Your certification process explained

MDR – MEDICAL DEVICE REGULATION (EU) 2017/745

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Contents

This important document outlines the process to obtain an MDR (EU) 2017/745 certificate from SGS Belgium NV, as a medical device Notified Body 1639. It describes each stage of the conformity assessment process and gives essential guidance to organizations seeking certification, as well as the regulatory and commercial conditions that apply. It must be read and understood to minimize nonconformances 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

Introduction

SGS Belgium NV (Notified Body 1639) is a medical device notified body. We are designated to certify all types of medical devices, including those without an intended medical purpose. Once certified with us, you will be entitled to affix the CE 1639 mark to your medical devices and to place them on the European Union market.

All devices certified by SGS NB 1639 require you to get an EU Quality Management System (hereafter QMS) certificate. Class III and implantable Class IIb[1] must also have an EU Technical Documentation Assessment certificate before using CE 1639.

We can also provide quality management certificates to distributors or importers carrying out any activity mentioned in points (a) and (b) of MDR Article 16(2), subject to an application and audit procedure. The sections applicable for this type of assessment will be indicated.

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

Information for new clients before submission

SGS Belgium NV (Notified Body 1639) is part of SGS Group, a world-leading testing, inspection, verification and certification company. In order to effectively meet your needs, we provide our services globally via a network of affiliates, referred to as "SGS Delivering Offices". Your local SGS Delivering Office will serve as your primary point of contact throughout your certification process.

The conditions established in the following documents apply to your CE certification with SGS:

- SGS Code of Practice
- SGS General Conditions for Certification Services
- Regulations Governing the Use of SGS Certification Marks

Do not hesitate to contact your SGS Delivering Office to obtain more information about the certification process.

Fees

A list of standard fees for conformity assessment activities under MDR (2017/745) is available on our EU Medical Device Regulation (MDR) Information Center.

Please contact your local SGS Delivering Office to discuss a price estimate tailored to your device portfolio.

Product Risk Classification & Conformity Assessment Route

The first step will be for you to determine your product(s) classification according to the rules defined in Annex VIII of the MDR. For clarification and further guidance, please refer to MDCG 2021-24.

Subsequently, you must decide which type of conformity assessment path you wish to apply, which is either:

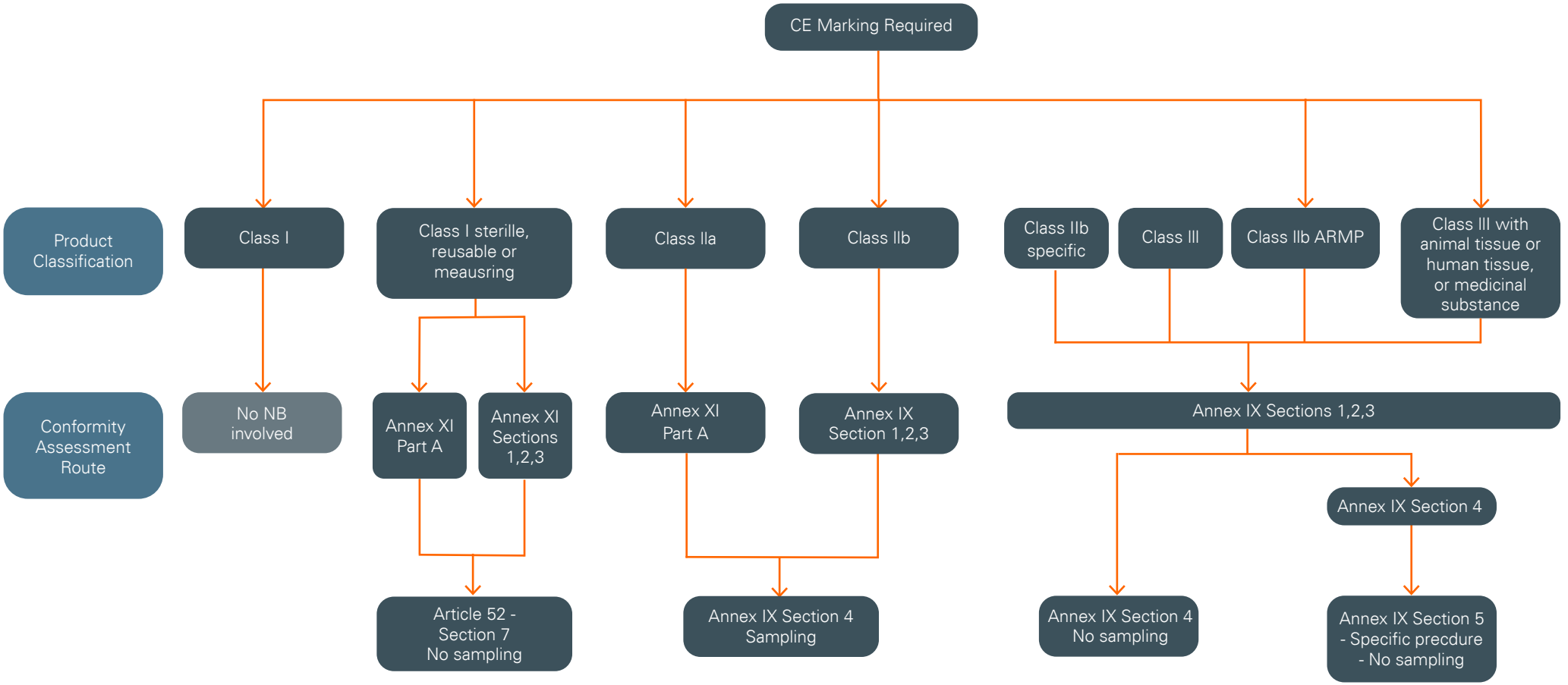
- Conformity Assessment based on the Quality Management System (QMS) and Technical Documentation Assessment (TDA), as per Annex IX of the MDR
- Conformity Assessment based on Product Conformity Verification (Production Quality Assurance), as per Annex XI Part A of the MDR

For devices that are "medicinal" and governed by Directive 2001/83/EC, according to Article 8 of the MDR, SGS NB 1639 can propose an assessment, according to MDR Article 117, to provide a Notified Body opinion on compliance with GSPR for the medical device part of a drug-device combination.

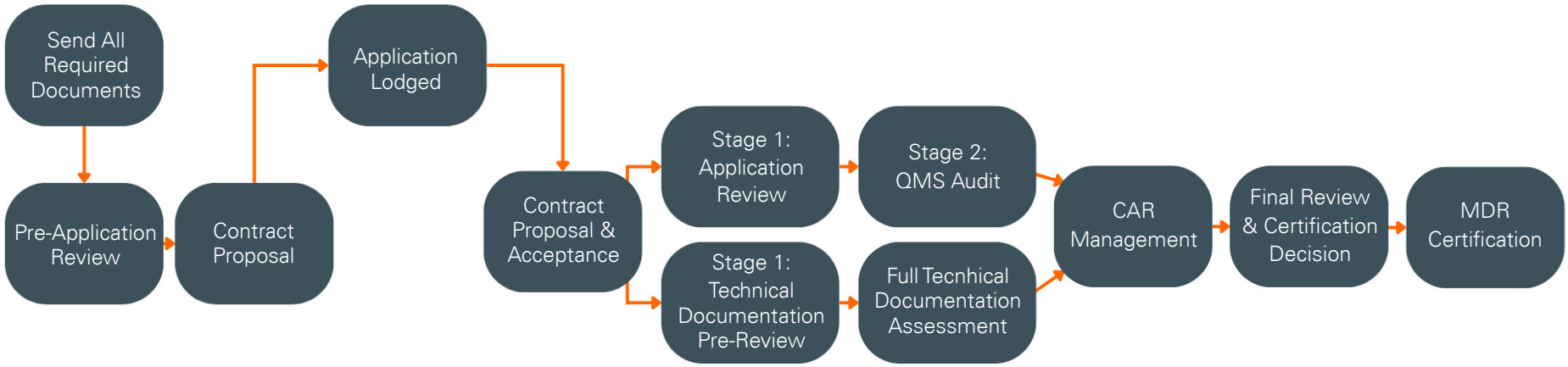
The diagrams below present the type of conformity assessment per device class and guide you through the appropriate certification process that we may offer. For these diagrams:

- "Class I Reusable" is an abbreviation of "Class I reusable surgical instruments".
- "Class IIb Specific" are implantable Class IIb devices, except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.
- "Class IIb ARMP" is an abbreviation of "Class IIb Administer and/or Remove Medical Product".
- "CAR" is an abbreviation of "Corrective Action Request".

Overview of Conformity Assessment routes from SGS NB 1639



Overall Conformity Assessment Process for QMS Audit and Technical Documentation Assessment



Important information

Certification Cycle and Surveillance

The certification cycle is normally five (5) years. However, as stipulated in the MDR, we reserve the right to shorten the cycle to four (4) years or less, based on the results of the initial, surveillance or re-certification conformity assessment, or due to other factors, such as vigilance issues or unannounced audit findings.

Throughout the certification cycle, we will periodically, at least once every 12 months, carry out surveillance audits and technical documentation assessments to ensure that your approved quality management system remains effective and that certified products remain safe and perform as intended.

Changes / Amendments

Once your CE certification is awarded, and in the event of any developments that would alter the scope of your current certificate (such as a change of site or product range, reductions in scope, change in the company name, etc.) you must inform us in advance and wait for SGS NB 1639 official approval issued in writing before implementation of respective changes. Please consult Annex 1 and the flowchart contained within to determine for which changes the prior notification to and official approval by SGS NB 1639 is required.

Lodging your application

(sending all required documents)

Please acknowledge that your application, technical documentation and any subsequent correspondence, including response to corrective action requests must be submitted in English. Nevertheless, we can generally accept that your QMS is either in your local language or English.

To apply for certification and to initiate the assessment process, please contact your local SGS Delivering Office which will provide you all the necessary application documents (Medical Device Questionnaire, Product Information Questionnaire[2] and List of Relevant Subcontractors and Suppliers) and will support you through every step of the certification process.

Subsequently, please complete, sign and return relevant documents to your local SGS Delivering Office.

In the Medical Device Questionnaire, as well as in the Product Information Questionnaire(s), the following must be clearly indicated:

- If your devices contain a component/element:
  - That has or may have a possible pharmacological, immunological, metabolic or antimicrobial activity (according to the European Medical Device Regulation (hereafter MDR) 2017/745
  - That contains animal tissue or derivatives thereof (according to Regulation (EU) No 722/2012)
  - That contains phthalate (according to MDR (EU) 2017/745 Annex I Section 10.4.3)
  - That contains human cells, blood, tissue or derivatives thereof (according to European Directive 2004/23/EC)
  - Substance(s) that is partially or fully absorbed, or undergoes a chemical change in the body
  - That contains nanomaterials (e.g. nano-hydroxyapatite, nano-silver) or may generate nanosized particles (e.g. due to wear-and-tear) according to Commission Recommendation 2011/66/EU of October 18, 2011

[2] Please note that for systems and procedure packs (MDR 2017/745 Article 22), the System and Procedure Pack Product Information Questionnaire shall be utilized instead of Product Information Questionnaire.

If any critical processes (such as sterilization, testing or full manufacturing process) are subcontracted or outsourced, copies of any relevant subcontractor/supplier certification should be sent together with the List of Relevant Subcontractors and Suppliers.

By submitting the Medical Device Questionnaire, as well as the Product Information Questionnaire(s), you confirm that as the legal manufacturer of the device you:

- Have an up-to-date documented quality management system available for audit by SGS.
- Fulfil the obligations imposed by the quality management system.
- Have a description of the procedures in place to ensure that the QMS remains adequate and effective, and the undertaking by the manufacturer to apply those procedures.
- Did not lodge nor will lodge an application with another Notified Body for the same device-related conformity assessment procedure.
- Have up-to-date technical documentation in English available for assessment by SGS NB 1639. This must contain or refer to documents which contain:
    - All the QMS requirements. No process related to the certified medical devices may be withheld from the Notified Body, including design, manufacture, purchase, inspections, etc. This applies to processes under direct control and those carried out by suppliers and subcontractors.
    - The full product specifications, including qualitative and quantitative descriptions of the product composition and list of components. No product specifications of the certified medical devices may be withheld from the Notified Body. This applies to components manufactured in-house and those purchased from external suppliers.
- Initiate and maintain a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Chapter VII Section 2 Article 87 of the MDR (EU) 2017/745, and to implement appropriate means to apply any necessary corrective action.
- Recognize your obligation to notify and submit relevant reports to the competent authorities and SGS NB 1639 of the following incidents immediately upon learning of them:
    - Any serious incident involving your devices made available on the European Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88,
    - Any field safety corrective action in respect of your devices made available on the European Union market, including any field safety corrective action undertaken in a third country, in relation to a device that is also legally made available on the European Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The above-mentioned reports shall be submitted through the electronic system referred to in Article 92 of the MDR.

Pre-application review

Your completed and signed Medical Device Questionnaire, Product Information Questionnaire(s) and List of Relevant Subcontractors and Suppliers are reviewed by SGS NB 1639. During this step, we 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 (Annex IX or XI Part A for SGS NB 1639).
- Request additional information, if necessary.
- 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 the MDR.
- Confirm that the devices and the conformity assessment procedures chosen lie within the scope of SGS NB 1639 designation.
- Confirm that SGS NB 1639 has sufficient and appropriate resources to carry out the conformity assessment in a timely manner.

Based on the pre-application review, we will create a contract proposal. A commercial proposal and associated master service agreement will be shared with you and henceforth SGS NB 1639 considers your application officially lodged.

At this point, you can decide whether to sign the contract proposal and proceed with the certification process with SGS NB 1639.

In exceptional circumstances, SGS NB 1639 may refuse the application following the pre-application review.

This could be caused by an incomplete application or problems in the application documents, when some of the devices included in the application are outside of the SGS NB 1639 designation scope, or where we do not have sufficient resources available to serve you.

Please note that any refusal or withdrawal from the point where your application is considered officially lodged by SGS NB 1639 or later, such as after contract signature or application review (Stage 1 audit), will be notified in EUDAMED by SGS NB 1639.

Information for existing clients

FOLLOWING APPLICATION SUBMISSION

Contract Proposal

The contract proposal, consisting of a Master Service Agreement and commercial proposal (including quotation) is presented to you by your local SGS Delivering Office for your consideration. If the contract proposal does not adequately include all your requirements or if you have questions, please contact your local SGS Delivering Office to discuss any queries and the next steps. The contract proposal is valid for 60 days.

Once the 60 days end, we will review the contract and issue a new quote, if necessary. Please note that we can only enter a contract with the legal manufacturer.

To apply for certification and to start the assessment process, the contract proposal (commercial proposal and associated Master Service Agreement) must be completed, signed and returned to SGS NB 1639 via your local SGS Delivering Office. We recommend this be done as soon as your decision to proceed has been made to allow maximum time for planning.

Once you have signed the contract, you must notify us of any change and receive official written approval from SGS NB 1639 before its implementation, as per the dedicated section on Notification of Changes below.

Your responsibilities and duties as an applicant (or certified client)

As the legal manufacturer making the application (the applicant), you retain full liability for registered products and/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 us before an application is accepted.

The applicant undertakes to carry out all obligations arising from a certified quality management system and applicable regulations and maintain its adequacy and efficiency.

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

The applicant undertakes to inform SGS NB 1639 in advance of implementation of any change that could impact the compliance of the device with the MDR (EU) 2017/745, affect the risk-benefit ratio or impact the clinical evaluation of the device.

The applicant undertakes to institute and maintain a post-market surveillance system in accordance with MDR Chapter VII and to inform SGS NB 1639 in writing of any substantiated Vigilance Reports on certificated devices.

The applicant undertakes only to affix the CE Mark when all requirements of the MDR (EU) 2017/745 are met. For Class III and implantable Class IIb[3] devices, this includes a valid EU Technical Documentation Assessment certificate.

The applicant is responsible for all fees and costs associated with any activity that SGS considers necessary to grant or maintain certification, or which are required by a European competent authority. If the proposal includes device certification with technical documentation under specific additional procedures required by MDR (EU) 2017/745 Section 5, and external scientific opinion must be requested by the Notified Body to complete certification, associated fees, not depending on the Notified Body, will be invoiced additionally.

The applicant is responsible for informing SGS of all information necessary to ensure that audits, unannounced audits, assessments and communications can be efficiently and effectively undertaken, that certification accurately reflects the current activities and product ranges, and that SGS is aware of all significant proposed changes. For more information, please consult the section dedicated to Notification of Changes and Annex I.

The applicant is responsible for the right of access of SGS to each of its sites covered by the certification scope, including defined suppliers and subcontractors, both for unannounced audits and scheduled audits (initial, surveillance and re-certification). Your contracts with relevant suppliers and subcontractors must include this stipulation. The applicant must annually inform SGS NB 1639 of any periods during which unannounced audits cannot be conducted for each of its relevant suppliers and subcontractors.

Details of the applicant's processes for certification and control of outsourced activities are not assessed at the contract proposal stage. Therefore, if certification and control of relevant subcontractors and suppliers are found to be inadequate after application, further audits may be required, incurring additional costs.

The applicant will facilitate, as far as legally possible, the obtaining of visas for auditors to undertake audits.

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

The applicant takes full responsibility for the safety and security of the audit team while on-site and for scheduled audits, including advising on safe travel and accommodation arrangements, when necessary.

SGS responsibilities and duties as Notified Body (NB 1639)

We will not disclose any client information to third parties, with the exception of regulatory or enforcement authorities, where they are entitled to be informed under the MDR (EU) 2017/745. This excludes information made publicly available in EUDAMED according to the MDR (EU) 2017/745, as this information cannot be considered confidential.

Competent authorities, including EU experts and the 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.

We retain the right to suspend, withdraw or amend the scope of certification by informing the organization in writing with justification for such a decision. This includes suspension following a refusal to accept a scheduled or unannounced audit, or following undue restrictions or pressure during the audit, either at your site or that of a listed relevant supplier or subcontractor.

We retain the right to take photographs of devices and manufacturing sites, collect samples from the audit site, to secure copies of documents and electronic data, and to purchase samples of devices.

We retain the right to undertake any audit, assessment or regulatory action deemed necessary to grant or maintain certification or check compliance, including visits to suppliers, subcontractors and distributors, and testing of product(s). Such activities may be carried out by us without a further application process and will be chargeable to the client. We will provide, upon request, a written explanation for the need for any additional audit, assessment, test or regulatory action, nonetheless we are not obliged to inform the client before such action is undertaken.

When requested, we will provide documentary proof of the identity of unannounced audit team members and a telephone number for clients to confirm the authenticity of the unannounced audit team.

Unless stated in the proposal, it has been assumed that no further audits of suppliers, subcontractors or additional sites are required. However, during the audit process, if further information indicates a different situation, you will be informed, and any extra visits will be agreed upon at an additional cost.

Based on the provided information, we will define the on-site audit duration, sampling plan of your technical documentation assessment and subsequently prepare a commercial contract that would contain the price for your certification cycle.

Audit overview

Application review: Stage 1 audit

This section does not apply to assessments conducted according to MDR Article 117.

The Stage 1 audit is primarily conducted on-site, however can be also performed off-site if specific circumstances are met. The Stage 1 audit includes an appraisal of your Quality Management System documentation and intended scope of certification, including products, processes, site locations and related statutory and regulatory aspects.

This stage will include:

- Review of all documents and elements listed in Annex IX Section 2.1:
  - A draft of an EU declaration of conformity according to MDR Article 19 and Annex IV for the device model(s) covered by the conformity assessment procedure,
  - The documentation on the manufacturer's QMS,
  - A documented description of the procedures in place to fulfil the obligations arising from the QMS and required under MDR, and the undertaking by the manufacturer in question to apply those procedures,
  - A description of the procedures in place to ensure that the QMS remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
  - The documentation on the manufacturer's post-market surveillance system and, where applicable, the Post-Market Clinical Follow-Up (hereafter PMCF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in MDR Articles 87 to 92,
  - A description of the procedures in place to ensure the post-market surveillance system and, where applicable, the PMCF plan are up to date, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in MDR 2017/745 Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
  - Documentation concerning the clinical evaluation plan,
  - A description of the procedures in place to keep up to date the clinical evaluation plan, considering the state-of-the-art aspect,
  - Your quality manual, procedures and any work instructions that ensure compliance with the MDR (EU) 2017/745, appropriate common specifications and the harmonized standard for QMS (including sterilization and other critical processes). These should be controlled and sent to the assessment team in an electronic format,
  - A copy of the current internal audit schedule, the last internal audit report and the minutes of the last management review to demonstrate that your internal audit and management review processes are functioning,
  - A list of your sets of technical documentation for the devices you wish to CE Mark, as you may be requested to send a copy of selected technical documentation to the SGS Delivering Office before the audit
- 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, concerning the identification of key performance or significant aspects, processes, objectives and operation of the quality 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 quality management system confirms that you are ready for the Stage 2 audit,
- Determination of compliance with the documentation requirements of the MDR (EU) 2017/745 and the allocation of resources, evaluation of codes and working documentation for the Stage 2 audit,

- The technical documentation is checked for preparedness to ensure that is up to date for technical documentation assessment. The technical documentation itself will be assessed off-site as per section Technical Documentation Assessment

You will receive a Stage 1 application review audit report outlining any deficiencies (findings) to enable immediate action to be taken before moving forward through the process. Serious deficiencies detected within the QMS during the Stage 1 audit, technical documentation preparedness, existing certification or certification of a relevant subcontractor and/or supplier could result in you being advised of additional costs and/or delays to the Stage 2 audit or technical documentation assessment. A Stage 2 audit plan will be provided to you after the Stage 1 audit.

Stage 2 audit

This section does not apply to assessments conducted according to MDR Article 117.

This step is usually conducted several weeks after the Stage 1 audit to ensure that you have sufficient time to implement the Stage 1 audit findings. We are led by you regarding the time between Stage 1 and Stage 2 activities, but four (4) weeks minimum would be recommended, and both stages should be planned well in advance.

A Stage 2 audit is performed on-site or as a hybrid audit (partially on-site and partially remote) and constitutes a comprehensive evaluation of your documented QMS compliance with the MDR (EU) 2017/745. This audit will also confirm the status of relevant suppliers and subcontractors, your critical processes and the eligibility of your products for medical device certification.

All assessment conclusions are based on sampling of audit evidence to demonstrate effective implementation of the quality management system, control over the processes and progress made toward achieving your stated quality objectives and compliance with the MDR (EU) 2017/745.

At the conclusion of the audit, the audit team leader will make a recommendation dependent on the findings. The audit team leader will discuss any findings that may comprise major and minor nonconformances. The audit team leader will also confirm with you the name, address and proposed scope details which will appear on your certificates.

Where non-conformances are identified as part of the audit, these will be described and provided to you as Corrective Action Requests. You will need to address any major non-conformances and SGS NB 1639 will need to evaluate them and approve as closed before your QMS certificate can be issued (please refer to Annex 2: Corrective Action Request).

Technical documentation assessment

This section does not apply to assessments conducted according to MDR Article 16.

General description

The assessment of your medical device technical documentation is conducted in parallel to the on-site audit and is performed on a sampling basis[4] for Class IIa and Class IIb. Class III, implantable Class IIb[5] and Class IIb active devices intended to administer and/or remove a medicinal product are not subject to sampling, and the technical documentation of each product must be assessed.

You must send to us:

- A completed MDR Technical Documentation Request Form, which presents a proposal of expected content of your technical documentation. This form is available on our EU Medical Device Regulation (MDR) Information Center EU Medical Device Regulation (MDR) Information Center.
- A complete copy of your technical documentation, including the applicable sections of your QMS required to support your technical documentation.
- All documentation should be presented in text searchable format (i.e., text recognition PDF or Microsoft Word format) and appropriately indexed to allow easy access to the relevant information.
- Technical documentation should be submitted in English.
- Send all documents electronically through a secured web-based application with prior agreement from SGS NB 1639.
- If any relevant processes are subcontracted or outsourced, copies of any subcontractor/supplier's current certification should also be sent.

In order to assess the overall readiness of your technical documentation, a Stage 1 (pre-review) will be conducted. Stage 1 review is performed to ensure that your submitted technical documentation is of sufficient quality to undergo a full review (Stage 2 - main review) within the allocated time and allowed rounds of follow-ups, and that it generally complies with the requirements of Annex II and Annex III of the MDR. The outcome of the Stage 1 (pre-review) is either positive or negative.

- If positive, the technical documentation is considered appropriate, and Stage 2 (main review) may proceed as scheduled.
- If negative, the technical documentation is not considered ready, and Stage 2 (main review) will be postponed. In this scenario you will be requested to appropriately update your technical documentation and resubmit thereof in the due time.

During the first round of Stage 2 (main review), to resemble a verbal dialogue between the assessor and auditee, all findings are raised as Potential Issues to be Clarified (PIC). PICs serve as a formal request for clarification or identification where the required information can be localized and do not necessarily reveal a non-fulfillment of a regulatory requirement. If PICs are not sufficiently clarified by your organization within the appropriate response, they will be subsequently escalated and reported as nonconformances using the SGS format of a Corrective Action Request (CAR). Please consult Annex 2 for detailed information on this process.

If the assessment of your technical documentation has led to a high number of nonconformances, of which a minimum of 50% remain insufficiently addressed at the first follow-up review, SGS NB 1639 may reject the technical documentation. In this scenario, we will ask you to provide fully updated technical documentation in order to restart the assessment. Please note that a fee will be charged for the initial assessment, even if it has been stopped early as the technical documentation is not compliant.

[4]Devices are sampled according to MDCG 2019-13

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

Specific procedure

Please acknowledge that specific procedures, for which the involvement of external bodies is required, are subjected to significant delays as they are not under the SGS jurisdiction. Applicable specific procedures:

- For Class III implantable devices and Class IIb active devices intended to administer and/or remove a medicinal product (Rule 12 of MDR), if the device is subject to the clinical evaluation consultancy procedure as per MDR Article 54, and does not fulfil the exemption criteria as listed under Article 54 (2), SGS NB 1639 will need to follow the requirement of Article 54 and submit the clinical evaluation assessment report with other related documents for the CECP procedure.
- For devices incorporating a medicinal substance, SGS NB 1639 shall verify the usefulness of the substance as part of the device and get a scientific opinion of the appropriate competent authority (designated according to Directive 2001/83/EC) or EMA. The manufacturer will be expected to supply technical documentation related to the drug substance, as well as the technical documentation for the device. This will be requested when SGS NB 1639 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 NB 1639 shall document a summary evaluation report according to Annex II of Regulation (EU) No 722/2012 and send it to the appropriate competent authority for comments.

It is a legal requirement to send any requested report to comply with the described specific procedure from MDR (EU) 2017/745 Annex IX Section 5 to the appropriate competent authorities. SGS NB 1639 will consider your comments on the established report before the consultation process starts and will begin the consultation process when your technical documentation is at the appropriate level (no nonconformances related to the specific procedure are open).

The consultation process will follow timelines set in MDR (EU) 2017/745 Annex IX Section 5. These timelines cannot be guaranteed by SGS NB 1639, as the schedule for these external reviews is set by the independent agency and is not under SGS control.

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

Feedback received from the concerned competent authority will be considered for the 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, outline your important documentation, review the history since original certification in the case of certificate renewals, and describe any outstanding non-critical nonconformances for which minor nonconformances (Corrective Action Requests) are raised. Non-critical nonconformances must be corrected within defined timescales, but do not delay certification.

After review by SGS NB 1639, the final report will either be uploaded to the European database on medical devices (Article 33, MDR (EU) 2017/745) (in this instance there will be no communication from SGS NB 1639) or SGS NB 1639 will inform you of further requested action. This is part of the Technical Documentation Assessment process and will be invoiced at the same time as the device certification.

Nonconformance and corrective actions request

The Stage 2 audit, Technical Documentation Assessment and any further surveillance activities, such as a regular on-site surveillance audit, unannounced audit, device testing, PSUR assessment or SSCP validation may lead to the identification of major or minor nonconformances by SGS NB 1639 auditors or products assessors.

Time to review and close the nonconformances will be invoiced in addition to the defined initial duration of the audit or Technical Documentation Assessment. Certification will be deferred until all major nonconformances are closed.

For further information on the closure of minor and major CARs and associated timelines, please refer to Annex 2.

Certification review

After completion of the Stage 2 audit and technical documentation assessment, respective reports will be compiled off-site and provided to you. Subsequently, we conduct an independent review of all the audit documentation, root cause analysis, corrective action plans, and any corrective actions taken. The independent review may in some cases trigger requests for additional information or clarification, which you will be required to provide.

Any queries raised during the final review must be appropriately addressed and closed before a certificate may be issued. A certification decision is made at the end of this review process. Limited changes to the certificate scope may be made at this point, however, we will inform you if this is the case. In certain circumstances, SGS NB 1639 may decide to reduce the duration of certificate validity and accordingly, we will provide you with a rationale justifying this decision.

The outcome of the conformity assessment and associated certification decision and - if applicable - the issued certificate, will be processed and registered in EUDAMED by SGS NB 1639.

Certification for product distributors and importers

SGS NB 1639 can also provide QMS certificates to distributors or importers carrying out activities mentioned in points (a) and (b) of MDR Article 16(2), subject to an application and audit procedure.

Article 16(2) states that any importer or distributor may translate the existing information supplied by the manufacturer as necessary to place the device in the relevant Member State. They may also change the outer packaging of a device and/or pack size if this is necessary to market the device in the relevant Member State, ensuring that the original conditions of the device are unaffected.

Therefore, distributors and importers must ensure that their QMS includes (where applicable):

- Procedures to ensure that the translation of information is accurate and up to date,
- Any repackaging is performed by maintaining the original condition of the device,

- Procedures ensuring the manufacturer informs the distributor or importer of any corrective action taken concerning the device to respond to safety issues or to bring it into conformity with the Regulation (EU) 2017/745.

Consequently, technical documentation assessment is not included in the MDR Article 16 certification process for distributors and importers, and therefore only the QMS aspects will be assessed for compliance with the MDR.

Following certification

Surveillance visits after CE certification

Once issued, certificates are only valid if subject to regular audits to ensure the satisfactory maintenance of your QMS. Ongoing scheduled audits (surveillance visits) must be conducted annually to verify the continued implementation of your QMS according to planned arrangements, the requirements of the standard(s) and applicable regulations.

The first surveillance audit should be scheduled within 12 months following the certification decision date. Subsequent surveillance audits must be completed within 12 months of the previous surveillance audit. Certain mandatory elements (including device testing and technical documentation assessment based on sampling plan) will be reviewed during every visit, alongside other pre-selected processes. Prior to every scheduled audit, we will send you a Medical Devices Pre-Audit Questionnaire (PAQ), that shall remind you to check on recent and gradual changes. The Pre-Audit Questionnaire serves as a summary of all changes submitted by your organization between respective audits. It is essential that PAQ is completed by you and returned to your local SGS Delivering Office well before the audit (no later than two months prior to scheduled visit). Please remember that PAQ must not be used as a replacement to the Medical Device Notification of Changes or Regulatory Action Form and does not exempt your organization from the reporting obligation (please refer to section Notification of Changes).

During surveillance audit, one or more devices will be tested (witnessing test) according to the defined sampling plan. However, if this cannot be achieved on-site, devices will be sampled and tested outside the manufacturer's site and the fee will be invoiced in addition to the audit cost.

Surveillance activities also cover the assessment of technical documentation, based on the established sampling plan. When requested by your local SGS Delivering Office, you must submit the required technical documentation, similar as for an initial certification, within four (4) weeks of the request to allow technical documentation assessment.

An audit plan will be provided to you prior to the agreed surveillance audit date. Please note that the flexibility in the timing of ongoing visits is strictly limited by requirements defined on surveillance and re-certification, as per MDR Annex IX Section 3.3, Annex VII Section 4.10 and 4.11.

Unannounced audit after CE certification

An unannounced audit cycle is associated with your certificate, therefore if you have multiple conformity assessment procedures leading to multiple certificates, you will have one unannounced audit cycle per certificate. Unannounced audits can be undertaken at any time within the certification cycle, excluding prior agreed periods of unavailability. Periods of unavailability of your organization and any relevant subcontractors and suppliers must be sent to your local SGS Delivering Office for the upcoming year and not later than the end of each calendar year using the Unannounced Audit Questionnaire,which can be provided by your local SGS Delivering Office upon request.

In the absence of this questionnaire, SGS will assume that your organization has no declared periods of unavailability for unannounced audits, or that the information previously declared during the pre-application process, or the most recent scheduled audit remains valid.

Any changes to these dates during the year shall be notified to us as soon as possible via the Medical Device Notification of Changes Regulatory Action, Consultancy, or Services Rendered form (please refer to section Notification of Changes).

As the name suggests, no notice will be given for an unannounced audit, therefore, you must always be ready to facilitate these audits.

Unannounced audits to investigate product compliance may be undertaken by us at any defined location. It is your obligation to define these locations and facilitate these audits.
If an unannounced audit cannot be performed, this could lead to suspension of your certificate.

Unannounced audits will focus 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 critical to the safety and regulatory compliance of the devices. Samples may be taken for subsequent testing.

You must ensure that the technical documentation is available at the audit site so it can be compared with actual or recent production.

The frequency of unannounced audits will be once every five-year cycle. However, the frequency can be increased at our discretion, following information received during audits or from other sources that devices may be nonconforming. The minimum duration of an unannounced audit is one (1) day for two (2) auditors simultaneously.

Re-certification

As part of this program, it is not necessary to conduct a new full Stage 1 audit (application review) and Stage 2 audit. Instead, we perform a re-certification audit, which is more in-depth than a surveillance visit, and which may include an off-site technical documentation assessment. Consequently, this will ensure that we review all aspects of your quality management system and technical documentation.

In the year before the expiry of your MDR EU Quality Management System certificate, you will be contacted by your local SGS Delivering Office to confirm your willingness to continue certification with SGS NB 1639 and a new contract proposal will be created. The Medical Devices Pre-Audit Questionnaire (PAQ) will be sent to you before the scheduled re-certification audit, which will remind you to check any recent and gradual changes.

The Pre-Audit Questionnaire serves as a summary of all changes submitted by your organization between respective audits. It is essential that PAQ is completed by you and returned to your local SGS Delivering Office well before the re-certification audit (no later than two months prior to scheduled visit).

Please remember that PAQ must not be used as a replacement to the Medical Device Notification of Changes or Regulatory Action Form and does not exempt your organization from the reporting obligation (please refer to section Notification of Changes).

Similarly, in the year before your MDR EU Technical Documentation Assessment certificate expires, you will be contacted by your local SGS Delivering Office to confirm your willingness to continue certification with SGS NB 1639 and a new contract proposal will be created. Re-certification of Class III and implantable Class IIb devices focuses on the assessment of changes, post-market activities and new risks.

For renewal of the EU Technical Documentation Assessment certificate, you are required to:

- Complete a Medical Devices Pre-Audit Questionnaire,
- Provide a copy of the full technical documentation, and
- A summary of changes and scientific findings, including all points as per MDR Annex VII Section 4.11 Paragraph 2:
    - All changes to the originally approved device, including changes not yet notified,
    - Experience gained from post-market surveillance,
    - Experience gained from risk management,
    - Experience from updating the proof of compliance with the general safety and performance requirements set out in MDR Annex I,

- Experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,
- Changes to the requirements, to components of the device or to the scientific or regulatory environment,
- Changes to applied or new harmonized standards, CS or equivalent documents,
- Changes in medical, scientific and technical knowledge, such as:
  - New treatments,
  - Changes in test methods,
  - New scientific findings on materials and components, including findings on their biocompatibility,
  - Experience from studies on comparable devices,
  - Data from registers and registries,
  - Experience from clinical investigations with comparable devices.

Notification of changes

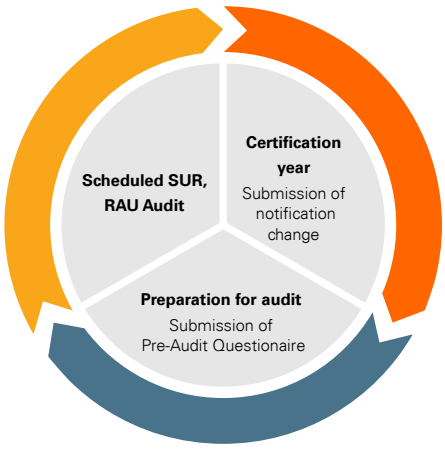
You shall inform SGS NB 1639 before implementation of any changes (see Annex 1) or regulatory actions that may affect:

- The approved quality management system or systems or the product-range covered,
- The approved design of a device,
- The intended use of or claims made for the device,
- The approved type of a device,
- Any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6 of Regulation (EU) 2017/745
- General operations of your company

This should be reported using the Medical Device Notification of Changes, Regulatory Action, Consultancy or Services Rendered form (NoC), which can be provided by your local SGS Delivering Office upon request

In order to determine if a proposed change must be reported to SGS NB 1639, please refer to Annex I which contains applicable submission flowcharts. Please acknowledge that any change which is not falling into the reportable category shall be nevertheless recorded in your QMS and will be evaluated by our auditors during the on-site visit.

Changes cannot be implemented, and devices cannot be placed on the market until formal approval of the change is issued in writing by SGS NB 1639. If changes are implemented affecting certified devices without formal approval by SGS NB 1639, then these devices would no longer be deemed covered by the issued certificate and thus not legally placed on the Union market.



Changes made between scheduled audits (excluding audit preparation stage) 9-10 months a year

Summary of all changes made between the audits. Return to SGS no later than two months before the planned audit.

The graph represents the suggested submission timeline, which will facilitate your Notification of Change being evaluated adequately and if necessary, your contract amended in due time before the audit preparation stage.

Please note that your organization is allowed to submit NoC outside of the suggested timeline. Nonetheless, you shall be aware that if a submission is done too close to the audit date, your NoC might not be processed in time and consequently it will not be possible to assess the respective change during the audit.

We shall assess the proposed changes, determine the potential need for an additional on-site audit or technical documentation assessment, and verify whether, after those changes, the QMS still meets the requirements referred to in Section 2.2 of Annex IX of the MDR.

We shall subsequently notify the manufacturer of our decision through the submitted Notification of Change form, which will be delivered to you by your local SGS Delivering Office. This will contain the conclusions of the assessment and, where applicable, conclusions of any additional on-site audit or technical documentation assessment. The approval of any substantial change to the QMS or the device range covered shall take the form of a supplement to the EU Quality Management System certificate or a supplement to the EU Technical Documentation Assessment certificate, if relevant.

The scheduling of any extension to the scope of certification can take place at the same time as the surveillance audit or re-certification audit or can be carried out between visits depending on the nature and timing of the change. This can be conducted as an on-site audit or, in some cases, by an off-site technical documentation assessment. The appropriate method will be shown in the approved notification of change form and associated contract proposal.

Vigilance

Vigilance events must be reported to the relevant competent authority by the manufacturer or, for manufacturers based outside the EU, their EU Authorized Representative. EUDAMED "vigilance and post-market surveillance" module must be used for vigilance reports six months after the module has been released. Until this point, it should be done via a Manufacturer Incident Form, available from the European Commission.

A copy of the report submitted to the competent authority must also be sent to SGS NB 1639. This allows SGS NB 1639 to decide if particular actions must be taken (such as extraordinary surveillance measures and the review of specific products or processes during the next audit,…) and to estimate the impact on the validity of existing certificates. It is not the role nor the responsibility of Notified Bodies to actively follow up on each incident thus, in some cases, we will review your reports, but not necessarily contact you.

To submit your vigilance report to SGS NB 1639, please send an email to: medicaldevices.vigilance@sgs.com.

The email should contain the following:

1. A copy of the vigilance report that was submitted to the competent authority, which could be one of the following:
    - Manufacturer's Incident Report (initial, final and combined, but 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

If you are reporting more than 10 serious incidents per month, we strongly recommend that you inform us of these in batches, in the form of a monthly report, to avoid additional administrative overheads. Irrespective of this, serious incidents must be reported to the relevant competent authority within 15 days of you becoming aware of them or sooner, as per Article 87 of the MDR.

2. The subject of the email should include the manufacturer's reference number for vigilance and the type of report as shown in this example: Ref. 20-24-BLA-RB-0001664 Initial Vigilance Report.

3. In the body of the email, please include the affected certificate(s) types and numbers. For example: MDD (CE), GB19/96541

After your submission and within a maximum period of 2 weeks, you will receive a confirmation email (as a reply) that your submission has been received. This will mark the start of the review process of your vigilance report.

After a review by SGS NB 1639, 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 NB 1639) or undertake additional actions, which must be executed as soon as possible. This could include:

- Request for additional information to be provided to SGS NB 1639,
- SGS NB 1639 assessing the technical documentation, or specific documentation relating to the vigilance action,
- SGS NB 1639 enforcing surveillance activities (for example increasing the frequency of your on-site audits or conduct the unannounced audit).

Work undertaken by SGS NB 1639 as a response to vigilance reports will be invoiced.

Please note that you can request a guidance document explaining how to report vigilance to SGS NB 1639 by sending a respective request to medicaldevices.vigilance@sgs.com.

Summary of safety and clinical performance (SSCP)

It is a requirement of the MDR (EU) 2017/745 for implantable devices and Class III medical device manufacturers to draft a Summary of Safety and Clinical Performance (hereafter SSCP) as part of their technical documentation. This summary will be validated by SGS NB 1639 and uploaded to the European database on medical devices (Article 33, Medical Device Regulation (EU) 2017/745).

An SSCP must be submitted as part of technical documentation or a stand-alone document, based on the template provided in MDCG 2019-9. Depending on the device classification, SGS NB 1639 will validate the SSCP, either as part of the initial Technical Documentation Assessment or during the certification cycle. After this review, we will only contact you if any further action is required relating to the SSCP or, otherwise, we will upload it to the European database on medical devices.

Note that a review of your SSCP may be followed by rounds of nonconformances and a review of responses until all nonconformances are closed. The costs quoted in the proposal assume no nonconformances will be raised – the review of responses to nonconformances will be invoiced.

Periodic Safety Update Report (PSUR)

As a requirement of the MDR (EU) 2017/745 (MDR), manufacturers of Class II (Class IIa and IIb) and Class III medical devices must:

- Prepare the Periodic Safety Update Report (PSUR) as part of their post-market surveillance activities,
- Update the PSUR at least annually for Class IIb and 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 Class IIb implantable and Class III only, and biennially for Class IIa implantable devices,
- Make PSURs available to the Notified Body involved in the conformity assessment and, upon request, to competent authorities for devices other than Class III or implantable devices

The PSUR of Class III devices or implantable devices will be assessed by SGS NB 1639. SGS NB 1639 will upload its evaluation report, detailing any actions taken, in the electronic system on vigilance and post-market surveillance (Article 92 of MDR).

After the assessment of PSUR, we might undertake additional actions, including:

- Request for the provision of additional information to SGS NB 1639
- SGS NB 1639 assessing the technical documentation for the device, or specific documentation relating to the PSUR update,
- SGS NB 1639 carrying out an unannounced audit.

Please note that review of PSUR may be followed by rounds of nonconformances and review of responses until all nonconformances are closed. Work undertaken by SGS in relation to PSUR updates will be invoiced.

Manufacturers of Class I devices shall prepare a post-market surveillance report and update it when relevant. This report may be requested by the competent authority.

This activity is undertaken off-site and will be identified in your proposal as an activity. If there is any appropriate action to be taken resulting from the PSUR assessment, you will be notified in writing by SGS NB 1639.

Voluntary change of notified body

If you hold certificates with another Notified Body, you may decide to undertake a voluntary change of Notified Body (MDR Article 58) and transfer certification to SGS NB 1639 at any point within your certification cycle. A voluntary change of Notified Body can only occur while your current certificates are valid. If you are uncertain whether you meet the criteria, contact us to discuss the available options for certification with SGS NB 1639.

To initiate your voluntary change of Notified Body to SGS NB 1639 you are required to apply as explained in the section above (Lodging your application). In addition, the following documents must be submitted:

- Copies of audit reports from your current Notified Body certification cycle,
- Copies of nonconformances raised in your current certification cycle,
- Copies of Technical Documentation Assessment Reports (if applicable),
- Copies of labelling (including, e.g. labels, Instructions for Use) for MDR Class III, implantable Class IIb[6] 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 incident reports or regulatory actions since your last audit,
- Copies of your current certificate(s) with date of validity,
- You may additionally submit, or we may request additional information, such as:
  - The last batch or series number under your current Notified Body responsibility,
  - The PSUR for your Class IIa, Class IIb and/or Class III devices,
  - The SSCP report for MDR Class III and implantable Class IIb and Class IIb active devices intended to administer and/or remove a medicinal product.

Upon receipt of all required documentation, the initial step will involve a comprehensive review of your current certification and the associated materials. The purpose of this assessment is to determine the applicable transfer scenarios, that are based on the outcome of risk level evaluation in accordance with SGS NB 1639 procedures, which include specific considerations for high-risk devices (Class IIb specific and Class III).

Following the outcome of this risk assessment, we will provide you with a proposal outlining the appropriate path forward - either the continuation of your existing certification within the current cycle (Scenario 1), or the initiation of a new certification cycle (Scenario 2).

- Scenario 1: Transfer takes place 'mid cycle' – in the event that the transfer occurs during prevailing certification cycle, SGS NB 1639 will assume responsibility for completing the current audit cycle in accordance with the respective schedule established by your existing notified body. The certification will be issued effective from the agreed transfer date and will retain the same validity period as your current certification.
- Scenario 2: Initiation of a new certification cycle based on existing certification– if the transfer 'mid cycle' is not feasible, SGS NB 1639 may initiate a new certification cycle based on your current certification. In this scenario, an initial audit will be required, and certificates will be issued with the full validity period.

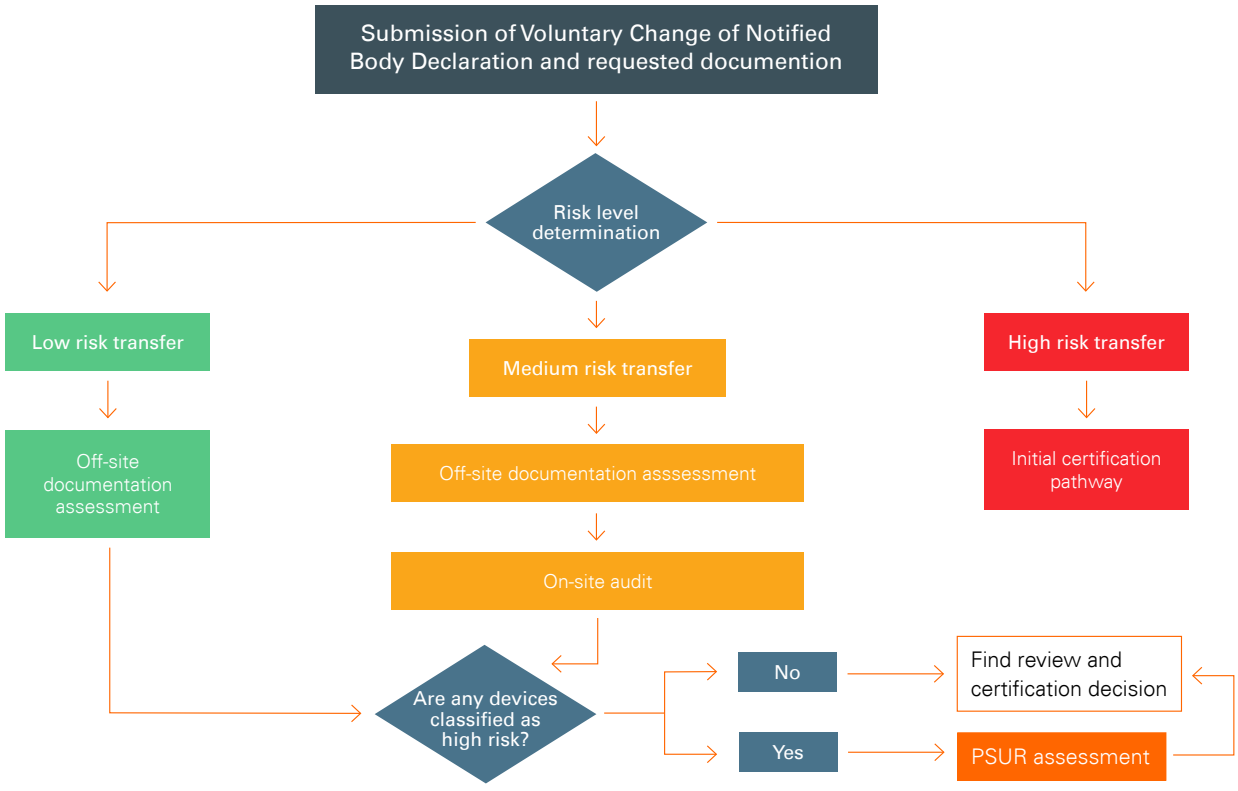
In addition to the normal contract proposal (see section on "Contract Proposal"), we will send you a Medical Device Voluntary Change of Notified Body declaration to complete and sign.

If the certification to be transferred is not current or valid at the time of voluntary change, SGS NB 1639 cannot issue valid certification by the voluntary change process and any certification may be subsequently withdrawn.
During the voluntary change process, from contract signature to certificate delivery, we may contact the current (i.e. outgoing) Notified Body to reconfirm validity of the certificates being transferred and agree on the transfer date – the date when the existing Notified Body certificates will be withdrawn and SGS NB 1639 certificates issued. Under normal circumstances, you will be covered by a valid certificate throughout the transfer process and your ability to place devices on the European Union market should not be disrupted.

The application for a voluntary change of Notified Body remains valid for up to one (1) year after the effective date of the signed contract. If the voluntary change assessment has still not been planned after one year, the contract proposal will become void. The applicant would then need to sign a new contract with SGS to continue the process.

After the transfer of Notified Body is completed, the applicant must update all labelling and other references to the previous Notified Body to refer to SGS Belgium NV (NB 1639) instead, as appropriate. This must be done as soon as possible, and no later than six (6) months after the transfer date.

The diagram below illustrates the applicable course of action for voluntary transfer process based on the risk level determined by SGS NB 1639. Please be advised that any CAR raised during the transfer audit or PSUR assessment might necessitate an increase in the depth of the assessment required, and consequently - the updated proposal.



Other medical device certification services offered by SGS

The global regulatory landscape for medical device products and services is complex, and many of our clients have a global reach. We offer a broad portfolio of certification and accreditation services covering various national and international requirements. Whether your organization currently has a global reach, or if you are planning to enter additional markets in the future, SGS will be able to support you in your certification journey with a service tailored to your needs.

Please consult your local SGS Delivering Office representative to receive a further guidance on how our range of offerings can help your products achieve a global reach. Our certification services include:

- MDR (EU) 2017/745
- IVDR (EU) 2017/746
- ISO 13485
- MDSAP Program
- UKCA (UK MDR)

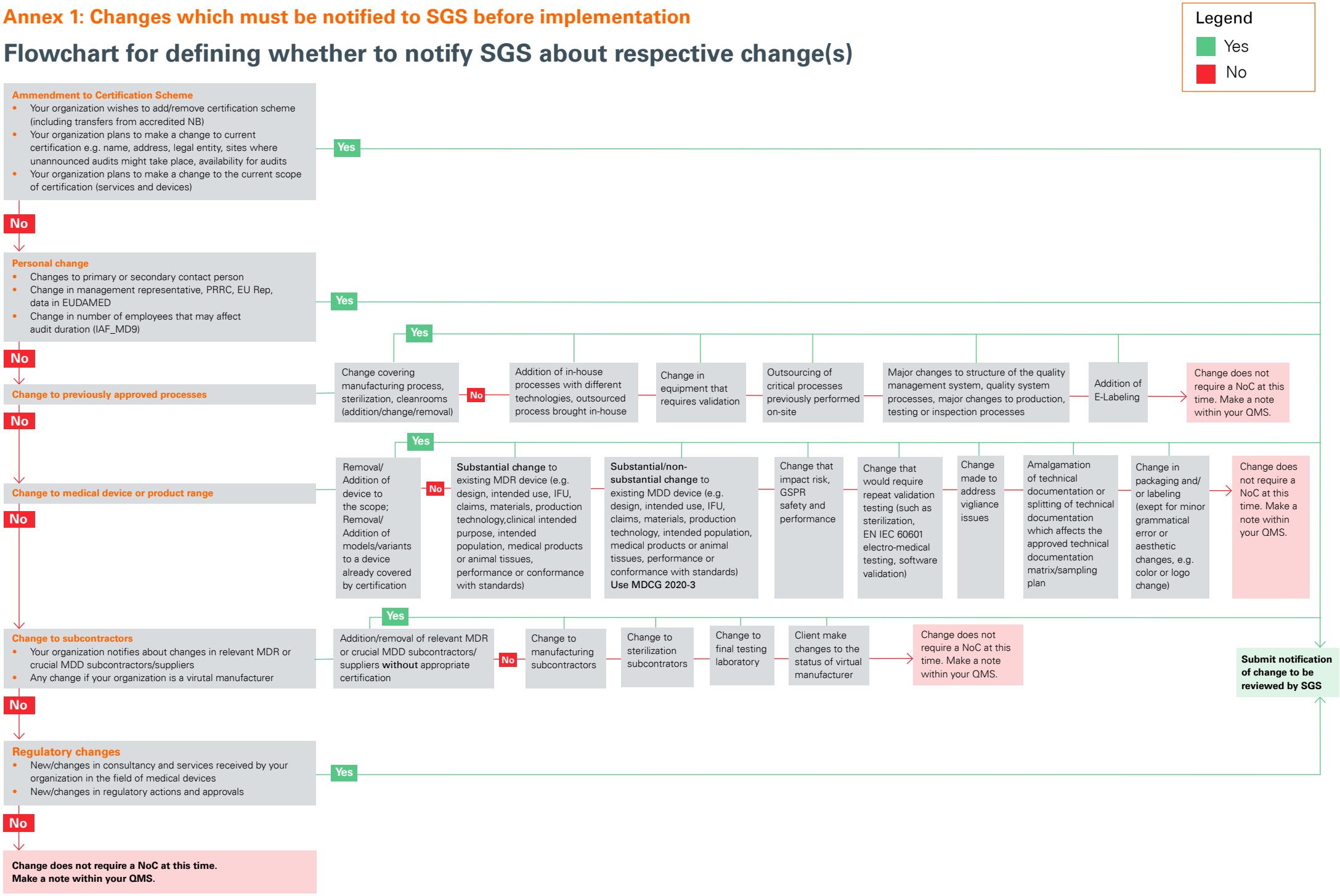
Useful references

- The European Commission portal on medical device regulations provides a broad range of up-to-date information and guidance documents, including:
  - Common Specifications provided by the Medical Device Coordination Group, which 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 published by the Medical Device Coordination Group, which is considered to represent a consensus interpretation of the regulatory requirements and is taken into account by Notified Bodies as part of their conformity assessment.
- European Harmonised Standards, whilst not strictly mandatory, are applied by most manufacturers as a means of demonstrating compliance with MDR requirements and thus, are recommended. The list of applicable standards is available on the Commission website.
  - It is highly recommended that you apply the standards EN ISO 13485 and EN ISO 14971 when constructing your QMS and technical documentation

For more information on any of our services, visit https://www.sgs.com/

Annex 1: Changes which must be notified to SGS before implementation

Flowchart for defining whether to notify SGS about respective change(s)



Annex 2: Corrective Action Request (CAR)

During a QMS on-site audit and/or technical documentation assessment, one or more nonconformances (non-ulfilment of a requirement) may have been detected and recorded. These nonconformances are presented to you in a Corrective Action Request (CAR) form for all QMS related nonconformances. For technical documentation assessments, the nonconformances or potential nonconformance are integrated directly into the assessment report as Potential Issues to be Clarified (hereafter PIC) at the initial assessment and, if not solved, as major CARs in the follow-up report. Both forms are formal requests to describe the specific corrections and corrective actions taken, or planned to be taken, to eliminate the detected nonconformances within a defined timeframe. In addition, for QMS nonconformances identified during an on-site audit, you are requested to analyse the root cause of the nonconformances and provide us with corrections and corrective actions.

Please be informed that any identified major CARs can result in the SGS audit team leader or product assessor recommending suspension of your device or certificate. Therefore, every major CAR shall be given the appropriate consideration for review and closing.

We would like to remind you that any delay in submitting a corrective action plan and the implementation of corrections or corrective actions for major CARs may lead to new certificates not being issued and current certificates being suspended, or a device being removed from the certification scope.

This document explains the underlying SGS NB 1639 process on corrective action requests, which starts from the moment of presenting the detected nonconformances to you (by the auditor and/or the product assessor). By default, the date of the nonconformance is the last day of the audit or technical documentation assessment. It is very important to respect the timelines associated with CAR closure as concession can be given only in very exceptional circumstances (force majeure).

These timelines for CAR closure are related to the severity and/or (potential) impact of the associated nonconformance and are defined by the auditor and/or product assessor according to SGS internal procedures. These timeframes are recorded and monitored by us, as well as by accrediting bodies and competent authorities.

CAR – general information

1. A nonconformance can be graded as minor or major by the auditor (QMS audit) or product assessor (technical documentation assessment), depending on its severity and impact on the product's safety.

- **A Minor QMS CAR** is raised when a nonconformity is identified during a Quality Management System audit, however based on the objective evidence, it does not compromise the overall system's ability to achieve its intended outcome or meet legal requirements. Minor QMS CARs are typically isolated, low-risk issues that do not indicate the failure of the system.
- **A Major QMS CAR** is issued when a nonconformity is identified during a Quality Management System audit and based on the objective evidence, it does compromise the system's ability to achieve its intended outcome or meet legal requirements. Major QMS CARs are significant issues that indicate the process failures or violations of legal and regulatory requirements.
- **Potential Issue to be Clarified (PIC)** is raised during the initial assessment of technical documentation for any finding that require further elaboration, however, PIC does not necessarily indicate a non-fulfilment of a regulatory requirement. PICs serve as a formal request for clarification or identification where the required information can be localized. If PICs are not adequately addressed by your organization – either through a submission of insufficient response or if provided information, based on the objective evidence, raises significant doubt on the ability of a medical device or process to meet regulatory requirements, PICs are escalated to **TDA CAR.**
- If all TDA CARs have been closed, however minor residual issues that do not pose immediate safety or performance concerns or systematic issues related to the QMS are still evident, they will be recorded by the product assessor and communicated to you by means of a Technical Documentation Assessment Report

provision. Please note that actions taken by your organization to resolve outstanding issues will be verified by SGS during the next on-site audit visit.

2. Make sure you understand the non-fulfilment of a requirement when the CAR is recorded
3. For each QMS audit CAR, a corrective action plan is requested. Your action plan must contain a sufficient level of analysis to demonstrate to the auditor that you understand the essential details of the findings of nonconformance, and that you have identified root causes and, subsequently, the corrective actions needed. If appropriate, you also need to demonstrate corrections, or you must have a sound justification for not having finalized corrections.
4. The timelines associated with CAR closure are presented below:

Stage	Classification	Timelines and a round of reviews
CARs raised at initial MDR Technical Documentation Assessment (before CE certification)	Major CARs	One (1) round of PIC that must be answered in a maximum of (2) months, followed by a maximum of three (3) rounds of major CAR reviews. Major CARs must be closed in a maximum of one (1) year from the date the initial Technical Documentation Assessment report has been sent to you.
	Minor QMS CARs (once all major CARs are closed)	Minor QMS CARs are reviewed during the next on-site audit.
CARs raised at MDR Stage 2 audit (before CE certification)	Major CARs	Two (2) rounds of major CAR reviews (major CARs must be closed within one (1) year of the last day of the Stage 2 audit).
	Minor CARs	Minor QMS CARs are reviewed during the next on-site audit.
CARs raised at MDR Surveillance /Re-certification Technical Documentation Assessment **(after CE certification)**	Major CARs	One (1) round of PIC that must be answered in a maximum of two (2) months, followed by maximum of two (2) rounds of major CAR review. Major CARs must be closed in maximum of six (6) months from the date the initial Technical Documentation Assessment report has been sent to you.
	Minor QMS CARs (once all major CARs are closed)	Minor QMS CARs are reviewed during the next on-site audit.
CARs raised at MDR Surveillance, Transfer Re-certification or Unannounced on-site audit (after CE certification)	Major CARs	Major CARs should be closed within 90 days and two (2) rounds of response reviews.
	Minor CARs	Minor QMS CARs are reviewed during the next on-site audit.
CAR raised at PSUR / light TDA review / SSCP validation	PSUR CAR / light TDA review / SSCP CAR	PSUR / light TDA review / SSCP CAR should be closed in a maximum of 90 days and within two (2) rounds of response review (one round of PIC and one round of CAR).

5. A specific date is scheduled and reserved for evaluation of action plans and associated evidence submitted by your organization as a response to the CAR. It is of utmost importance that action plans and associated data are correct, complete and submitted on time, sufficiently resolving the nonconformance(s). It is neither SGS's responsibility nor the auditor and/or product assessor to send reminders to ensure this information is submitted on time according to planned arrangements.
6. Poor "quality" of corrective action plans and/or failure to submit on time will cause serious delays that are the manufacturer's sole responsibility. If objective evidence is correct, complete, on time and sufficiently demonstrates the resolution of the nonconformance, the auditor and/or product assessor can close the CAR.
7. If after an initial assessment of your technical documentation, a large number of Potential Issues to be Clarified (PIC) have been raised, SGS NB 1639 can allow the product assessor to recommend voiding the technical documentation assessment if less than 50% of the PICs (with consideration of their nature and severity) can be closed at the first follow-up review. You will be notified of this in writing in the technical documentation assessment report.

To close a MAJOR CAR from a QMS on-site audit, the following steps must be followed:

- Conduct the root-cause analysis, define the appropriate correction and compile a relevant corrective action plan immediately.
- Send the corrections and corrective action plan to the auditor as soon as possible, but within two (2) working days following the receipt of the CAR.
- The auditor reviews the action plan, comments on or accepts it as presented. However, it remains your sole responsibility to resolve the findings of nonconformance. The action plan is a precondition to demonstrate the appropriate intended actions to the auditor and give confidence of a successful review and closure at the planned date.
- Documented evidence of the corrections and corrective actions implemented or being implemented must be sent to the auditor not later than 30 calendar days following the opening of the major CAR.
- The auditor reviews the evidence and determines if it is acceptable. If the provided evidence is not acceptable, the auditor will provide their feedback in writing, including the date on which you must send corrected evidence of the corrections and corrective actions implementation.
- Only two (2) iterations of evidence sent and auditor's feedback are authorized within one (1) year (for the initial certification audit) or 90 days (for the surveillance/re-certification/unannounced audit). If after two iterations the provided evidence is not satisfactory, the expected new certificates will not be issued and current certificates will be suspended, or the corresponding device removed from the certificate scope.
- In order to reinstate the device on the certificate or lift the suspension, all outstanding major CARs must be resolved, reviewed and closed.
- If the auditor has determined that a follow-up visit on your site shall be performed to close the major CAR, the follow-up visit must be organized after a review of the evidence and within 1 year (for the initial certification) or 90 days (for the surveillance/re-certification/unannounced audit). This visit will evaluate actions taken and implemented, their effectiveness, and determine whether certification can be granted or continued.
- If a major CAR is not closed as per established timeliness, certification will be at risk of suspension or withdrawal. Suspended and withdrawn CE certificates are automatically reported to the relevant competent authority and in EUDAMED.
- Successful review and closure of all open CARs will lift (potential) sanctions on certification unless certificates have been withdrawn permanently.

To close a MAJOR CAR resulting from Technical Documentation Assessment, the following steps must be followed:

- Send documented evidence of the corrections and corrective actions that have been implemented or are being implemented to the agreed SGS contact, not later than 30 calendar days following the opening of the PIC or major CAR.
- The product assessor reviews the evidence and determines if it is acceptable. If the provided evidence is not acceptable, the product assessor provides their feedback in writing, including the date by which you must send updated evidence of the corrections and corrective actions implementation
- Only four (4) iterations (for CARs raised during the initial technical documentation assessment) or three (3) iterations (for CARs raised during the surveillance/re-certification technical documentation assessment) of evidence sent, and product assessor's feedback are authorized within the one (1) year or six (6) months' timeframes, respectively. If by the defined timeline and round of iterations, the provided evidence is not satisfactory, the expected new certificates will not be issued or current certificates will be suspended, or a device may be removed from the certificate scope.
- In order to reinstate the product on the certificate or lift the suspension, the major CAR must be resolved, reviewed and closed.

To close a MINOR CAR from a QMS on-site audit, the following steps must be followed:

- Conduct the root-cause analysis, define the appropriate corrections and compile the relevant corrective action plan immediately.
- Send the correction and corrective action plan to the auditor as soon as possible, but not later than within two (2) working days following the receipt of the CAR.
- The auditor reviews the action plan, comments on or accepts it as presented. However, it remains your sole responsibility to resolve the findings of nonconformance. The action plan is a precondition to demonstrate the appropriate intended actions to the auditor and gives an indication of a successful review and closure at the planned date.
- Implement your corrections and corrective actions according to your plan and prepare documented evidence for the next SGS on-site audit.
- The review will take place during the next scheduled on-site audit. Evidence of corrections, root-cause analysis and corrective actions will be reviewed. In the case of multi-site companies, where sites are sampled during the next planned audit, the review will be performed on the main site/headquarters.
- Any minor CARs that cannot be closed on time will be automatically upscaled to major CARs.

Guidance on Root Cause Analysis and Corrective Action/Preventive Action (CAPA):

- **Correction:**
  - The nonconformance recorded is a non-fulfilment of a requirement and, therefore, requires a correction to resolve the detected nonconformance. The nature of the correction can be diverse and depends on the character and significance of the deviation. The causal relationship between the deviation and the correction is that the correction lifts the nonconforming situation without necessarily knowing what caused the deviation to occur in the first place. When multiple issues are mentioned in the CAR, they all must be addressed.
- **Root Cause Analysis:**
  - The manufacturer should clarify why the non-fulfilment of a requirement (the nonconformance) occurred. What contributed to the circumstances and which aspects are more likely than others to be the real root cause? Thorough root cause analysis includes validating that the correct factor of influence has been discriminated. Only the determination of the correct root cause leads to a corrective action that ensures that the reason for the occurrence of this nonconformance will be removed.
- **Corrective Action:**
  - The corrective action has one goal only: create a solution that removes the root cause found and that proves to be sustainably effective in assuring that this deviation will not re-occur.
  - Corrective actions always need a diligent review and verification to ensure that the new situation will not introduce new causes of identical, similar or other deviations.
- **General:**
  - Please report in a fact-based manner, with a clear relation to the CAR requirement and deviation found. A clear relation to revised evidence is important to understand the chosen resolution (where needed, it shall be added with reading instructions for the auditor/product assessor).
- **Preventive Action:**
  - Preventive actions only apply to nonconformances that have not occurred yet.
  - Preventive action shall be added to explore similar situations to those reported in the CAR but are different from those reported in the CAR and have not caused nonconformances yet.
  - The review of preventive action will not be part of the review of a CAR, it may, however, be part of a review of your CAPA system.

When you need to be sure

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