Your medical devices certification process explained

Your organization wishes to get CE Marking for your medical device(s), according to Medical Device Regulation (EU) 2017/745. Please, see below, how SGS can support your organization.

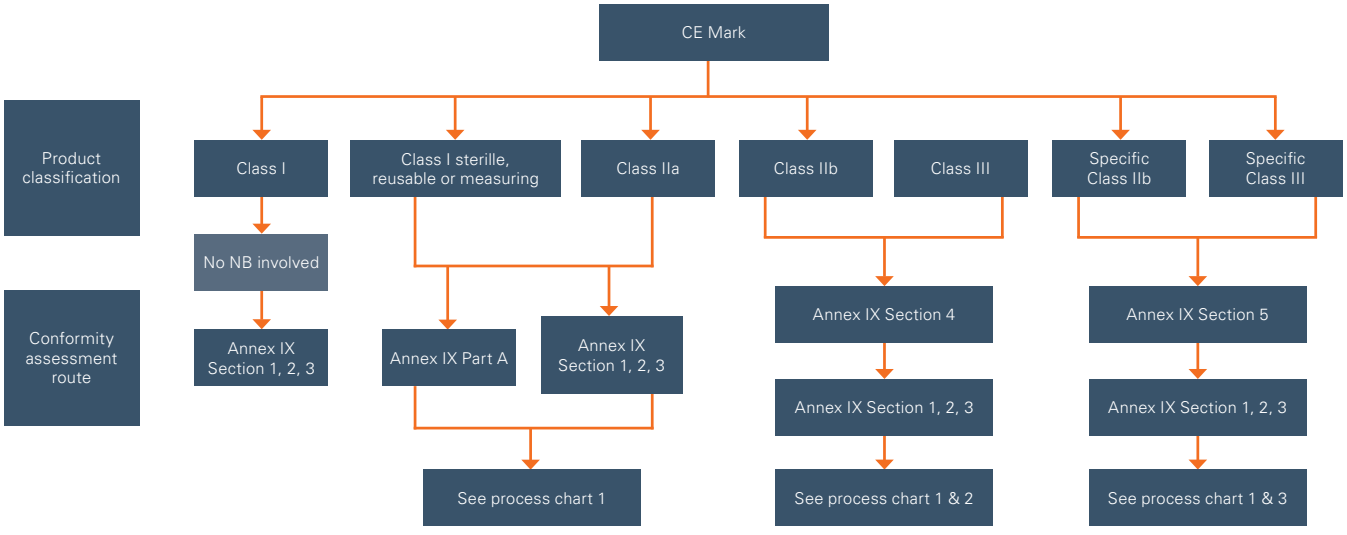
SGS is a Medical Device Notified Body for your range of products and certification will be undertaken as Notified Body 1639 for SGS Belgium NV. This means you are entitled to use CE 1639 on devices within your scope on the completion of a successful audit and technical documentation assessment. Class 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 examination certificate before using CE 1639.

The first step will be for you to determine your product(s) classification, according to rules defined in Annex VIII of the Regulation (EU) 2017/745. Then decide which type of conformity assessment path you wish to apply, either based on a quality management system and assessment of technical documentation, as per Annex IX of the Regulation (EU) 2017/745, or on Product Conformity Verification (Product Quality Assurance), as per Annex XI Part A of the Regulation (EU) 2017/745.

To apply for certification and start the assessment process, you must complete, sign and return the contract proposal to your local SGS office. We recommend that this is done as soon as your decision to proceed has been taken to allow the maximum time for SGS audit planning. Your application will be processed and we will contact you to arrange the next steps of the audit process and dates.

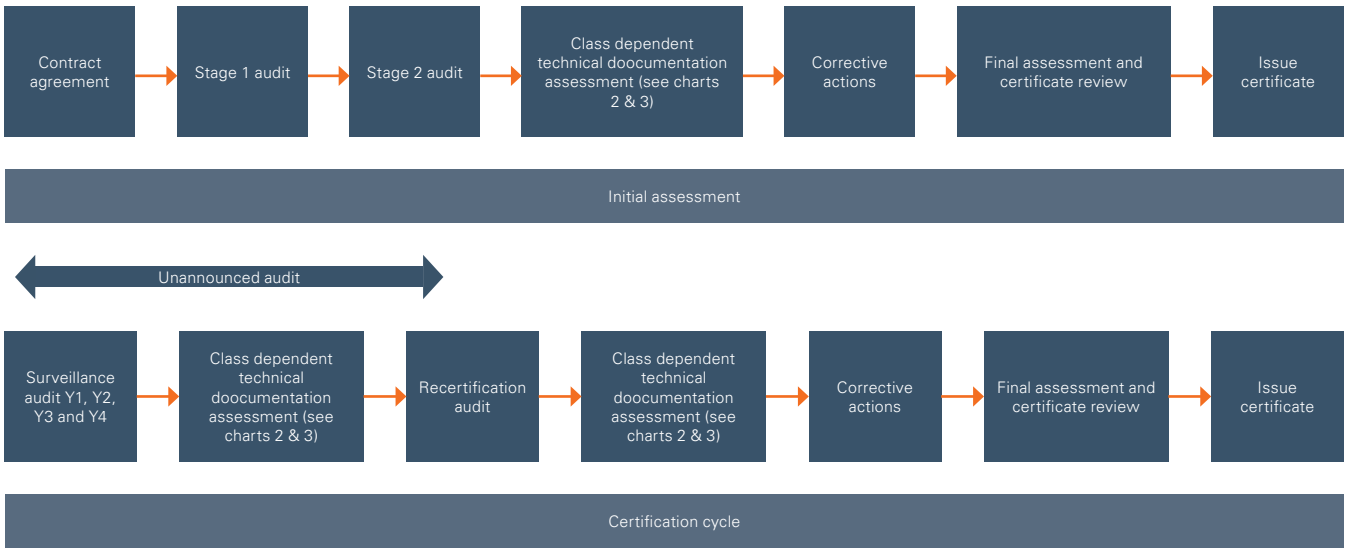
The diagrams below present the type of conformity assessment per device class and guide you to the appropriate certification process that SGS may offer you. For these diagrams:

- "Class 1 reusable" is an abbreviation of "Class I reusable surgical instruments"
- "Specific Class IIb" are:
  - Active Class IIb devices intended to administer and/or remove a medicinal product (Rule 12 Annex XIII of MDR)
  - 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
- "Specific Class III" are implantable Class III devices, Class III devices incorporating a medicinal substance, Class III devices utilizing animal tissue

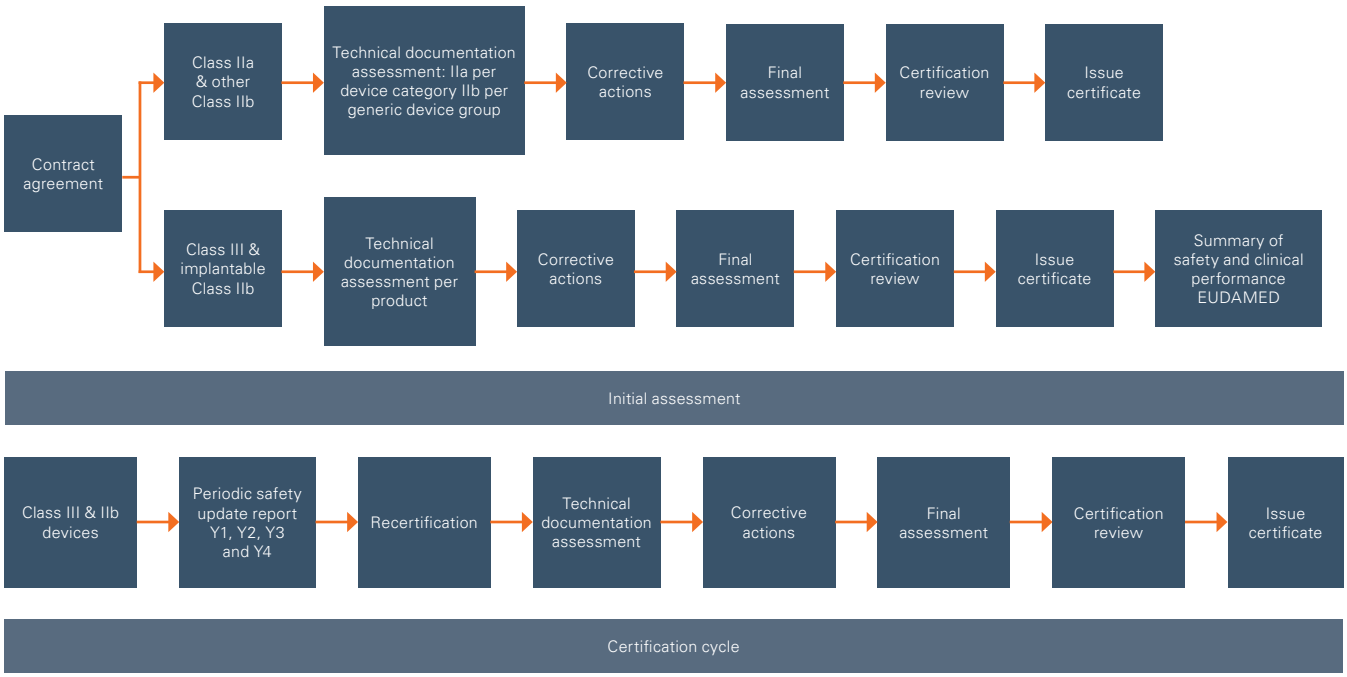


[1]*Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.*

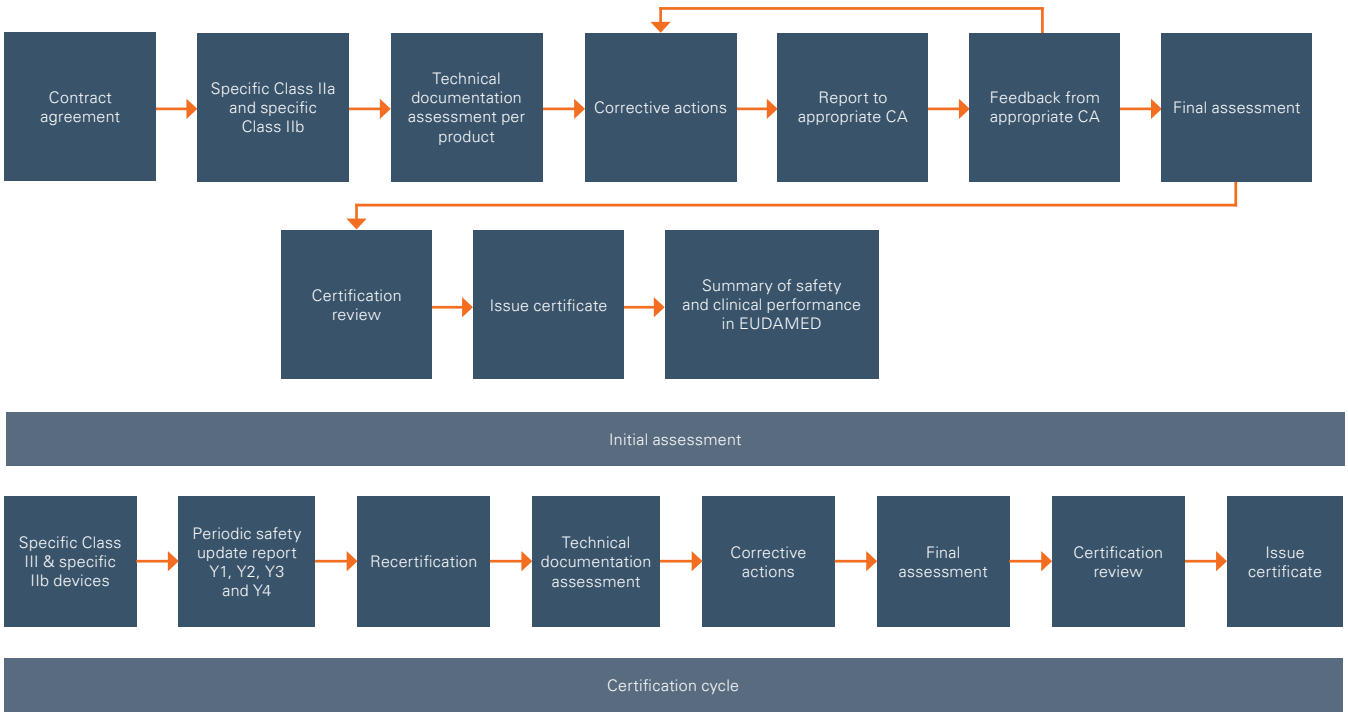
PROCESS CHART 1: OVERALL CONFORMITY ASSESSMENT PROCESS FOR QUALITY SYSTEM AUDIT AND TECHNICAL DOCUMENTATION ASSESSMENT



PROCESS CHART 2: TECHNICAL DOCUMENTATION ASSESSMENT FOR PARTICULAR CLASSES OF PRODUCT (ANNEX IX SECTION 4)



PROCESS CHART 3: TECHNICAL DOCUMENTATION ASSESSMENT FOR PARTICULAR CLASSES OF PRODUCT (ANNEX IX SECTION 5)



GENERAL INFORMATION

The certification cycle is usually based on five years. However, SGS may, based on documented evidence, decide to reduce the cycle to four years or less, depending on the results of initial, surveillance and recertification conformity assessment or due to other factors, such as vigilance issues or unannounced audit findings, as authorized by MDR (EU) 2017/745. Throughout the certification cycle, SGS will, periodically, at least once every 12 months, carry out surveillance audits and assessments to ensure that you apply the approved quality system and post-market surveillance plan.

All applicable conditions can be consulted in our contractual annexes provided with the contract proposal and available for downloading on our website.

Your application needs to be submitted in English. We can accept that your quality management system is in your local language or English. Your technical documentation, as well as any further evidence in response to corrective action requests, should be submitted in English and electronically through a secured web-based application with prior agreement from SGS. The acceptable language for any further correspondence with NB 1639 is English. Documents should be presented in a text-searchable format (i.e. text-recognition PDF or Microsoft Word). All information should be appropriately indexed to allow easy access to the relevant information. Annex 1 of this document presents a proposal of expected content for your technical documentation.

Corrective action request: Any major nonconformance will have a corrective action plan and date agreed during the audit.

Certification will be deferred until corrective action has been taken and verified by SGS, either on-site or by document review, as appropriate. For further explanation, please refer to Annex 3.

After you get your CE certification and in the event of any developments that will alter your scope of current certification, e.g. change of site or product range, reductions in scope, company name change, etc., you need to inform us as soon as possible and in advance of the change implementation. Please determine those changes that need to be notified to SGS using the decision tree in Annex 2 of this document.

To get more details on each certification process or specific steps, do not hesitate to contact your SGS delivering office.

ANNEX 1: MDR PROPOSAL OF TECHNICAL DOCUMENTATION TABLE OF CONTENT

The technical documentation should be based on guidelines provided in Annex II and III of MDR, and summarized in the following section. In addition, to help you in preparing your technical documentation, we provide a Technical Documentation Request form that can be downloaded from our website.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

a. Product or trade name, and a general description of the device, including its intended purpose and users.

b. The Basic UDI-DI.

c. The intended patient population and medical conditions.

d. Principles of operation of the device and its mode of action.

e. The rationale for the qualification of the product as a device.

f. The risk class of the device and justification for the classification rule(s).

g. An explanation of any novel features.

h. A description of the accessories for a device, other devices and products that are not devices, which are intended to be used in combination with it.

i. A description or complete list of the various configurations/variants of the device that are intended to be made available on the market.

j. A general description of the key functional elements.

k. A description of the raw materials.

l. Technical specifications.

1.2. Reference to previous and similar generations of the device

a. An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist.

b. An overview of identified similar devices available in the EU or international markets, where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

a. The label or labels on the device and its packaging.

b. The instructions for use in the languages accepted in the Member States, where the device is envisaged to be sold.

3. DESIGN AND MANUFACTURING INFORMATION

a. Information to allow the design stages applied to the device to be understood.

b. Complete information and specifications (manufacturing processes and their validation, adjuvants, continuous monitoring and final product testing).

c. Identification of all sites, including suppliers and subcontractors, where design and manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Demonstration of conformity with the general safety and performance requirements set out in Annex I.

a. The general safety and performance requirements that apply to the device and an explanation as to why others do not apply.

b. The method or methods used to demonstrate conformity with each applicable general safety and performance requirement.

c. The harmonized standards, CS or other solutions applied.

d. The precise identity of the controlled documents offering evidence of conformity with each harmonized standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements.

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

a. The benefit-risk analysis referred to in Sections 1 and 8 of Annex I.

b. The solutions adopted and the results of the risk management.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate the conformity of the device with the requirements of this Regulation and the applicable general safety and performance requirements.

6.1. Preclinical and clinical data

a. Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device.

b. Detailed information regarding test design, complete test or study protocols and methods of data analysis, in addition to data summaries and test conclusions, in particular:

— The biocompatibility of the device, including the identification of all materials in direct or indirect contact with the patient or user.

— Physical, chemical and microbiological characterization – electrical safety and electromagnetic compatibility.

— Software verification and validation.

— Stability, including shelf life.

— Performance and safety.

c. The clinical evaluation report and its updates, and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV.

d. The PMCF plan and evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.

6.2. Additional information required in specific cases

a. Statement about medicinal product(s) contained in the device and the associated data (source of that substance and the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device).

b. Statement and data about tissues or cells of human or animal origin, or their derivatives. The documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity.

c. Statement and data about devices that are composed of substances or combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body.

d. Information and tests on devices containing CMR or endocrine-disrupting substances.

e. Statement and data about sterility and environmental conditions for the relevant manufacturing steps.

f. Statement and data about devices placed on the market with a measuring function.

g. Combination/configuration of devices.

h. For devices related to MDR (EU) 2017/745, evidence of compliance with relevant CS.

7. THE POST-MARKET SURVEILLANCE PLAN IN LINE WITH MDR ARTICLES 83 & 84

— Information concerning serious incidents, including information from PSURs, and field safety corrective actions.

— Records referring to non-serious incidents and data on any undesirable side effects.

— Information from trend reporting.

— Relevant specialist or technical literature, databases and/or registers.

— Information, including feedback and complaints, provided by users, distributors and importers.

— Publicly available information about similar medical devices.

— A proactive and systematic process for collecting any information.

— Effective and appropriate methods and processes to assess the collected data.

— Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis, and the risk management as referred to in Section 3 of Annex I.

— Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field.

— Methods and protocols to manage the events subject to the trend report.

— Methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users.

— Reference to procedures to fulfil the manufacturer's obligations laid down in Articles 83, 84 and 86.

— Systematic procedures to identify and initiate appropriate measures, including corrective actions.

— Effective tools to trace and identify devices for which corrective actions might be necessary.

— A PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

— PSUR referred to in Article 86 and the post-market surveillance report.

ANNEX 2: CHANGES THAT MUST BE NOTIFIED TO SGS BEFORE IMPLEMENTATION

Please see the below table to identify which types of changes must be notified to SGS:

IMPACTED ELEMENT	SIGNIFICANT CHANGES THAT NEED TO BE NOTIFIED
CLINICAL	
Change of intended purpose or indications	All changes to the intended purpose or indications
PMCF conditions	Any change to the agreed PMCF plan
Change or additions to the operative technique, manual	All changes to the operative technique or manual
DESIGN	
Change of design specification	All changes impacting design specifications
Change of device performance or specification	All changes to the device's performance or specifications
Change of software	If there is any impact on diagnosis, delivered treatment or software validation
Product range	Adding or withdrawing devices included in an existing range
Material	Any replacement of materials concerning the device or device component(s)
Mode of operation	Any change

IMPACTED ELEMENT	SUBSTANTIAL CHANGES THAT NEED TO BE NOTIFIED
MANUFACTURING PROCESS, EQUIPMENT AND SUPPLIER	
Change of sterilization method	Any changes
Change or new contractor / supplier	Any changes concerning the supplier
Manufacturing process and equipment	Any changes impacting manufacturing validation
New cleanrooms or significant change (e.g. expansion) of existing cleanroom	Any changes
LABELING, PACKAGING AND SHELF LIFE	
Labeling	Any changes in labeling (except minor grammatical errors or aesthetic changes (color/logo change)
Change of packaging (all levels)	Any changes
Change in shelf life	Any changes to the device shelf life
Agreed conditions or plan for CAPA on remaining open minor CARs	Any extension in time Stop or reduction of agreed study
QMS CHANGES	
Contractual data	Company name / address / no. of employees / legal entity
Management representative	Any changes
Person responsible for regulatory compliance	Any changes
Change in quality management system	Any changes
Significant change in the number of staff	Yes
OTHER	
Design / manufacturing / labeling / packaging changes related to CAPA	Any changes
Data in certificate	Any information recorded in EUDAMED
Changes that impact compliance with GSPR (Annex I)	All changes
Changes that impact the safety and performance of the device	All changes
Changes that impact risk	All changes

This is a non-exhaustive list of significant examples and, in case of doubt, please contact our team.

ANNEX 3: CORRECTIVE ACTION REQUEST (CAR)

During a quality management system on-site audit and/or a technical documentation assessment, one or more nonconformities (non-fulfillment of a requirement) may have been detected and recorded. These nonconformities are presented to you in the corrective action request (CAR) form for all quality management system-related nonconformities.

For technical documentation assessments, the nonconformities are generally integrated directly into the assessment report. Both forms are formally a request to describe the specific corrections and corrective actions taken, or planned to be taken, to eliminate the detected nonconformities within a defined timeframe. In addition, for quality management system on-site nonconformities, you are requested to analyze the root cause of the nonconformities, as well as provide SGS with corrections and corrective actions.

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

This document explains the underlying SGS process that starts from the moment of presenting the detected nonconformities to you (either by the auditor and/or product assessor). By default, the date of the nonconformity is the last day of the audit or technical documentation review. It is very important to respect the timeframes given, as if the timeline is not fulfilled, you will endanger current or future certification as **no concession will be given**.

These timeframes are related to the severity and/or (potential) impact of the associated nonconformities, and are defined by the auditor and/or product assessor, according to SGS internal procedures. These timeframes are recorded and monitored by SGS as a Notified Body, as well as by accrediting bodies and competent authorities.

CAR – GENERAL INFORMATION

1. Nonconformity can be graded as minor or major by the auditor or product assessor, depending on its severity and impact on the product's safety.
2. Make sure you understand the non-fulfillment of a requirement when the CAR is recorded.

3. For each quality management system CAR, an action plan is requested. Your action plan must contain a sufficient level of detail to demonstrate to the auditor that you understand the essential details of the findings of nonconformity, 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. A major CAR must be closed, at the latest, 90 calendar days after it has been raised. If a major nonconformity is detected impacting the safety of the product, the auditor/product assessor must close the nonconformity by a follow-up visit on- or off-site within the 90 days, and would inform you of this specific condition during the audit/assessment. Since 90 days includes assessment by SGS, the client will have less than 90 days to address the issue, which will be decided by the designated auditor or assessor.
5. A specific date will be scheduled and reserved for the evaluation of action plans and evidence as a response to the CAR to be submitted by a client. It is of utmost importance that action plans and associated data are correct, complete and submitted on time, sufficiently resolving the nonconformity. It is neither SGS's responsibility nor the auditor and/or assessor to send reminders to ensure that this information will be submitted on time, according to planned arrangements.
6. Poor "quality" of corrective action plans and/or not submitting on time will cause serious delays that are the manufacturer's sole responsibility. If objective evidence is correct, complete and on time, and it does sufficiently demonstrate the resolution of the nonconformity, then the auditor and/or product assessor can close the CAR.

TO CLOSE A MAJOR CAR FROM A QUALITY MANAGEMENT SYSTEM ON-SITE AUDIT, THE FOLLOWING STEPS MUST BE FOLLOWED:

- Do the INITIAL root-cause analysis and define the appropriate correction, and set the relevant corrective action plan **immediately**.
- Send the corrections and corrective actions plan to the auditor as soon as possible, but **within two working days** after receipt of the CAR.
- The auditor comments on the action plan or accepts it as presented. However, it remains your sole responsibility to resolve the findings of nonconformity, 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.
- Send root cause analysis, documented evidence of the corrections and corrective actions implemented, or being implemented to the auditor, **no 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 at which you must send corrected evidence of the corrections and corrective actions implementation.
- **Only two iterations** of evidence sent and auditor's feedback are authorized within the 90-day timeframe. If, by the second review, 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. Nevertheless, the major CAR must be resolved, reviewed and closed after the second iteration. Unresolved CARs cannot serve as a future lift of suspended certificates.
- If the auditor has determined that a follow-up visit to your site shall be performed to close the major CAR, the follow-up visit must be organized after the review of evidence and within 90 days. This visit will be to evaluate actions taken and implemented, and evaluate their effectiveness, and determine whether certification can be granted or continued.
- If major CAR is not closed in a timely manner, 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 close out 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, **no later than 30 calendar days** following the opening of the major CAR.
- The product assessor reviews the evidence and determines if they are acceptable. If the provided evidence is not acceptable, the product assessor provides their feedback in writing, including the date at which you must send updated evidence of the corrections and corrective actions implementation.
- **Only two iterations** of evidence sent and product assessor's feedback are authorized within the 90-day timeframe. If, by the second review, 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.
- 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 QUALITY MANAGEMENT SYSTEM ON-SITE AUDIT, THE FOLLOWING STEPS MUST BE FOLLOWED:

- Do the root-cause analysis and the appropriate corrections, and set the relevant corrective action plan **immediately**.
- Send the correction and corrective action plan to the auditor as soon as possible, but **no later than two working days** after receipt of the CAR, or earlier.

- The auditor comments on the action plan or accepts it as presented. However, it remains your sole responsibility to resolve the findings of nonconformity, 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.
- Implement your corrections and corrective actions, according to your plan and prepared 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 case of multisite companies, where sites are sampled during the next planned audit, the review will be performed on the main site/headquarters.
- Any minor CAR that cannot be closed out on time, will automatically be raised to a major CAR.

TO CLOSE A MINOR 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, as determined on the CAR form by the product assessor. This is usually within six months and one year from the review.
- The product assessor reviews the evidence and determines if they are acceptable. If the provided evidence is not acceptable, the product assessor provides their feedback in writing, including the date at which you must send updated evidence of the corrections and corrective actions implementation.
- **Only two iterations** of evidence sent and product assessor's feedback are authorized. If, by the second review, the provided evidence is not satisfactory, the minor CAR will be escalated to a major CAR and, if the client fails to address it within three months, the product or certification will be at risk of withdrawal or suspension, as discussed for major CAR raised during technical documentation assessment.

GUIDANCE ON ROOT-CAUSE ANALYSIS AND CORRECTIVE ACTION/PREVENTIVE ACTION (CA/PA):

- Correction:
  - The nonconformity recorded is a non-fulfillment of a requirement and, therefore, requires a correction to resolve the detected nonconformity. The nature of the correction can be diverse and depends on the nature and significance of the deviation. The causal relationship between the deviation and 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, all of them must be addressed.
- Root-cause analysis:
  - The manufacturer should clarify why the non-fulfillment of a requirement (the nonconformity) occurred. What contributed to the circumstances, and which aspects are more likely than others to be the real root cause. Thorough RCA includes validation that the correct factor of influence had 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 nonconformity will be removed.
- Corrective action:
  - The corrective action has one goal: create a solution that removes the root cause found, and that proves to be sustainably effective in assuring that this deviation found will not reoccur.
  - Corrective actions always need to be reviewed and verified thoroughly to ensure that the new situation will not introduce new causes for identical, similar or other deviations.
- General:
  - Please report fact based, 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 to be added with reading instruction for the auditor/reviewer).
- Preventive action:
  - Preventive actions only apply to nonconformities 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 nonconformities 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.