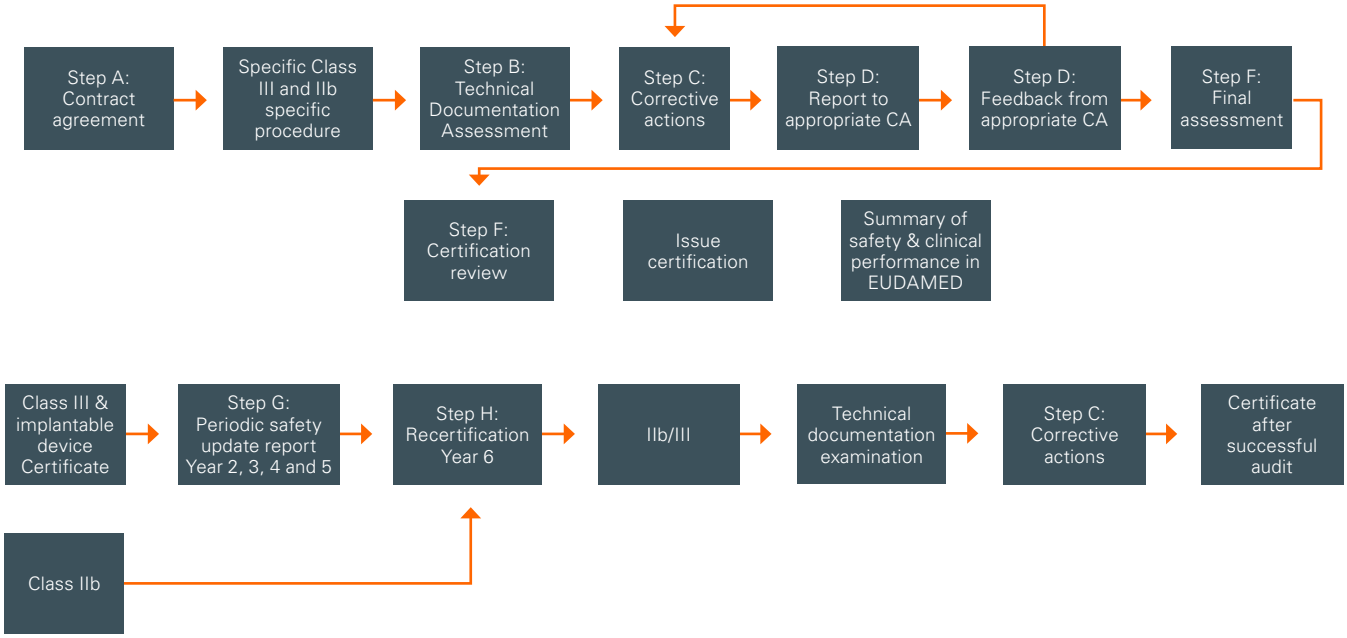
You are advised that by its nature and the involvement of governmental bodies this certification process takes a significant time and 6 to 18 months is typical dependent on the experience of the manufacturer.

SGS designation and approval status

SGS Belgium NV is a Notified Body for this range of Class III and IIb devices and certification will be undertaken as Notified Body 1639. This means you are entitled to use CE1639 on devices covered by your Technical Documentation Assessment Certificate on the completion of a successful assessment.

Please note class III and implantable class IIb[1] and class IIb active devices intended to administer and/or remove a medicinal product using CE1639 must also be covered by a current Annex IX (Section 1, 2, 3) certificate from SGS Belgium NV involving site audits.

OVERVIEW OF OUR CERTIFICATION PROCESS



The certification cycle is based on 5 years. However, SGS may, based on documented evidence, decide to reduce the cycle in 1 or 4 years 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.

Step A
Proposal and application

A proposal is submitted by SGS for consideration. If this does not adequately include all your requirements or you have questions, please contact this office as we are happy to discuss any queries and the next steps. This proposal is valid for 60 days. Once 60 days end, we will review the contract again and issue a new quote if necessary.

Application: To apply for certification and to start the assessment process the application form must be completed, signed and returned to this office. We recommend this is done as soon as your decision to proceed has been taken to allow maximum time for planning. Your application will be processed, and we will contact you to arrange the next steps of the audit process and dates.

What you need to send us: Please send any application fee shown in the proposal with the application form to allow us to start the assessment process promptly. SGS requires the following elements:

- a complete copy of your technical documentation. Technical documentation should be submitted in English and electronically on a secured USB stick or alternatives or by electronically secured web-based application with prior agreement from SGS (preferable SGS secured server Share Files). Documents should be presented in text searchable format (i.e. Text recognition PDF or Microsoft word format), All information should be appropriately indexed to allow easy access to the relevant information.
- If any relevant processes are subcontracted or outsourced, copies of any subcontractor/ supplier current certification should also be sent.
- This must include the supplier and processor of the animal material and any EDQM certificate issued to the animal material supplier. This must also include the supplier of the medicinal product.

For recertification, SGS also requires: sales numbers and a review of any complaints and PMS data and others any experience gained from post-market surveillance; a list of any changes since certificate issue; a recent or recently reviewed and revised risk analysis highlighting any new or emerging risks; any concessions or nonconformities raised since certificate issue; any change in relevant subcontractors and/or suppliers since certificate issue; any updated proof of compliance with general safety and performance requirements, change to applied or new harmonized standards, CS or equivalent document, change in any clinical data and change in medical, scientific and technical knowledge the current Authorized Representative (if appropriate) and the current labeling and instructions for use.

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 apply:

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 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 to benefit ratio or clinical evaluation of the device.

The applicant undertakes to institute and maintain a 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 certified devices.

The applicant undertakes only to affix the CE Mark when all requirements of Annex IX of the Regulation (EU) 2017/745 are met including a valid Technical Documentation Assessment Certificate for Class III devices and implantable class IIb[2] and class IIb active devices intended to administer and/or remove a medicinal product.

The applicant is responsible for all of 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 procedure required by MDR (EU) 2017/745 section 5 and external scientific opinion have to be requested by the Notified Body to complete certification, associated fees not depending on the Notified Body will be invoiced additionally.

The application is valid for a period of up to 1 year maximum 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 re-confirm all submitted information to get a new Contract proposal.

SGS

SGS undertakes that no confidential information will be disclosed to a third party, except to a regulatory or an 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 SGS as this cannot be considered confidential.

Competent Authorities including EU experts and EU Joint Assessment Team may access all information gathered during assessment of the applicant to verify that conformity assessment has been conducted by SGS in accordance with MDR requirements.

[2] 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 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 relevant supplier and/or subcontractor or following undue restrictions or pressure during the audit.

Unless stated in the proposal it has been 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 visits agreed at additional cost.

Step B
Application review and Assessment

An application review is conducted on- or off-site once we have received your application. During this step, the Notified Body will

- review the completeness of the application with respect to the requirements of the relevant conformity assessment procedure, 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 are applicable to the device in question under MDR
- reconfirm that the devices and the conformity assessment procedures chosen are within the designation of the Notified Body SGS
- reconfirm the availability of sufficient and appropriate Notified Body assessment resources for timely performing all tasks.

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

If the application is accepted, consecutively, the assessment is undertaken offsite. The assessment process commences with an appraisal of your technical documentation. This is to determine compliance with the general safety and performance requirement of Regulation (EU) 2017/745, EU Commission Guidelines, Common Specifications and any relevant standards. If there are significant nonconformities, you will receive an Initial Report outlining the nonconformities (Findings). All nonconformities must be corrected before a certification can be undertaken recommended. If this Assessment results in no nonconformities the process moves immediately to STEP D and the report, you receive is a draft Final Report.

Serious nonconformities with the Technical documentation, preparedness or existing certification could result in you being advised of additional costs and/or delay to the initial technical assessment of the Technical Documentation.

Step C
Corrective Action

Nonconformities may include documentation not included in the initial technical documentation, nonconformance to relevant standards and guidelines or weaknesses in the justification for the safety and performance of the device. Nonconformities must be fully corrected before submission to the relevant external agency can be made. After reviewing the Initial Report, you should as soon as possible contact your delivering affiliate to indicate the timescale for correction and if technical clarification is needed. When all Nonconformities have been addressed the relevant documentation must be sent to SGS for Review. If the assessment again finds significant Nonconformities, you will receive an updated Report indicating those nonconformities which have been closed and those which are not yet adequately addressed, and STEPS B and C will be repeated at additional cost. Note that subsequent annual reviews of your Summary of safety and clinical performance documentation is following the same review process as the initial assessment, with a review that can be followed by rounds of nonconformities and responses until all nonconformities are closed.

For new clients, if a Major CAR isn't closed in 1 year or two iterations (corrections/review), then the contract will be closed and so the entire audit process must start again from proposal stage. For other clients, Major CARS have a 30 days deadline, which may be extended if there is justification and at SGS discretion, if unclosed at 6 months the certification will be suspended and certification withdrawn after 1 year if still open.

Step D
Specific Procedure

Step D is the legal requirement to send any requested report to comply with described specific procedure from Regulation (EU) 2017/745 annex IX section 5 to appropriate competent authorities. SGS will consider your comments on the established report before the consultation process starts.

SGS will start the consultation process when your technical documentation is considered has been at the appropriate level (No nonconformities in relation to the specific procedure is open).

Applicable specific procedures (these procedures can be subject to significant delay as external bodies are not under the jurisdiction of SGS):

- For class III implantable devices and Class IIb active devices intended to administer and/or remove a medicinal product (rule 12 of MDR), SGS will prepare a clinical evaluation assessment report based on the clinical data provided as part of the assessment process. This report is sent to the Commission to get a scientific opinion from the relevant expert panel.
- For devices incorporating a medicinal substance, SGS shall verify the usefulness of the substance as part of the device and get a scientific opinion of the appropriate Competent Authority (designated in accordance with Directive 2001/83/EC) or EMA The manufacturer will be expected to supply technical documentation which relates to the drug substance as well as the technical documentation for the device, this will be requested when SGS is in a position to create a usefulness report for submission.
- For devices incorporating tissues or cells of animal origin or their derivatives, it is important to understand that only devices which can claim specific additional benefits from using TSE risk species will be certified. These claims and their justification must be fully documented in the technical documentation. SGS shall document a summary evaluation report in accordance with annex II of regulation (EU) n°722/2012 and send it to the appropriate Competent Authority for comments.

The consultation process will follow timelines set in Regulation (EU) 2017/745 annex IX section 5.

These timelines cannot be guaranteed by SGS, as the schedule for these external reviews is set by the external agency and is not under SGS control.

If negative feedback from the EU regulatory bodies is received this needs to be addressed by you by further justification or documentation. If concerns cannot be adequately addressed, certification will not be in your interests and will not be issued despite the earlier preliminary recommendation of the reviewer.

Step E
Completion of Assessment

Feedback received from the concerned competent authority will be taken into consideration for certification decision and the final report will be updated with the details of the external review and any actions required post-certification that are normally raised as Minor CARs or as interim review requirements. The report will fully describe the device, outlines your important documentation, reviews the history since original certification in the case of certificate renewals and describes any outstanding non-critical nonconformities for which minor nonconformities (Corrective Action Requests) are raised. Noncritical nonconformities must be corrected within defined timescales but do not delay certification.

It is a requirement of Medical Device Regulation (EU) 2017/745 for implantable 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 in the European database on medical devices (article 33, Medical device regulation (EU) 2017/745).

After review by SGS, we will, either upload it 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. This is part of the technical documentation examination process and will be invoiced at the same time as the certification of the device.

Step F
Certification review

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At the end of the assessment, including any consultation with the EU regulatory authorities and any other correspondence, the Final Technical Documentation Assessment report is compiled and reviewed with the other audit documentation and a certification decision is made including final approval of the summary of safety and clinical performance. This step can sometimes lead to limited changes in the non- conformities and scopes about which you will be informed. Once the certification decision has been made, the certificate is processed, and the summary of safety and clinical performance is uploaded by SGS to EUDAMED. You must be informed that Certificate validity may be reduced between 1 to 4 years during the certification decision process based on multiple aspects that would be justified to you if relevant.

Step G
Periodic Safety Update Report (PSUR)

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

- prepare the periodic safety update report (PSUR) as part of its post-market surveillance activities
- update at least annually for class IIb, 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 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 devices or implantable devices.

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

After assessment and uploading of the assessment by SGS, we 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 file or information received or an unscheduled audit. Work undertaken by SGS will be invoiced.

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

Step H
Recertification

Approximately one (1) year prior to certificate expiry you will receive a proposal for recertification. This should be accepted as a priority.

STEPS A to E are followed, although the assessment will be shorter and focus on changes, post-market activities and new risks.

For recertification, SGS requires a copy of the full dossier plus the following additional information:

- sales numbers
- a review of any complaints, PMS data and any experience gained from post-market surveillance
- a list of any changes since the certificate was issued
- a recent or recently reviewed and revised risk analysis highlighting any new or emerging risks
- any product released to the market under concession or nonconformities raised since certificate issue
- any changes in relevant subcontractors and/ or suppliers since certificate issue
- any updated proof of compliance with general safety and performance requirements
- changes to applied or new harmonized standards, CS or equivalent document
- changes in any clinical data and change in medical, scientific and technical knowledge
- the current Authorised Representative (if appropriate).

Changes

REQUESTS FOR CHANGES TO YOUR SCOPE OF CERTIFICATION

Changes to the product (design or method of manufacture or changes to relevant subcontractors and/ or relevant suppliers can be covered at any time during the certification cycle. SGS requires to be informed in advance so that they can be reviewed and an SGS form Notification of Proposed Significant Design Changes is available for this purpose and should be sent to this office. You will receive a proposal and application form which must be signed and sent to this office. STEPS A to E will then be followed.

Significant changes are described in MDCG guidance 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”

Although not all changes will require a review by an external authority, SGS recommends that you identify all changes that will require an external assessment, so you are prepared and have undertaken the correct validation processes when making design changes to your device.

Vigilance

REPORTING OF VIGILANCE

It is a requirement of Medical Device Regulation (EU) 2017/745 to report cases of Vigilance to the appropriate EC Competent Authority either on the European Electronic system on vigilance and on post-market surveillance when fully functional or using the relevant form, by you or your European Authorised Representative. A copy of the report submitted to the competent authority must also be sent to SGS with a completed SGS form LPMDREG2003 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. 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, we 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, review by SGS of a technical file or information received or an unscheduled 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 Class IIb implantable and Class III medical device manufacturers to draft a summary of safety and clinical performance as part of its technical documentation. This summary must be validated by SGS and upload in the European database on medical devices (article 33, Medical device regulation (EU) 2017/745).

After review by SGS, we 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.

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 the policy of the SGS Group to obtain all possible global approvals to support you. Therefore, we have auditors with knowledge of a wide range of regulatory requirements.

Currently, these include:

- In Vitro Diagnostic Device Regulation (EU) 2017/746 (IVDR CE marking for Europe)
- MDSAP Program
- Pharmaceutical Affairs Act and ISO 13454 (ROC Taiwan)

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 their website (https://ec.europa.eu/docsroom/documents?locale=en&keywords=medical%20device) :
  - 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 provides a means of complying with the legal obligations applicable to a device, process or system
  - Guidance's (MDCG guidance)

European Harmonised Standards whilst not being mandatory are used by most manufacturers to demonstrate compliance with Medical Device Regulation (EU) 2017/745 (MDR) and so are recommended.

- Devices incorporating animal materials will be subject to assessment against EN 12442:2000 Parts 1, 2, 3 Animal Tissues and their Derivatives Utilised in the Manufacture of Medical Devices and MEDDEV 2.5.8 Guidelines on Assessment of Medical Devices incorporating Materials of Animal Origin with Respect to Viruses and Transmissible Agents.

About SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 93,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world.

We offer the following main services:

- 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 (for example, 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 over 50 different training solutions in a variety of management systems complemented by a wide range of other specialized courses. These are offered publicly, 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:

- Quality Management Systems (ISO 9001)
- Environmental Management (ISO 14001)
- Information Security Management (ISO 27001)
- Public Sector Customer Service Excellence
- Occupational Health and Safety (ISO45001)
- Corporate Responsibility (SRA)
- EC directives (CE Mark) and other regulations;
- Medical Device Certification (ISO 13485 and MDSAP)
- Food Safety Management Systems (ISO 22000).

For more information on any of our services visit www.sgs.com.