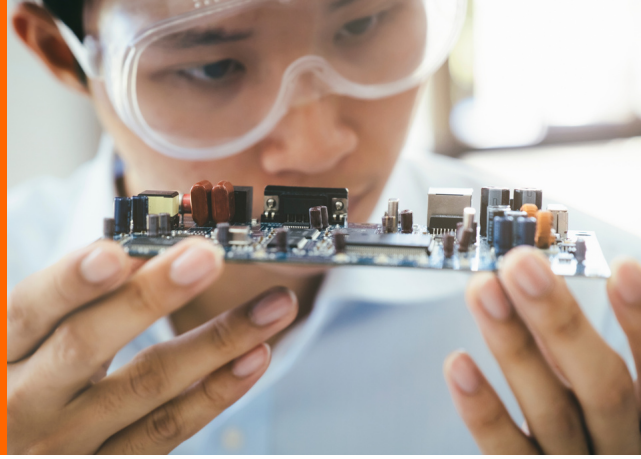
Your certification process explained

MEDICAL DEVICE REGULATION (EU) 2017/745

Article 117



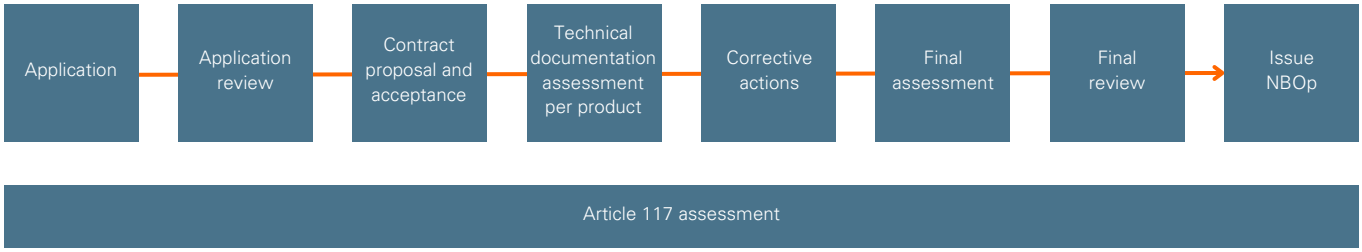
This document outlines the assessment process for the above regulation. It outlines each stage of the assessment process and gives essential guidance to organizations seeking certification and the regulatory and commercial conditions that apply. It must be read and understood to minimize nonconformities 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 and Conditions. These are defined in the Special Conditions in this document.

SGS DESIGNATION AND APPROVAL STATUS

SGS Belgium is a Notified Body for Medical Devices according to its official Designation in NANDO https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.notifiedbody&refe_cd=EPOS%5F55053, including assessment according to MDR Article 117.

OVERVIEW OF OUR CERTIFICATION PROCESS



For applications under Article 117, following a satisfactory assessment of your technical documentation, SGS shall provide a Notified Body Opinion (NBOp) on compliance with the GSPRs. This is a one-off statement. A certificate will not be issued, there will be no annual fee or requirement to undergo recertification.

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 format). 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

APPLICATION REVIEW

A review of your application is conducted off-site. 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
- Verify that assessment according to Article 117 is 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

Based on the application review a contract proposal is created. 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 technical documentation assessment is conducted off-site.

CONTRACT PROPOSAL

A contract 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 contract proposal is valid for 60 days. Once the 60 days end, we will review the contract proposal again and issue a new quote if necessary.

Application: To apply for certification and to start the assessment process, the contract proposal must be completed, signed and returned to this 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 maintain its adequacy and efficiency.

The application is valid for up to one (1) year maximum after the effective date of the contract. If the assessment has not been scheduled after this period, then the contract becomes void and the applicant needs to reconfirm all submitted information to get a new contract proposal.

The applicant is responsible for all fees and costs associated with any activity that SGS considers necessary to provide the Notified Body Opinion (NBOp) on compliance with the GSPRs, including additional review time to close the potential nonconformities detected during the assessment.

SGS

SGS undertakes that no information will be disclosed to a third party, except to a regulatory or enforcement authority, where they are entitled to be informed under MDR (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 EU Joint Assessment Team, may have access to all information gathered during assessment of the applicant to verify that the conformity assessment has been conducted by SGS in accordance with MDR requirements.

TECHNICAL DOCUMENTATION ASSESSMENT

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 Annex I, MDCG Guidance, Common Specifications and any relevant standards. If there are significant deficiencies, you will receive an initial report outlining the nonconformities.

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 start the assessment again. The review will be charged, even if the review has been stopped early as the technical documentation is not compliant. Serious nonconformities with the technical documentation could result in you being advised of additional costs and/or delays to the initial assessment of the technical documentation.

CORRECTIVE ACTIONS

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 a positive Notified Body Opinion (NBOp) on compliance with GSPRs can be provided. After receiving the technical documentation assessment report, we request you to indicate as soon as possible the timeline for correction of any nonconformities and provide any technical clarification if needed. When all deficiencies have been corrected, the relevant documentation must be sent to SGS for review to confirm the deficiencies have been addressed. It is not advisable to send further documents until you have corrected all nonconformities. If the assessment again finds significant deficiencies, you will receive an updated assessment report indicating the nonconformities that are corrected and those that are not yet adequately corrected.

If a major nonconformity is not closed within one (1) year, then the contract will be closed and so the entire assessment process must start again from the proposal stage. Additional time to review and close the nonconformities will be invoiced in addition to the technical documentation assessment.

COMPLETION OF ASSESSMENT

Following completion of the technical documentation assessment and closure of all nonconformities, the assessor will make a recommendation for issuing the Notified Body Opinion (NBOp) on compliance with the GSPRs. The final assessment report is compiled and describes the device, outlines your important documentation, contains details of all deficiencies raised and the methods by which they have been closed.

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.

These include:

- MDSAP program
- ISO 13485
- 3P510k
- 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 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 provide a means of complying with the legal obligations applicable to a device, process or system
  - Guidance (MDCG guidance)
- European Harmonised Standards. While not being 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: http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation

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 98,000 employees, SGS operates a network of over 2,650 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 (e.g. ISO 9001), or our customers' products. We also develop our own standards to meet 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 and unrivaled expertise in virtually every industry, SGS covers the entire supply chain, from raw materials to final consumption
- Training services – we offer over 50 training solutions in a variety of management systems, complemented by a 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:

- 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.