Your certification process explained

MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX IX SECTION 4 AND 5

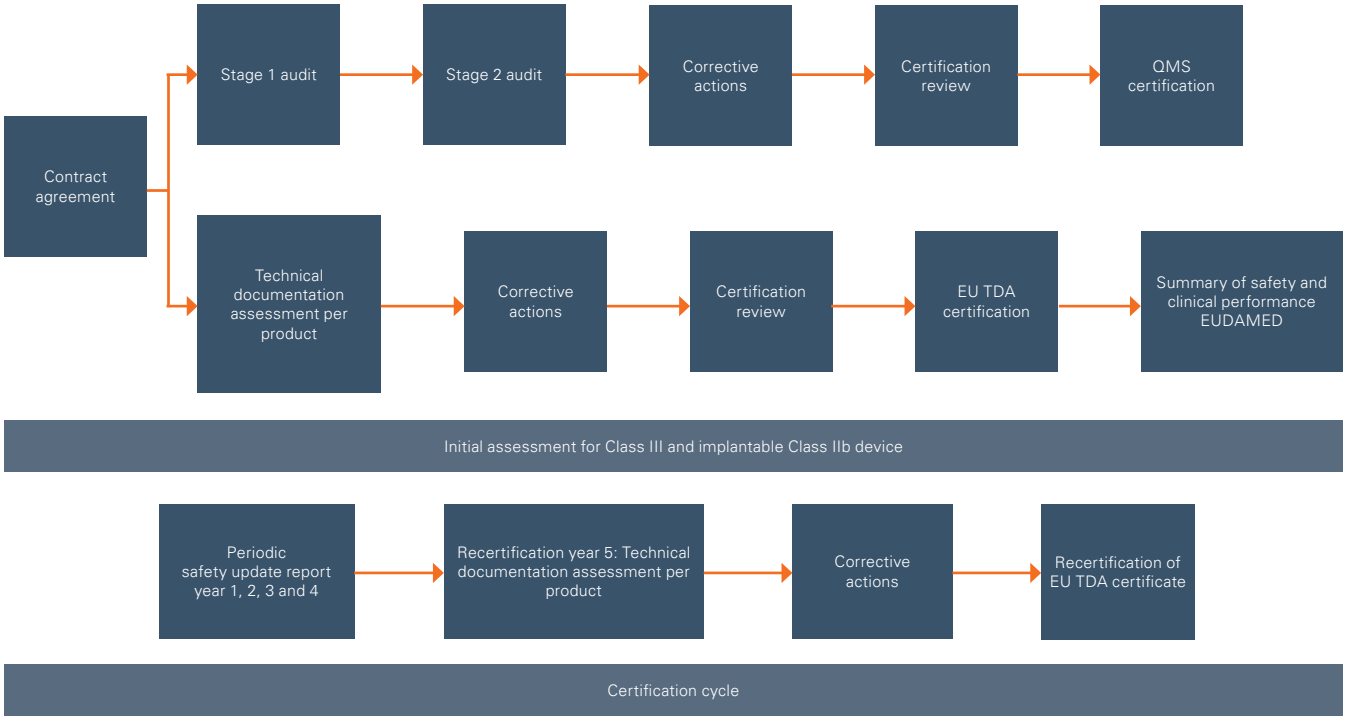
This document outlines each stage of the assessment process for the above regulation and gives essential guidance to organizations seeking certification. You must read and understand it to minimize nonconformities and delays in certification.

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.

SGS DESIGNATION AND APPROVAL STATUS

SGS Belgium is a Notified Body for Class III and implantable Class IIb devices, and certification will be undertaken as Notified Body 1639. This means 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 Class III and implantable Class IIb[1] must also be covered by a current Annex IX (Sections 1, 2 and 3) certificate from SGS Belgium 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.

[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 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 a 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

APPLICATION REVIEW AND CONTRACT PROPOSAL

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

TECHNICAL DOCUMENTATION ASSESSMENT

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

Once all nonconformities have been closed, the assessor will make a recommendation for certification. The final report fully describes the device, outlines your important documentation, reviews the history since original certification in the case of certificate renewals, contains details of all deficiencies raised and the methods by which they have been closed and describes any outstanding non-critical deficiencies for which minor nonconformities (corrective action requests) are raised. These must be corrected before a given date but do not delay certification.

CERTIFICATION REVIEW

CE 1639

Following the completion of the technical documentation assessment, 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 assessment certificate is processed and the summary of safety and clinical performance is uploaded by SGS in EUDAMED. 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.

RECERTIFICATION

Approximately one year before 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, vigilance reports, 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 change in relevant subcontractors and/or suppliers since certificate issuance
- 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 medical, scientific and technical knowledge
- Current Authorised Representative (if appropriate)