YOUR MEDICAL DEVICES CERTIFICATION PROCESS EXPLAINED

Your organisation wishes to get CE Marking for your medical device(s) according to the Medical Device Regulation (EU) 2017/745. Please see below how SGS can support your organisation. 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 CE1639 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 CE1639.

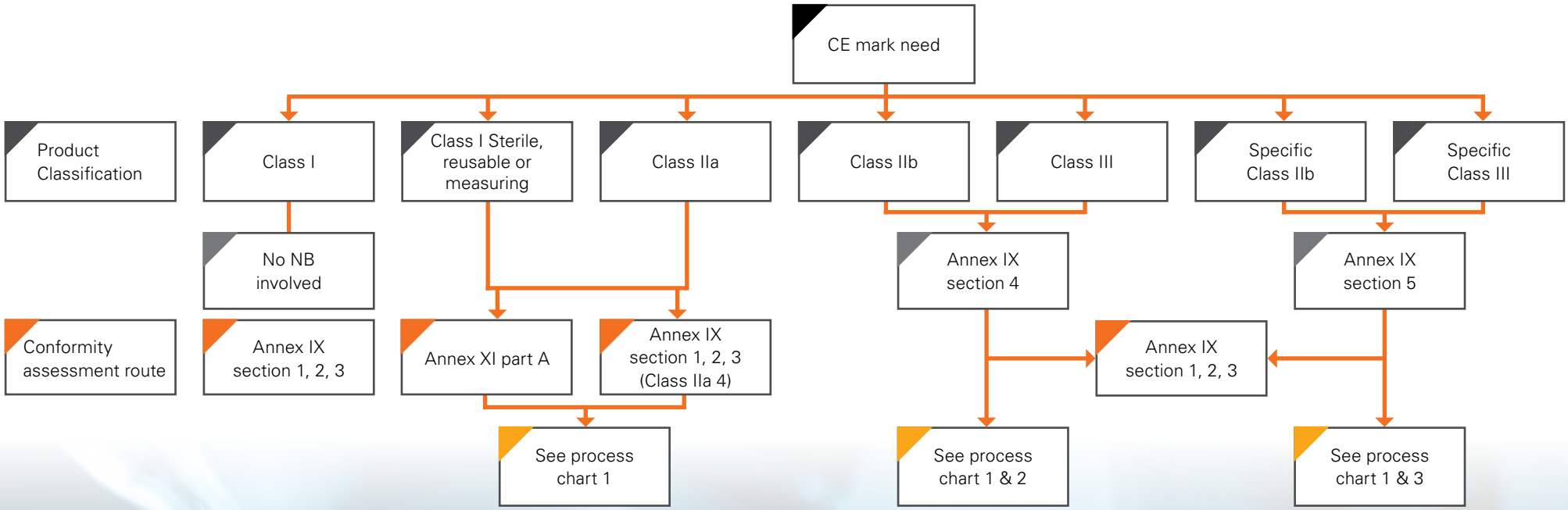
The first step will be for you to determine your product(s) classification according to rules defined in Annex VII of the Regulation (EU) 2017/745. Then to decide which type of conformity assessment path you wish to apply: either based on Quality Management System and assessment of technical documentation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

To apply for certification and to start the assessment process you must complete the "**application form**", **sign it and return it to your delivering office**. We recommend this is done as soon as your decision to proceed has been taken to allow maximum time for SGS audit visit 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 presents the type of conformity assessment per class of device and then guides you to the appropriate certification process that SGS may offer you. For the purpose of these diagrams:

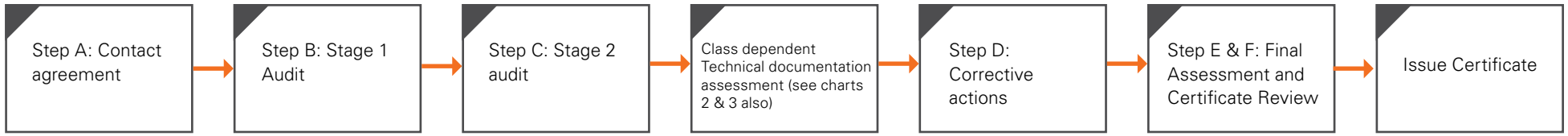
- "Class 1 Reusable" is an abbreviation of "class I reusable surgical instruments"
- "Implantable Class IIb" means implantable Class IIb devices except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling
- "Specific Class IIb" are active class IIb devices intended to administer and/or remove a medicinal product (rule 12 Annex XIII of MDR)
- "Specific Class III" are implantable Class III devices, Class III devices incorporating a medicinal substance, Class III devices utilising 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.

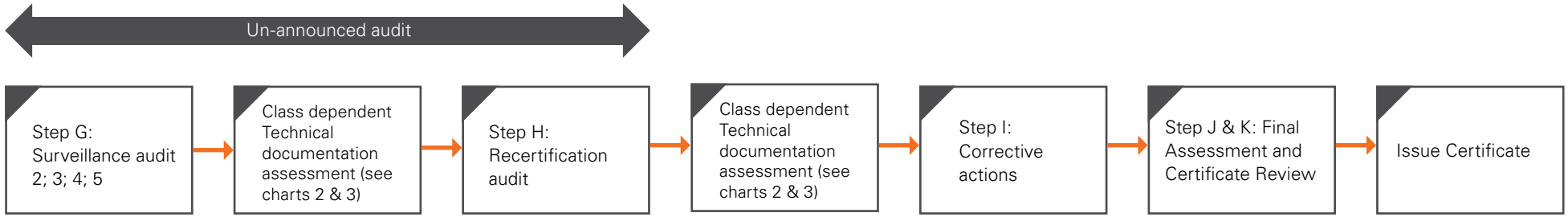

CE mark need
Product Classification
Class I
Class I Sterile, reusable or measuring
Class IIa
Class IIb
Class III
Specific Class IIb
Specific Class III
No NB involved
Annex IX section 4
Annex IX section 5
Conformity assessment route
Annex IX section 1, 2, 3
Annex XI part A
Annex IX section 1, 2, 3 (Class IIa 4)
Annex IX section 1, 2, 3
See process chart 1
See process chart 1 & 2
See process chart 1 & 3

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

INITIAL ASSESSMENT

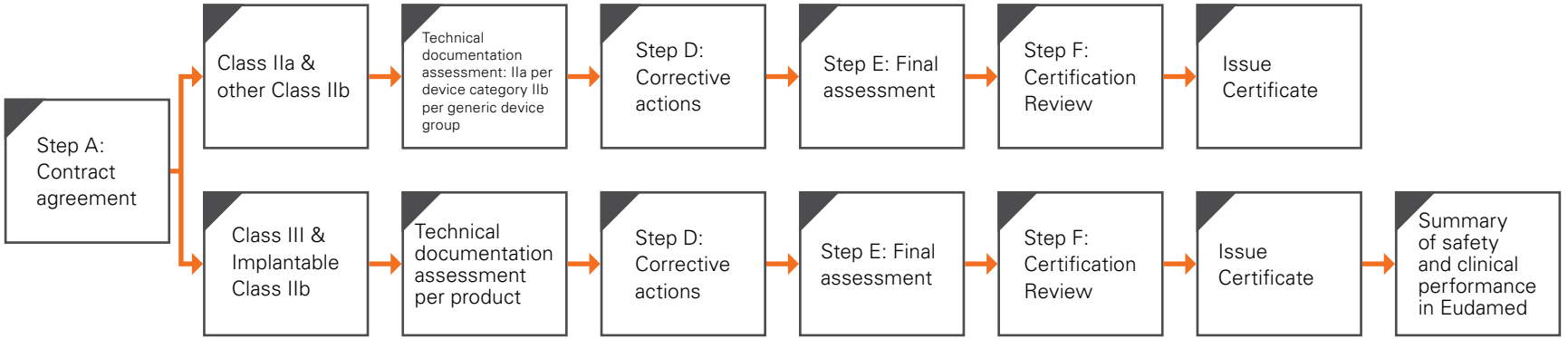


CERTIFICATION CYCLE

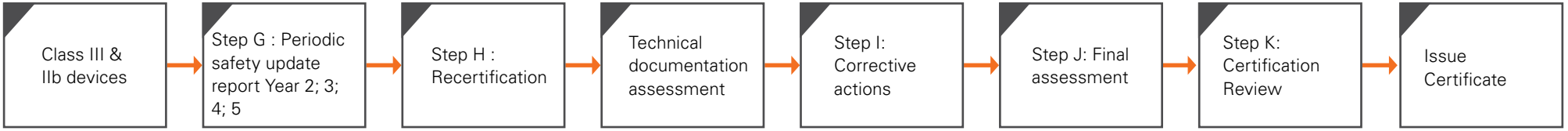


PROCESS CHART 2: TECHNICAL DOCUMENTATION ASSESSMENT FOR PARTICULAR CLASSES OF PRODUCT (ANNEX IX SECTION 4)

INITIAL ASSESSMENT

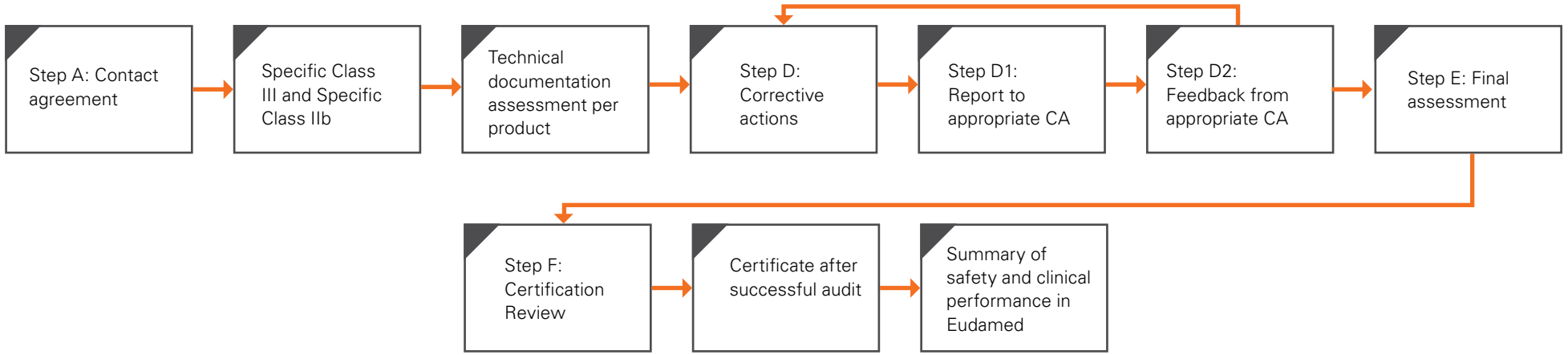


CERTIFICATION CYCLE

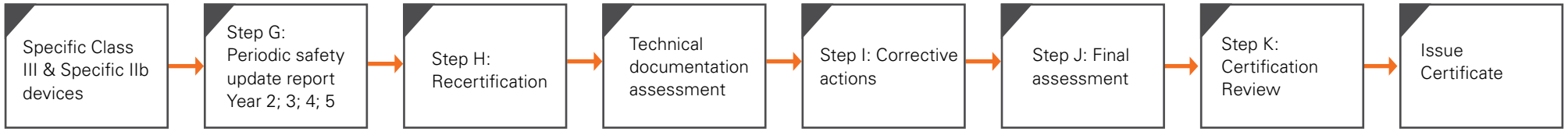


PROCESS CHART 3: TECHNICAL DOCUMENTATION ASSESSMENT FOR PARTICULAR CLASSES OF PRODUCT (ANNEX IX SECTION 5)

INITIAL ASSESSMENT



CERTIFICATION CYCLE



GENERAL INFORMATION

Certification cycle is normally based on 5 years. However, SGS may, based on documented evidence, decide to reduce the cycle to between 1 and 4 years depending on 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 make sure that you apply the approved quality system and your 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 QMS is in your local language or in English. Your technical documentation as well as any further evidence in response to corrective action requests should be submitted in English and electronically on a secured USB stick or alternatives or by electronically secured web-based application with prior agreement from SGS. Documents should be presented in text searchable format (i.e. Text recognition PDF or Microsoft word format). All information should be appropriately indexed to allow easy access to the relevant information. Annex 1 of this document is presenting a proposal of expected content for your technical documentation.

Corrective action request: Any major non-conformance 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 it is important for you 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 on specific steps, do not hesitate to contact your delivering office

ANNEX 1: MDR PROPOSAL OF TECHNICAL DOCUMENTATION TABLE OF CONTENT

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 intended 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 the 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 other 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 on the Union or international markets,

where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

(a) the label or labels on the device and on 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, their adjuvants, the continuous monitoring and the final product testing).

(c) identification of all sites, including suppliers and sub-contractors, 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 harmonised standards, CS or other solutions applied;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised 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 conformity of the device with the requirements of this Regulation and the applicable general safety and performance requirements.

6.1. PRE-CLINICAL 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, methods of data analysis, in addition to data summaries and test conclusions regarding 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 characterisation; — 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 PMCF 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 contained in device and associated date (source of that substance and contain 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

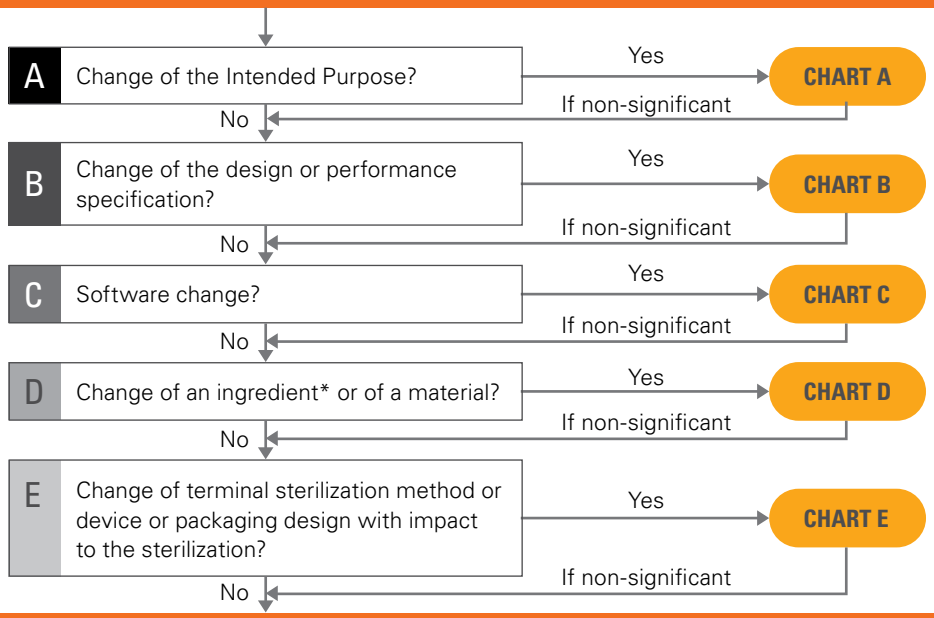
7. THE POST_MARKET SURVEILLANCE PLAN

- 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 feedbacks and complaints, provided by users, distributors and importers;
- publicly available information about similar medical devices.
- a proactive and systematic process to collect any information.
- PSUR referred to in Article 86 and the post-market surveillance report

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

CHANGE ON MDD OR IVDD CERTIFIED DEVICES

CHANGE OF AN EXISTING MEDICAL DEVICE CERTIFIED UNDER MDD OR AIMDD



*The term ingredient used in this document include but are not limited to medicinal substances.

THE CHANGE IS CONSIDERED A NON-SIGNIFICANT CHANGE PER MDR ART. 120(3)

CHART A

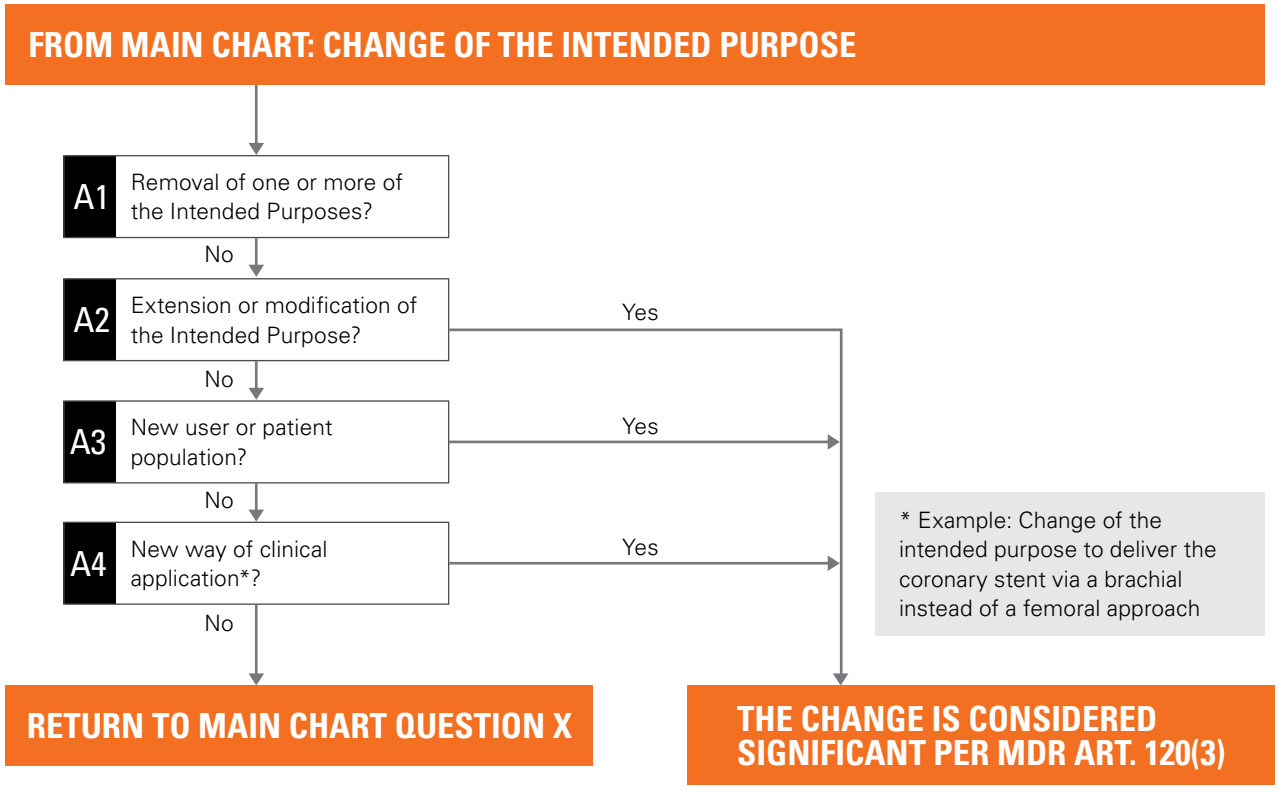
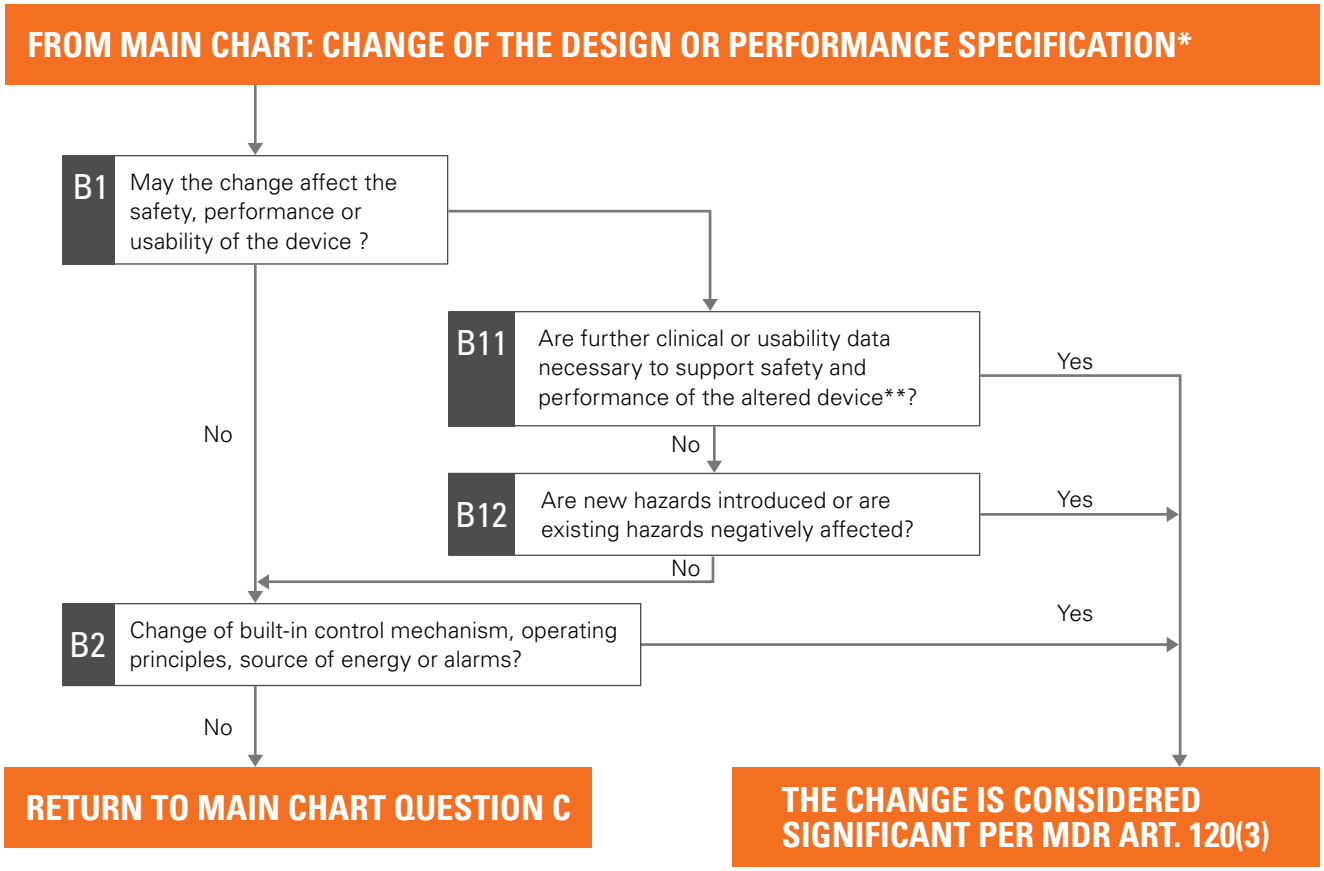

FROM MAIN CHART: CHANGE OF THE INTENDED PURPOSE
A1
Removal of one or more of the Intended Purposes?
No
A2
Extension or modification of the Intended Purpose?
Yes
No
A3
New user or patient population?
Yes
No
A4
New way of clinical application*?
Yes
No
RETURN TO MAIN CHART QUESTION X
THE CHANGE IS CONSIDERED SIGNIFICANT PER MDR ART. 120(3)
* Example: Change of the intended purpose to deliver the coronary stent via a brachial instead of a femoral approach

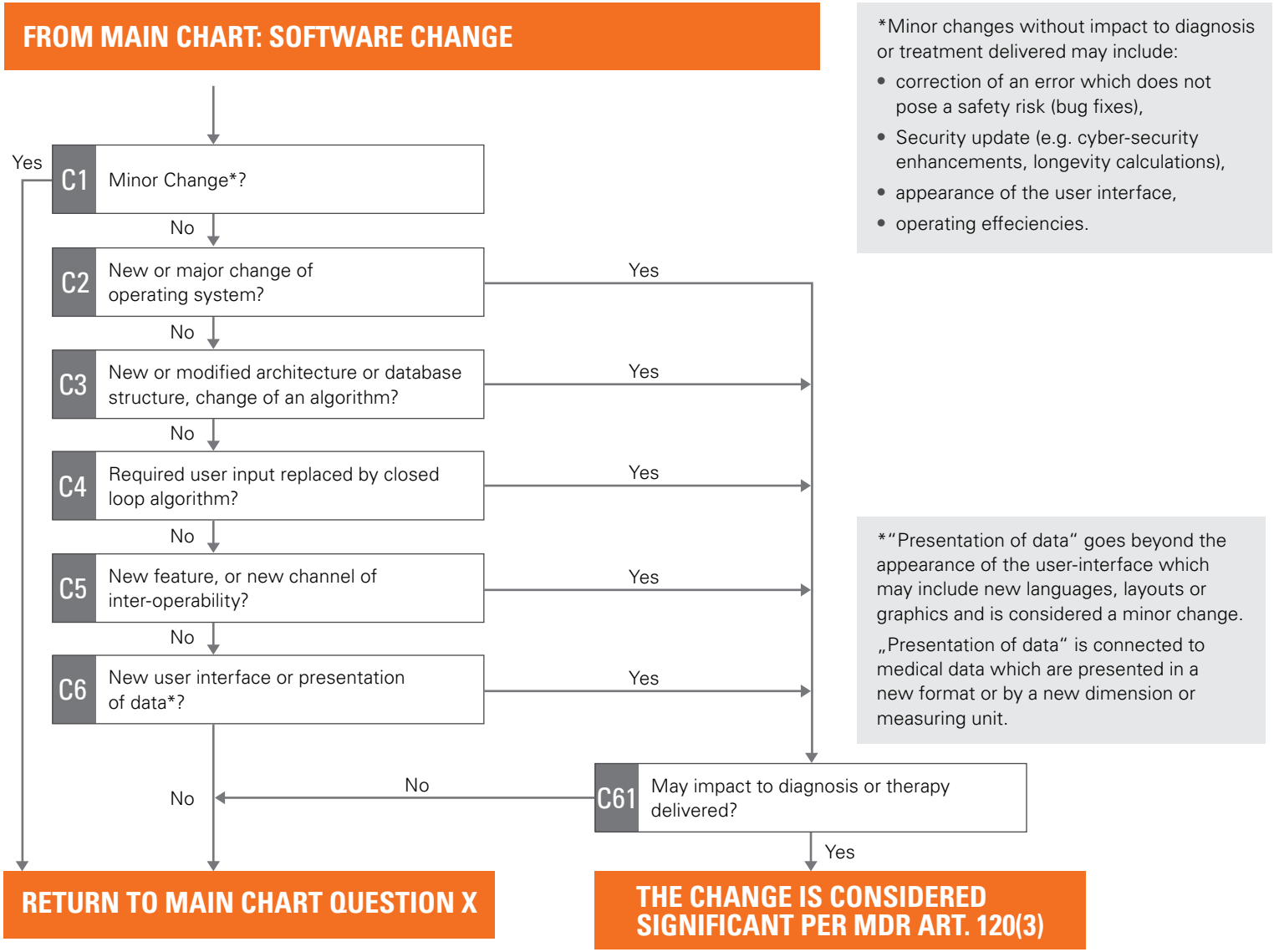
CHART B



* It shall not be differentiated how the change is achieved. A change in specification may be triggered by, but is not limited to, change of hardware or software, including change of a component.

** In acc. with MEDDEV 2.7/1 rev.4

CHART C



*Minor changes without impact to diagnosis or treatment delivered may include:

- correction of an error which does not pose a safety risk (bug fixes),
- Security update (e.g. cyber-security enhancements, longevity calculations),
- appearance of the user interface,
- operating effeciencies.

*"Presentation of data" goes beyond the appearance of the user-interface which may include new languages, layouts or graphics and is considered a minor change.

„Presentation of data" is connected to medical data which are presented in a new format or by a new dimension or measuring unit.

CHART D

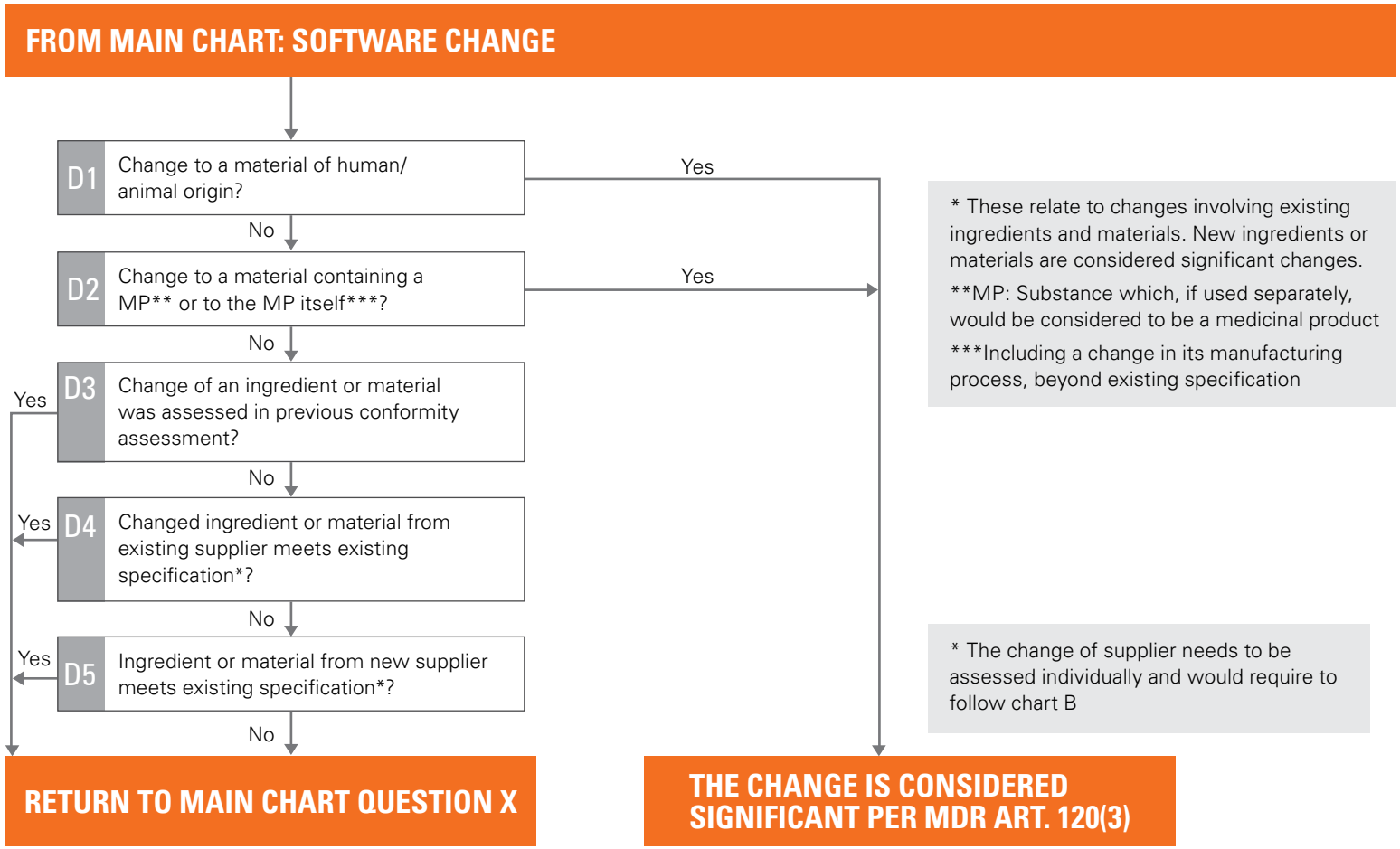
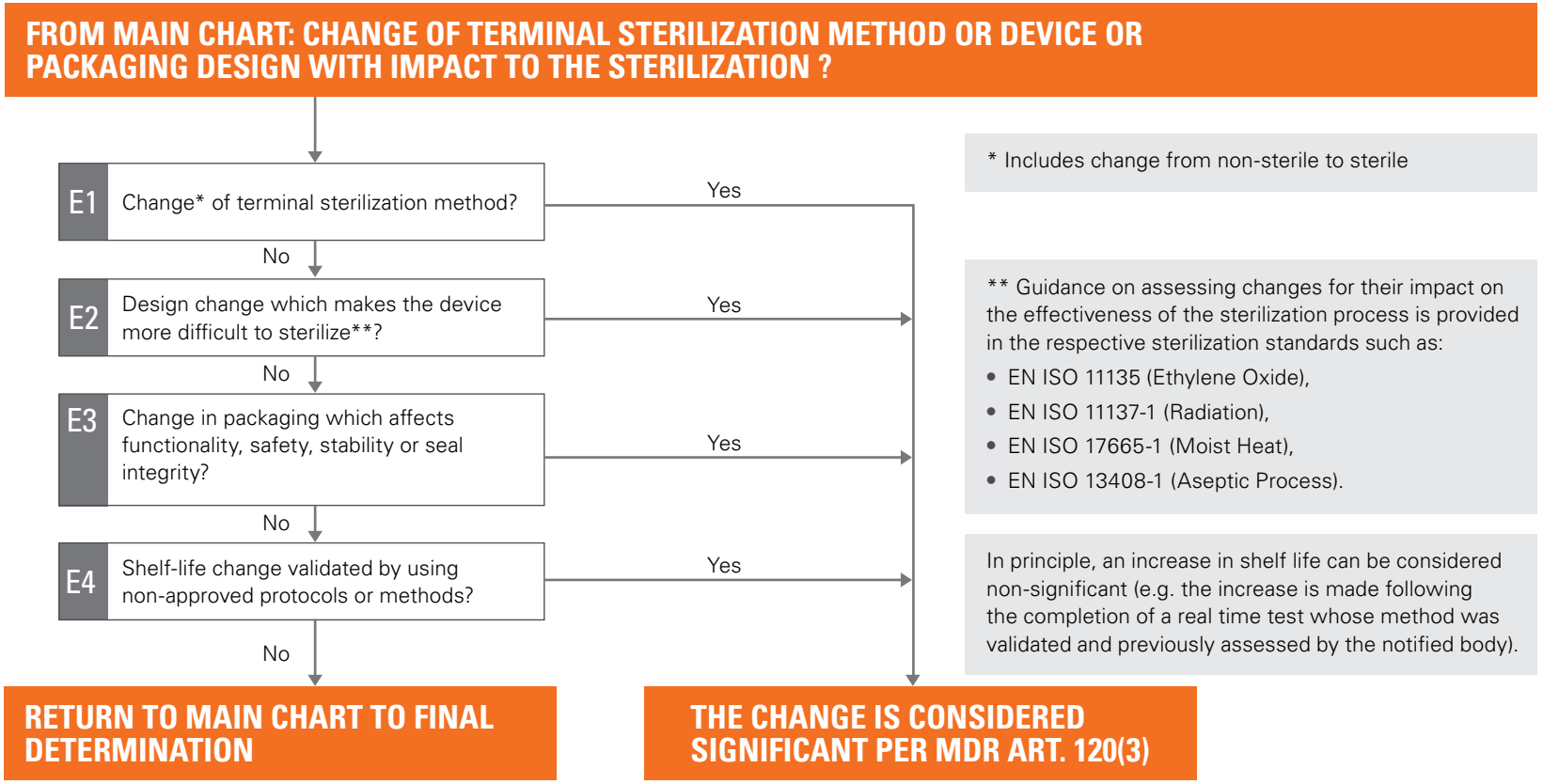

FROM MAIN CHART: SOFTWARE CHANGE
D1
Change to a material of human/ animal origin?
Yes
No
D2
Change to a material containing a MP** or to the MP itself***?
Yes
No
D3
Change of an ingredient or material was assessed in previous conformity assessment?
Yes
No
D4
Changed ingredient or material from existing supplier meets existing specification*?
Yes
No
D5
Ingredient or material from new supplier meets existing specification*?
Yes
No
RETURN TO MAIN CHART QUESTION X
THE CHANGE IS CONSIDERED SIGNIFICANT PER MDR ART. 120(3)
* These relate to changes involving existing ingredients and materials. New ingredients or materials are considered significant changes.
**MP: Substance which, if used separately, would be considered to be a medicinal product
***Including a change in its manufacturing process, beyond existing specification
* The change of supplier needs to be assessed individually and would require to follow chart B

CHART E



* Includes change from non-sterile to sterile

** Guidance on assessing changes for their impact on the effectiveness of the sterilization process is provided in the respective sterilization standards such as:

- EN ISO 11135 (Ethylene Oxide),
- EN ISO 11137-1 (Radiation),
- EN ISO 17665-1 (Moist Heat),
- EN ISO 13408-1 (Aseptic Process).

In principle, an increase in shelf life can be considered non-significant (e.g. the increase is made following the completion of a real time test whose method was validated and previously assessed by the notified body).

ANNEX 3: CORRECTIVE ACTION REQUEST GUIDANCE

During a QMS on-site audit and /or a Technical Documentation assessment, one or more non-conformities (= non-fulfilment of a requirement) may have been detected and recorded. These non-conformities are presented to you in Corrective Action Request (CAR) forms for all QMS related nonconformities. For Technical documentation assessments, the non-conformities are integrated directly in 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 QMS on-site non-conformities you are requested to analyse the root cause of the nonconformities as well as providing SGS with corrections and corrective actions.

We like to remind you that any delay in submission of corrective action plans and the implementation of corrective actions for Major CAR's may lead to new certificates not been issued and current certificates to be 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 the product assessor). By default, the date of the non-conformity is the last day of the audit or technical documentation review. It is very important to respect the timeframes given as if 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 non-conformities 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. Non-conformity can be graded as Minor or Major by the auditor or product assessor depending of its severity and impact on the product's safety. Major non-conformity leads to major corrective action request and minor non-conformity to minor corrective action request.
2. Make sure you do understand the non-fulfilment of a requirement when the CAR is recorded.
3. For each individual QMS CAR an action plan is requested. Your action plan must contain 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. Major CAR must be closed at the latest 90 calendars days after it has been opened. If a major non-conformity detected on site is impacting the safety of the product the auditor must closed the non-conformity by a follow up visit in site within the 90 days' time period and would inform you of this specific condition during the audit.
5. A specific date will be scheduled and reserved for evaluation of action plans and evidence as 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 non-conformity. 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 non-conformity, then the auditor and/or product assess will be able to close the CAR.

TO CLOSE A MAJOR CAR FROM A QMS ON-SITE AUDIT THE FOLLOWING STEPS MUST BE FOLLOWED:

- Do the INITIAL root cause analysis & define the appropriate correction and set relevant corrective action plan immediately,
- Send the corrections and corrective actions plan to the auditor as soon as possible but not later than within 2 working days after receipt of the CAR, or earlier.
- The auditor comments on the action plan or accepts as presented. However, it remains your sole responsibility to resolve the findings of non-conformity, 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 not later than 30 calendar days following opening of the major CAR.
- The auditor reviews the evidence and determines if it is acceptable. If 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 (2) iterations of evidence sent and auditor's feedback are authorized within the 90 days' 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 needs to be resolved, reviewed and closed after the second iteration. Unresolved CAR's cannot serve a future lift of suspended certificates.
- 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 review of evidence and within 90 days. This visit will be to evaluate actions taken and implemented and to evaluate their effectiveness and determine whether certification can be granted or continued.
- Suspended and withdrawn CE certificates are automatically reported to the relevant Competent Authority and in EUDAMED.
- Successful review and close out of all open CAR's 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 being implemented to the agreed SGS contact not later than 30 calendar days following 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 (2) iterations of evidence sent and auditor's feedback are authorized within the 90 days' 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 a device removed from the certificate scope.
- Nevertheless, the major CAR needs to be resolved, reviewed and closed after the second iteration. Unresolved CAR's cannot serve a future lift of suspended certificates.

TO CLOSE A MINOR CAR THE FOLLOWING STEPS MUST BE FOLLOWED:

- Do the root cause analysis & define the appropriate corrections and set relevant corrective action plan immediately,
- Send the correction and corrective action plan to the auditor as soon as possible but not later than within 2 working days after receipt of the CAR, or earlier.
- 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 multi-site companies where sites are sampled during a 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.

GUIDANCE ON ROOT CAUSE ANALYSIS AND CA/PA:

CORRECTION

- The non-conformity recorded is a non-fulfilment of a requirement and therefore requires a correction to resolve the detected non-conformity. 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 the correction is that the correction lifts the non-conforming 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 need to be addressed.

ROOT CAUSE ANALYSIS

- Why could the non-fulfilment of a requirement (the nonconformity) occur. 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 determination of the correct root-cause leads to a corrective action that ensures that the reason for the occurrence of this non-conformity will be removed.

CORRECTIVE ACTION

- The corrective action has one goal only: create a situation that removes the root cause found, and that proofs to be sustainably effective in assuring that this deviation found will not re-occur.
- Corrective Actions always need to be reviewed and verified thoroughly to assure 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 the deviation found. A clear relation to revised evidence is of importance to understand the chosen resolution (where needed to be added with reading instruction for the auditor/reviewer)

PREVENTIVE ACTION

- Preventive Actions only apply to non-conformities 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 non-conformities yet.
- The review of Preventive Action will not be part of the review of a CAR, it may however be part of review of your CAPA system.