Your certification process explained

MEDICAL DEVICE REGULATION (EU) 2017/745
ANNEX IX SECTION 5 SPECIFIC PROCEDURES

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.

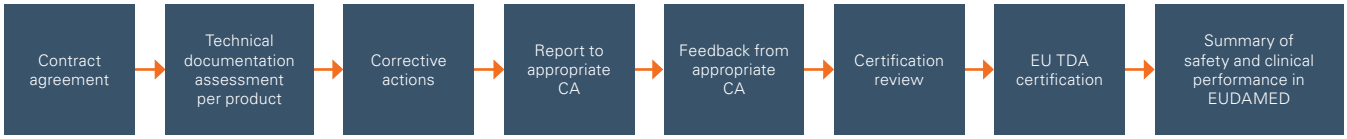
You are advised that, by its nature and the involvement of governmental bodies, this certification process takes a significant time, up to 6 to 18 months depending on the experience of the manufacturer.

Please note that this contractual annex is to be read together with Your Certification Process Explained – Medical Device Regulation (EU) 2017/745 Annex IX or XI Part A and Your Certification Process Explained – Medical Device Regulation (EU) 2017/745 Annex IX Section 4 and 5.

SGS DESIGNATION AND APPROVAL STATUS

SGS Belgium NV is a Notified Body for Class III and IIb devices, and certification will be undertaken as Notified Body 1639. This means that you are entitled to use CE 1639 on devices covered by your EU technical documentation assessment certificate, on completion of a successful assessment. Please note that devices covered by Annex IX Section 5 specific procedures must also have 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 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.

APPLICATION

WHAT YOU NEED TO SEND 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 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

APPLICATION REVIEW AND CONTRACT PROPOSAL

Application review and contract proposal follow the same process as described in Your Certification Process Explained – Medical Device Regulation (EU) 2017/745 Annex IX or XI Part A and Your Certification Process Explained – Medical Device Regulation (EU) 2017/745 Annex IX Section 4 and 5.

TECHNICAL DOCUMENTATION ASSESSMENT – SPECIFIC PROCEDURE

It is a legal requirement to send any requested report, to comply with the described specific procedure from Regulation (EU) 2017/745 Annex IX Section 5, to the appropriate competent authorities. SGS will consider your comments on the established report before the consultation process starts, and will start the consultation process when your technical documentation is considered to be at the appropriate level (no nonconformities relating to the specific procedure are 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 that 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 that 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) 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's 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.

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 corrective action requests (CARs) or as interim review requirements. The report will fully describe the device, outline your important documentation, review the history since original certification in the case of certificate renewals and describe any outstanding non-critical nonconformities for which minor nonconformities (CARs) are raised.

Noncritical nonconformities must be corrected within defined timescales but do not delay certification.

After review by SGS, SGS will either upload it to 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.

CERTIFICATION REVIEW

CE 1639

At the end of the assessment, including any consultation with the EU regulatory authorities and any other correspondence, the 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 scope about which you will be informed. Once the certification decision has been made, the EU technical documentation certificate is processed, and the summary of safety and clinical performance is uploaded by SGS to EUDAMED. You must be informed that the 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.

RECERTIFICATION

Approximately one year before the certificate expiry, you will receive a proposal for recertification that focuses on the assessment of 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 the certificate was issued
- Any changes in relevant subcontractors and/or suppliers since the certificate was issued
- 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 medical, scientific and technical knowledge
- The current Authorised Representative (if appropriate)