Medical Device Regulation (EU) 2017/745 Voluntary change of Notified Body

This document outlines the voluntary change of Notified Body (certification transfer) process and must be read in conjunction with the equivalent document for each type of certification being transferred. It outlines the transfer process and gives essential guidance to organizations seeking certification transfer to SGS.

SGS designation and approval status

SGS Belgium NV is a Notified Body with a notification scope described in the official European Nando database.

Based on the information we received from you, SGS Belgium NV is a Notified Body for your range of products and certification will be undertaken as Notified Body 1639. This means you will be entitled to use CE 1639 on devices within your scope of certification on the completion of a successful on-site audit and technical documentation assessment. Class III, implantable class IIb[1] and class IIb active devices intended to administer and/or remove a medicinal product must additionally have a Technical Documentation Assessment certificate before using CE 1639.

Generality

If you have other current certifications assessed by a designated certification body and this certification is up to date and in good standing, you can decide to voluntary change of Notified Body from your current Notified Body to SGS Belgium NV at any time during the certification cycle. We will conduct a review of your current certification and, in order for us to do this, you will need to send us a copy of the relevant certificate(s), the actual cycle audit reports, 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 per our risk assessment.

Voluntary change of Notified Body to SGS Belgium NV includes certification as Notified Body 1639 under European Medical Device Regulation (EU) 2017/745 (MDR).

Voluntary change of Notified Body can only take place whilst your current certificates are valid and the first SGS audit should take place in accordance with the audit schedule of your current certification.

If you think you may not meet the above criteria, please contact us to discuss the options available to you for certification with SGS.

The certification cycle is normally 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.

Application

On receipt of the application form, SGS will send you a Medical Device Voluntary Change of Notified Body Agreement to complete and sign. This will ask you to supply the following information to allow the transfer process to proceed:

- Copies of Audit reports from your current Notified Body certification cycle
- Copies of nonconformities raised in your current certification cycle
- Copies of Technical Documentation Assessment Reports (if applicable)
- Copies of labeling (which includes e.g., labels, Instructions for Use) for MDR Class III and implantable class IIb[2] and class IIb active devices intended to administer and/or remove a medicinal product
- A summary of complaints since your last audit
- A summary of any adverse event reports or regulatory actions since your last audit
- Date of validity of your current certificate.
- Other information can be requested (or is sent by you in addition) such as:

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

- last batch or series number under your current Notified Body responsibility
- PSUR (Periodic Safety Update Report) for your class IIa, IIb and/or III devices
- SSCP (Summary of safety and clinical performance) report for MDR Class III and implantable class IIb2 and class IIb active devices intended to administer and/or remove a medicinal product.

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 understands that if the certification which is to be transferred is not current or valid at the time of voluntary change, SGS cannot issue valid certification by the voluntary change process and that any certification may be subsequently withdrawn.

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 understands that following a positive voluntary change process and the decision to issue SGS certificates but before the certificates have been issued SGS must contact the current certification/Notified Body to reconfirm validity of the certificates being transferred and agree the date at which the existing Notified Body certificates are withdrawn and SGS certificates are issued (transfer date). In normal circumstances, the applicant will retain valid certification at all times during the voluntary change process so that business will not be disrupted.

The application is valid for a period of up to 1 year maximum after the effective date of the contract. If the voluntary change assessment has still not been scheduled after this period, then the contract proposal becomes void and the applicant will require to sign a new contract with SGS.

The applicant undertakes to inform NB1639 in advance of implementation, of any change that could impact the compliance of the device with the Medical device regulation (EU) 2017/745 affect the risk- benefit ratio or clinical evaluation of the device.

Technical documentation should be submitted in English and electronically sent to the SGS secured server ShareFile. Documents should be presented in text searchable format (i.e. Text recognition PFD or Microsoft word format), All information should be appropriately indexed to allow easy access to the relevant information.

The applicant understands that as soon as possible and within 6 months of SGS certification all references and labelling (where applicable) must have been changed to refer to SGS Belgium N.V. and Notified Body 1639 (where applicable).

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 devices certification with technical documentation under specific additional procedure required by MDR (EU) 2017/745 section 5 and external scientific opinion is to be requested by the Notified Body to complete certification, associated fees not depending on the Notified Body will be invoiced additionally.

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 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 as confidential. Competent authorities including EU experts and the Joint assessment team may access to all information gathered during assessment of the applicant to verify that 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 critical supplier or sub-contractor or following undue restrictions or pressure during the audit.

Transfer audit

APPLICATION REVIEW AND STAGE 1 AUDIT – PREPAREDNESS REVIEW

An application review & stage 1 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).

The application review /stage 1 is conducted on-site as default but could be off site if specific circumstances are met. Application review 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:

- 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 the identification of 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 level of implementation of the management system confirms that you are ready for the stage II audit.

Stage 1 determines compliance with the documentation requirements of Medical Device Regulation (EU) 2017/745 and the allocation of resources and working documentation for the Stage 2 audit.

You will receive a Stage 1 audit report outlining any deficiencies (findings) to enable immediate action to be taken prior to moving forward through the process. An audit plan for the stage 2 on-site audit will also be forwarded to you at this stage. Technical Documentation (which is a mandatory part of the application) will also be reviewed, where applicable, on a sampling basis, and you will receive an assessment report including nonconformities if appropriate. The reviews will normally be incorporated into one final report at the end of Stage 2. Serious deficiencies with the QMS and technical documentation, preparedness, existing certification or certification of a relevant sub-contractor and/or supplier could result in you being advised of additional costs and/or delay to the Stage 2 audit QMS audit or initial technical review of the technical documentation.

STAGE 2 AUDIT

This Step replaces the Stage 2 Audit step for quality management certification. The checks made, and documentation viewed will allow SGS to complete the transfers in accordance with relevant documents listed at the end of this document.

This step will take place as an off-site review or on-site review (as detailed in the proposal) of the information supplied with the Medical Device Voluntary Change of Notified Body Agreement. If undertaken off-site, the auditor will probably contact you to confirm some of the details before completing the report. If undertaken on-site the auditor will briefly review your major processes, management review and internal audit.

All existing nonconformities issued during the current certification cycle will be reviewed and nonconformities without confirmation of effective corrective action will be issued as SGS Corrective Action Requests.

At the conclusion of the audit, the audit team will make a recommendation dependent on the findings. The auditor will also agree with you the name, address and scope details that will appear on your certificates when they differ from the existing certificates.

Serious deficiencies with the QMS & Technical documentation, preparedness, existing certification or certification of a relevant sub-contractor and/or supplier could result in you being advised of additional costs and/or delay to the Stage 2 QMS audit or initial assessment of the Technical Documentation.

CERTIFICATION REVIEW

Once the certification decision has been made to issue the certificates and a date agreed for voluntary change, your existing Certification Body /Notified Body is contacted to confirm certificate

Corrective actions and plans

Any major nonconformities (major Corrective Action Requests) raised by the previous Certification Body/Notified Body will result in SGS reassessing the transfer and contacting you in order to discuss what actions are required to achieve SGS certification. This may be the submission of further documentation, a short site audit or a full recertification audit depending on the circumstances. You will be informed of any additional costs associated with this supplementary action. Certification will be deferred until SGS can confirm the status of your existing certification and the conformance of your organization with the certification requirements.

For new clients, if a Major CAR isn't closed in 1 year, 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 day 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.

All minor nonconformities (minor Corrective Action Requests) raised by the previous Certification Body/Notified Body should have the root cause and a corrective action plan considered and documented by you on the form and your corrective action will be followed up at the first scheduled audit.

Certification review

CE
1639

Once the certification decision has been made to issue the certificates and a date agreed for voluntary change, your existing Certification Body /Notified Body is contacted to confirm certificate validity.

Certificates will be issued valid from the agreed transfer date to the date when your existing certificates expire. You must be informed that Certificate validity may be reduced in 1 to 5 years during the certification decision process, based on multiple aspects that would be justified to you if relevant.

Unannounced audits

These audits can be undertaken at any time within the certification cycle excluding prior agreed periods of unavailability. 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 will be asked once a year per SGS using the Unannounced audit questionnaire. In the absence of feedback to this questionnaire, in the month following the request by SGS, 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 and, so it is your obligation to help define these locations and to facilitate these audits.

These audits will concentrate 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 normally be once in every five-year period. However, this frequency is increased for high- risk devices in every three-year period or at the discretion of SGS if we receive information during audits or from other sources that devices may be nonconforming. Minimum duration of an unannounced audit is 1 day for 2 auditors at the same time.

This applies even if the current Notified Body has undertaken an unannounced audit.

Surveillance and recertification

Subsequent audits will take place in line with the schedule from your previous certification body.

General

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.

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 2,400 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, unrivalled 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.

The SGS certification section provides independent certification and audits to a range of standards, including:

- Quality Management Systems (ISO 9001)
- Environmental Management (ISO 14001, BS8555 and EMAS)
- 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.

WHEN YOU NEED TO BE SURE