G-420_01e_SERVICE DESCRIPTION & CONFORMITY ASSESSMENT PROCEDURES ACCORDING TO MDR

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Content

1 Foreword

This document provides a description of the application and conformity assessment procedures under the Regulation (EU) 2017/745 (MDR) according to MDR Annex VII 4.2 a) by which manufacturers can obtain certification from it **based on the scope of designation of DQS Medizinprodukte GmbH (DQS MED).**

The current version of the standard fees (MDR Art. 50 and Annex VII 4.2 (b)) applicable for the conformity assessment activities can be obtained from the DQS MED website.

The documentation provided by our clients for the conformity assessment procedures (MDR Annex VII 4.2 (a) shall be provided either in German or English. Test reports originally prepared in other languages shall be presented with an official translation into German or English. All documents provided for assessment shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include the elements listed in applicable MDR Annexes such as MDR Annex II and III for TDA, MDR Annex XIV for clinical evaluation and MDR Annex IX 2.1 and 2.2 for QMS assessment. Please consider for technical documentation "Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Devices Regulation (EU) 2017/745".

2 Subject Matter

2.1 Conformity Assessment

The service description explains the requirements for providing the various conformity assessment procedures under Regulation (EU) 2017/745 for which DQS MED acts as an EU Notified Body (NB).

The Regulation (EU) 2017/745 applies to:

- Medical devices (Article 2 (1))
- Accessories for medical devices (Article 2 (2))
- Products listed in Annex XVI and their accessories
- Custom-made device (Article 2 (3))
- Systems and procedure packs (Article 22 (3))

This regulation does not apply to:

- In vitro diagnostic medical devices (Regulation (EU) 2017/746)
- Medicinal products (Directive 2001/83/EC), considering the product's principal mode of action
- Advanced therapy medicinal products (Regulation (EC) No 1394/2007)
- Human blood, blood products, plasma, or blood cells of human origin, except for certain devices
- Cosmetic products (Regulation (EC) No 1223/2009)
- Transplants, tissues, or cells of animal origin or their derivatives, unless non-viable
- Transplants, tissues, or cells of human origin (Directive 2004/23/EC), unless nonviable
- Products containing viable biological material or organisms, like living microorganisms
- Food (Regulation (EC) No 178/2002)

In-house device according to MDR Art. 5 (5), a device that is manufactured and used only within a health institution established in the Union is out of scope for the conformity assessment services provided by the DQS MED. Class III Implantable Custom-made devices are also out of scope for the conformity assessment services provided by DQS MED.

2.2 MDR Certification

Prior to placing a device on the market, manufacturers require an assessment of the conformity of that device, in accordance with the one or more conformity assessment procedures set out in MDR Annexes IX to XI (MDR Art. 52). The required conformity assessment procedure depends on the risk classification (Class I, Class IIa, Class IIb and Class III devices) and type of device (sterile condition, measuring function, reusable surgical instruments or implantable device).

DQS MED provides conformity assessment services according to MDR Annex IX and Annex XI as described below, and according to the notification details officially published in the European in the EU NANDO Information System. Depending on the applicable conformity assessment procedures, the MDR certification can result in either one or more combined types of EU Certificates (three different types available at DQS MED).

These certificates can be valid for no longer than five years. On renewal application by the manufacturer, the validity of the certificate may be renewed for further maximum five-year periods, based on an assessment according to Annex VII, 4.11 on Re-certification.

Each certificate refers to only one conformity assessment procedure (MDR Annex XII, Ch. I, 2.) and is issued exclusively to one manufacturer (MDR Annex XII, Ch. I, 3.). Certificates of conformity are drawn up primarily in German and English languages. The communication between DQS MED and manufacturer is mainly in German and/or English.

EU quality management system (QMS) certificates and EU production quality assurance (PQA) certificates include the identification of the devices or groups of devices, the risk classification and the intended purpose in general. Individual devices covered by these certificates are recorded with further information including classification in the certificate related documentation at the Notified Body. Whereas EU technical documentation assessment (TDA) certificates include a clear identification, including the name, model and type, of the device or devices, the intended purpose as indicated by the manufacturer in the instructions for use.

Types of Devices	Conformity Assessment Procedure	Type of EU Certificates
MDR Class Is, m, r MDR Class IIa MDR Class IIb non-implantable MDR Class IIb implantable WET	MDR Annex IX Chapter I and III	EU Quality Management System certificate
MDR Class Is, m, r MDR Class IIa	MDR Annex XI Part A	EU Quality Assurance certificate
MDR Class IIb implantable non-WET MDR Class III	MDR Annex IX Chapter I and III + MDR Annex IX Chapter II	EU Quality Management System certificate + EU Technical Documentation certificate

DQS MED provides conformity assessment services according to MDR Annex IX and Annex XI Part A for manufacturers. The conformity assessment activities by DQS MED do not include certification for distributors and importers according to MDR Art. 16 (4).

3 General Conditions

3.1 Obtaining the Certification

To obtain EU Certification under MDR, the manufacturer must identify the appropriate conformity assessment procedure(s) depending on the classification of the device(s) and apply at a Notified Body to undergo the conformity assessment. Upon contact with the Notified Body the procedure starts with the (pre-)application phase concluded with an application review of the NB, and contractual agreements between the manufacturer and the Notified Body. The conformity assessment, depending on the classification, includes the assessment of technical documentation, and QMS auditing at the manufacturer's site and/or other sites involved as manufacturer´s critical supplier and subcontractors. The EU Certification depends on the positive outcome of the conformity assessment activities performed under applicable conformity assessment procedure(s).

3.2 Test Samples

If required, the physical, laboratory or other tests to be carried out by DQS MED in the context of sample tests and assessment of technical documentation in accordance with MDR Annex IX, Sections 3.4 and 4.3. The manufacturer provides test samples required free of charge for the purposes of testing and bear costs for logistic arrangements. Regardless of the outcome of the activity, if the devices subjected to testing are returned, they are sent to the manufacturer in their post-testing condition. DQS MED reserves the right to request the manufacturer to keep the samples subjected to testing, or a part of them, at its premises, duly marked or sealed. In case of destructive testing, DQS MED disposes the materials according to applicable disposal requirements.

3.3 Internal Personnel, Subcontractors and External Experts

DQS MED ensures that personnel involved in conformity assessment activities are qualified according to documented procedure required by MDR Annex VII, 3.2.1 including as regards knowledge, experience and other competence required and defined qualification criteria in MDR Annex VII, 3.2.

DQS MED may subcontract certain clearly defined assessment parts of auditing of quality management systems or of product-related reviews according to MDR Annex VII, 3.4.1. Where subcontractors or external experts are used in the context of a conformity assessment, the manufacturer is informed in detail of the activity outsourced to the external expert and/or subcontractors.

DQS MED retains full responsibility for being able to produce appropriate evidence of the competence of its subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf. DQS MED ensures that the subcontractor and external persons meet the relevant requirements of MDR Annex VII and do not further subcontract work to organisations or personnel.

3.4 Confidentiality, Independence and Impartiality

DQS MED is committed to maintaining the highest standards of confidentiality and impartiality in all our conformity assessment activities related to the MDR. DQS MED ensures that all information obtained during the conformity assessment process is treated with the utmost confidentiality and not affect the rights and obligations of the European Commission, Member States and notified bodies regarding exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law. The documents of manufacturer required for conformity assessments that have been submitted to DQS MED are kept by DQS MED during the whole certification period and retain at least 10 years and in the case of implantable devices at least 15 years starting from expiry date of the EU Certification. DQS MED top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties
b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities
c) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated
d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the devices or processes under assessment; and
e) be linked to any organisation which itself provides consultancy services as referred to in the point (d). Such restriction shall not preclude general training activities that are not client specific and that relate to regulation of devices s or to related standards.

3.5 DQS MED Code of Conduct

In order to ensure compliance worldwide, it is particularly important for DQS MED that all employees follow the uniform principles of DQS MED Code of Conduct, which is binding for all locations worldwide. Therefore, in conducting business with DQS MED, the Manufacturer must read it and conduct itself according to the highest ethical standards.

3.6 Terms and Conditions (T&Cs)

The T&Cs become part of the contract with the manufacturer either after its acceptance (for new contracts) or information of the change by the respective DQS MED company (for existing contracts).

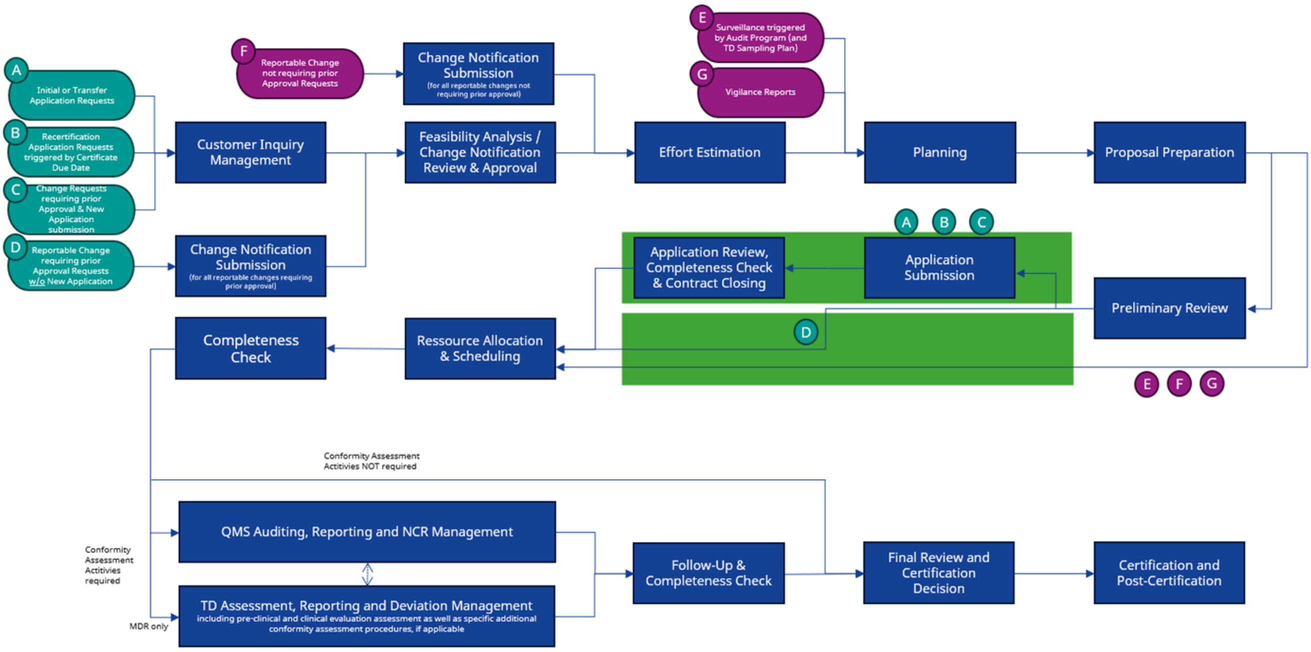
3.7 Cessation of Conformity Assessment Activities of DQS MED

Where DQS MED decides to cease its conformity assessment activities it will inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities.

4 Conformity Assessment Procedure

DQS MED provides conformity assessment services according to MDR Annex IX and Annex XI Part A for manufacturers.

General overview on certification process



The certification process under MDR Annex VII includes various phases of a five-year certification cycle: Initial certification (Pre-application activities to Certification), Changes and modifications, Surveillance activities and post certification monitoring, and Renewal. After renewal, another new five-year certification cycle starts again with Changes and modifications, and Surveillance activities and post certification monitoring until next renewal. All conformity assessment procedures (MDR Annex IX and IX Part A) under MDR follows the same steps. However, the content of application and conformity activities vary depending on the conformity assessment routes which are determined by the class of device and the specific characteristics of the device concerned.

4.1 Pre-Application Activities and Notified Body Quotations

DQS MED offers structured dialogues for the manufacturers before and during the conformity assessment process aimed at exchanges on regulatory procedures, i.e., exchanges of technical information and regulatory guidance between the notified body and the manufacturer. As part of the structured dialogue, DQS MED provide to the manufacturer a comprehensive overview of the certification process, including pre-application and application processes.

During pre-application activities, DQS MED requires manufacturer to submit the information on applicable conformity assessment procedure, manufacturer´s organisation, devices to be covered by certification, and manufacturer’s sites and supplier/sub-contractor using the dedicated form “Customer and Medical Devices Information Form” provided by the individual responsible for conformity assessment at DQS MED. The manufacturer provides all the information listed above in writing to DQS MED. DQS MED reviews the pre-application information as part of the Feasibility Analysis which includes preliminary verification that the product is covered by MDR and its classification relating to a specific conformity assessment (MDR Annex VII 4.2 (d)).

After this preliminary verification, DQS MED estimates the effort and conducts a preliminary planning of the certification cycle. Based on the results of the effort estimation, DQS MED creates a quote including following information: description of service requested, general certification cost, individual conformity assessment activities and their cost according to current price list, and financial conditions related to quotation.

Depending on the certification type, DQS MED performs a Preliminary Review of the process steps completed so far.

Along with quotation manufacturer receives the required application form, agreement and related appendices from DQS MED. In case of acceptance of the quotation, the manufacturer must provide filled and signed application form, agreement and related appendices as well as signed purchase order.

The application on conformity assessment requires to submit documents depending on the chosen conformity assessment procedure during different stages. The MDR General Information provided to manufacturer along with application includes the information on required documents for submission depending on the conformity assessment procedures and the class and the type of devices as well as at various stages.

4.2 Application Review and Contracts (Written Agreements)

Once the application and related documents are received, the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure is checked by the individual responsible for conformity assessment at DQS MED and submitted for application review. DQS MED’s personnel perform application review according to MDR Annex VII, 4.3 (a) to (e) and check following points:

- Completeness of applications with respect to the requirements of the relevant conformity assessment procedure including required documentation as part of the application by DQS MED.
- Verification of the qualification of products covered by those applications as devices and their respective classifications.
- In case of any dispute between manufacturer and DQS MED regarding the classification of the device covered under application, either DQS MED or Manufacturer according to MDR Article 51 (2) shall report the issue to the competent authority of the Member State in which the manufacturer has its registered place of business for EU manufacturer or competent authority of the Member State in which the authorised representative for non-EU manufacturer and follow the decision provided by competent authorities. In this case, application review can be only concluded once the decision on classification is received from the competent Authority.
- Correctness of the chosen conformity assessment procedures by applicant regards to the device in question under this Regulation
- Ability of DQS MED to assess the application based on its designation.
- Availability of sufficient and appropriate resources for application.

Any clarification or correction required for submitted application during the application review, DQS MED requests the manufacturer to provide response with required documents with modification / amendment within 30 days.

In the absence of a response to open clarification within agreed timeline and /or negative outcome of application review, the DQS MED will refuse the application. In case of refused application, DQS MED will communicate the negative outcome to the manufacturer and register the refused application to EUDAMED referred to in MDR Article 57 (g).

Upon positive outcome of the application review, DQS MED countersigns the contract and provides it along with purchase order confirmation to the manufacturer. DQS MED will start then conformity assessment activities as planned. DQS MED cannot guarantee that the assessment will be successful or that the EU Certification will be granted.

5 Assessment of the Quality Management System according to MDR Annex IX Chapter I and III

Conformity assessment procedure according to MDR Annex IX Ch. I and III is based on assessment of quality management system (QMS) and applicable to all type of Class I sterile condition, measuring function, reusable surgical instruments, Class IIa, Class IIb and Class III devices.

The assessment of QMS includes an assessment of technical documentation (excluded for Class Is, m, r).

For Class IIa, Class IIb implantable WET and Class IIb non-implantable devices, it is done on representative basis.

For Class III devices or Class IIb implantable non-WET devices the procedure in annex IX (chapter I) could be performed only when the assessment procedure according to annex IX (chapter II) will be concluded with positive outcome.

The assessment of QMS requires an audit of the manufacturer's QMS by a Notified Body in order to verify that the QMS ensures that the devices covered conform to the relevant provisions of the MDR which apply to devices at every stage, from design through final quality control. When the QMS conforms to the relevant provisions of MDR, EU QMS certificate is issued by the Notified Body.

5.1 Initial EU QMS Certification

5.1.1 Conformity Assessment Planning

With the application, the manufacturer provides QMS documentation according to MDR annex IX, 2.1 to DQS MED, which is considered to draw up the assessment planning for the initial certification and subsequent surveillance activities of the five years cycles according to Annex VII. The assessment planning includes the cycle’s TD assessment activities and audit program. The audit program covers manufacturer's QMS, devices, technologies and processes involved, sites and relevant suppliers and/or subcontractors. In case, the manufacturer is certified or request certification for additional QMS Standards such as (EN) ISO 13485 or (EN) ISO 9001, DQS MED will plan the MDR audits in combination of additional QMS Standards.

For each device of class III or implantable non-WET Class IIb devices the technical documentation according to MDR Annex IX, Ch. II needs to be assessed by DQS MED. Technical documentation assessment results and information will feed into the initial QMS auditing. For Class IIa devices, Class IIb exempted implantable devices, and other Class IIb devices DQS MED draws up and keeps up to date a sampling plan for the assessment of technical documentation on representative basis covering the range of such devices covered by the manufacturer's application. DQS MED will request the submission of technical documentation as referred to in Annexes II and III according to sampling plan (MDCG 2019-13).

For Class I sterile devices, measuring devices or reusable surgical instruments, the involvement of the notified body in the annex related conformity assessment procedure is limited to aspects relating to establishing, securing and maintaining sterile conditions, conformity with the metrological requirements, and/or aspects relating to the reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use. The certification cycle for MDR QMS assessment is five years, whereas the certification cycle for QMS standards (for example (EN) ISO 13485, (EN) ISO 9001 and MDSAP) are three years. As most of the MDR QMS audits by DQS MED are performed in combination with (EN) ISO 13485 scheme, the audit cycle of both schemes is harmonised to the three years (EN) ISO 17021-1 cycle as shown below. However, the recertification audit according to MDR after the three years does not trigger a re-issuance of the MDR certificate. Only with the renewal procedure and review at the end of the five years MDR certification cycle, a new MDR certificate is issued. This approach ensures efficient use of resources, time and alignment, of different audit cycles between MDR QMS assessment and additional QMS Standards.

5.1.2 Assessment of Technical Documentation on Representative Basis

DQS MED requests for the initial certification the technical documentation acc. Annex II and III for representative devices of Class IIa devices (incl. implantable), Class IIb and exempted implantable Class IIb devices. DQS MED follows the sampling criteria acc. MDCG 2019-13 which defines the term device for the purpose of sampling as a Basic UDI-DI, and the sampling on qualitative and quantitative criteria. The minimum requirement for the initial certification is one representative device per device categories for Class IIa, and one representative device per generic device categories for Class IIb.

DQS MED performs technical documentation assessment along the aspects described in Annex II and III of MDR as well as the demonstration of fulfilment of the General Safety and Performance Requirements according to MDR Annex I. Based on the manufacturer’s technical documentation, DQS MED audits in the next step the manufacturer's QMS in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of the MDR are met (refer to Section 4.3.).

If non-conformities are identified during the technical document assessment, the product reviewer involved will provide the manufacturer a deficiency report and request the resolution of identified non-conformities. The manufacturer is required to send response including the required technical documentation in a timely manner to DQS MED. Upon receival of manufacturer’s response, the product reviewer involved reviews the response including the required technical documentation and provides written feedback on the closure or additional clarification with updated deficiency report.

If the manufacturer doesn't respond within agreed timelines or fails to close all non-conformities after three additional rounds, DQS MED can terminate the evaluation and refuse the EU QMS Certification.

The initial quotation of technical documentation assessment includes the cost of two deficiency rounds. The costs associated with additional deficiency round are borne by the manufacturer and notified through a dedicated quotation, according to the DQS MED’s price list.

5.1.3 Assessment of Quality Management System

DQS MED performs the assessment of the quality management system based on the developed audit program in combined with the technical documentation assessments. The initial audit program covers the full certification cycle and is adjusted in course of the assessment activities throughout certification cycle, when necessary.

5.1.3.1 Individual Audit Planning

Based on the audit program, DQS MED selects and assigns appropriately qualified and authorised personnel with sufficient experience in relation to the technology concerned for conducting the certification audit. The project leader plans and sets up the audit dates with the manufacturer. At least two weeks before the audit the audit agenda is provided to the manufacturer. Before the audit, the audit team prepares on the basis of provided manufacturer data from the application including QMS documentation and relevant technical documentation.

5.1.3.2 Initial Stage 1 Audit

The Stage 1 audit is generally performed at premises of manufacturer. In cases the manufacturer is known to DQS MED through certification of other QMS Standards, DQS MED may decide to perform the Stage 1 audit offsite.

The primary purposes of a Stage 1 audit are:

1. to determine if QMS documentation required by MDR Annex IX/XI Part A and Art. 10 (9) and other applicable MDR documentation requirements have been adequately defined, and documented
2. to assess the medical device organization’s preparedness for the onsite audit, so-called Stage 2 audit
3. to provide a focus for planning the Stage 2 audit by gaining a sufficient understanding of the manufacturer’s QMS
4. to collect necessary information regarding the scope of the management system, including the manufacturer’s site(s), processes and equipment used, levels of controls established (particularly in case of multisite organizations), applicable statutory and regulatory requirements.

During the Stage 1 audit, the lead auditor will collect evidence of implementation of QMS documentation required by MDR Annex IX/XIA and Art. 10 (9) requirements and evaluate if the internal audits and management reviews are being planned and performed and that the level of implementation of the QMS substantiates that the client is ready for Stage 2 audit. If lead auditor identifies the areas of concerns in the Stage 1 audit that could be classified as a non-conformity during Stage 2 audit, the manufacturer is required to correct it prior to the Stage 2 audit. If manufacturer cannot resolve the areas of concern, the Notified Body needs to revise the arrangements for Stage 2 audit or cancel the Stage 2 audit depending on the identified areas of concern. If any significant changes which would impact the QMS occur after Stage 1 audit, the Notified Body will repeat all or parts of Stage 1 audit.

5.1.3.3 Initial Stage 2 Audit

Stage 2 audit takes place on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes (MDR

Annex IX, 2.3). This Stage 2 audit must be performed within and not later than six months from the Stage 1 audit.

The purpose of a Stage 2 audit is to determine if all applicable requirements of MDR and the relevant regulatory requirements have been implemented. DQS MED will ensure that all relevant regulation requirements for conducting audits (i.e. MDR Annex VII, 4.5.2, and Annex IX, 2.2 and 2.3) are assessed completely during Stage 2 audit.

The Stage 2 audit include an evaluation of:

1. the effectiveness of the medical device organization's QMS incorporating the applicable regulatory requirements
2. product/process related technologies
3. adequate product technical documentation management in relation to relevant regulatory requirements
4. the medical device organization's ability to comply with these requirements

As part of achieving these objectives, the auditor verifies that the medical device manufacturer maintains sufficient and reliable objective evidence to demonstrate its devices meet general safety and performance requirements, and effectiveness and any other regulatory requirement identified in the audit tasks. During the audit, information relevant to the audit objectives, scope and criteria are obtain by appropriate sampling and verified to become audit evidence. This includes the verification of conformity at every stage, from design through final quality control to ongoing surveillance.

At the end of Stage 2 audit, audit team analyses all information and audit evidence gathered during Stage 1 and Stage 2 audits to review the audit findings and agree on the audit conclusions. At the end of Stage 2 audit, the lead auditor presents the audit conclusions (positive and negative results), including the recommendation regarding certification. The lead auditor explains the non-conformities in such a manner that they are understood and agrees the timeframe for response with manufacturer. The lead auditor may or may not recommend issuance of the certificate(s) depending on the outcome of the audit conclusion.

5.1.3.4 Audit Closure

If non-conformities are identified during the stage 2 audit, the EU QMS certificate issuance depends on the successful resolution of these non-conformities. The manufacturer is required to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate the detected non-conformities, within a defined time. In case of minor non-conformities, manufacturer must provide a Corrective and Preventive Action (CAPA) plan including root cause analysis, planned for corrections and corrective actions, as soon as possible and no later than 30 days after audit end date. In case of major nonconformities, manufacturer is required to provide the CAPA plan as soon as possible and no later than 30 days after audit end date and evidence of implementation of the corrective actions as soon as possible and no later than 60 days after audit end date.

The lead auditor and respective audit team review the corrections, identified causes and corrective actions submitted by the manufacturer to determine if these are acceptable. In case of major non-conformities, lead auditor verifies the effectiveness of any correction and corrective actions taken. The lead auditor informs the manufacturer about the result of the review and verification. The audit team draws up a specific audit report including any nonconformity and recommendations. If all identified non-conformities are resolved and the effectiveness of any correction and corrective actions taken is verified, the lead auditor concludes the positive recommendation for certification and make a recommendation for a final review and for a final decision to the Notified Body. If non-conformities remain unresolved, the lead auditor cannot recommend the certification.

5.1.4 Final Review and Certification Decision

DQS MED assigns authorized personnel who is different from those who conducted the audit/TD assessment. This personnel reviews all the documentation and evidence related to the applicable conformity assessment procedure and verifies that the assessment reports are complete and sufficient with respect to the scope of the application. They ensure that all regulatory requirements are met and that the assessments were conducted impartially and thoroughly.

Based on the comprehensive evaluation of the documentation and evidence, DQS MED decides either to approve the certification to the applicable conformity assessment procedure, requests additional information, or rejects the application if it does not meet the necessary requirements.

If there are no unresolved non-conformities preventing issuance of a certificate, the final review and final decision is completed by issuing an EU QMS certificate with five years validity. DQS MED informs the manufacturer of the outcome of the assessment and the decision to issue the EU QMS certificate, along with relevant audit and assessment reports. Information of the EU QMS certificate is entered into EUDAMED (MDR Art. 57) if the EUDAMED module is functional. In the absence of the EUDAMED module, the EU QMS certificate data is registered according to the alternative and national provisions (corresponding provisions of Directives 90/385/EEC and 93/42/EEC (MDR Art. 123)).

If the EU QMS certification is not approved, DQS MED informs the manufacturer of this decision in writing including the reason for rejection of certification. DQS MED notifies any rejection, restriction, suspension or withdrawal of EU QMS certificates to the EUDAMED database (MDR Art. 57), respectively according to the alternative and national provisions.

5.2 Changes and Modifications to EU QMS Certificate

DQS MED assesses the planned changes and decides whether the planned changes require a new conformity assessment in accordance with MDR Article 52 or whether they could be addressed by means of an amendment or a supplement to the existing EU QMS certificate. In the latter case, DQS MED assesses the substantial changes, notifies the manufacturer of its decision and, where the changes are approved, provides it with a supplement to the EU QMS certificate. Once the substantial changes are approved by the Notified Body, they can be implemented by the manufacturer.

5.2.1 Changes to the approved Quality Management System

The manufacturer is required to inform DQS MED of any planned substantial change(s) to the QMS using the Change Notification Form.

The regulatory requirements can be found in MDR Annex IX, Chapter I, Section 2.4, Chapter III, Section 7 and MDR Annex XI, Part A, Section 6.4 and 9.

This Chapter provides non-exhaustive lists of examples of substantial and non-substantial changes, as well as, where relevant, reportable changes not requiring prior approval, grouped into the following categories:

- Changes to the approved processes and procedures
- Changes related to the scope of the QMS
  - Changes to manufacturer's sites or organisational structure
  - Changes involving a critical supplier
  - Changes to critical processes
  - Changes to sterilisation processes
  - Changes to packaging processes
  - Changes to reprocessing process
  - Changes resulting from new or revised legislation

5.2.1.1 Changes to the approved processes and procedures

Substantial changes to the approved processes and procedures, including approved critical procedures and approved procedure for management of modifications, are **reportable changes requiring prior approval** when for example they include:

- Substantial changes in the approved **risk management process** (e.g., changes in occurrence and severity rating for risk management).
- Substantial changes to the approved **design processes** (e.g., outsource the design process).
- Substantial changes in the **vigilance process** (e.g., changes in the notice period).

5.2.1.2 Changes related to the scope of the QMS

5.2.1.2.1 Changes to manufacturer's sites or organisational structure

Changes occurring to manufacturer's sites or organisational structure are considered **substantial changes** if they might introduce potential risks related to process consistency, safety conditions and / or regulatory compliance.

Examples of substantial changes, which are **reportable changes requiring prior approval**, related to the manufacturer's sites or organisational structure include:

- Introduction of a **new facility or relocation of a facility**. In this case, the new or relocated facility must still be subject to the notified body's QMS auditing program.
- Introduction of a **new technology or horizontal codes** (MDT / IVT or MDS / IVS code) to an existing facility.
- Addition of a **new production line** not covered by existing horizontal codes.
- Modification of the **manufacturing environment** not covered by existing horizontal codes.

Examples of reportable changes not requiring prior approval include:

- **Removal of a manufacturing facility.** This needs to be reported to the notified body for information, as an administrative change that does not require prior approval (see Chapter 5.4). However, outsourcing is a substantial change.
- **Changes in the organisation's Person Responsible for Regulatory Compliance (PRRC).** This needs to be reported to the notified body for information, as an administrative change that does not require prior approval (see Chapter 5.4).

5.2.1.2.2 Changes involving a critical supplier

The assessment of critical suppliers falls under the manufacturer's QMS and is verified by the notified body during audits. Examples of critical suppliers include (non-exhaustive list):

- Supplier of critical (active) ingredients or materials (e.g., raw materials, antigens, antibodies, substances, parts, components or software)
- Supplier of devices
- Supplier of design / development activities or parts thereof
- Supplier of manufacturing processes or parts thereof
- Supplier providing superficial treatments / coatings
- Supplier providing sterile barrier packaging or sterilisation services
- Supplier performing product testing / final verification activities
- Supplier providing regulatory services
- Supplier providing translation services

Examples of substantial changes, which are **reportable changes requiring prior approval**, related to critical suppliers include:

- Introduction of a **new critical supplier** (including the addition of an alternate critical supplier).
- Changes in a **critical supplier's location**.
- Substantial changes in critical supplier's **processes, technology, or site**, as defined for manufacturers in Chapter 5.1.2.
- Changes in the **EU Authorised Representative**.

Examples of reportable changes not requiring prior approval include:

- **Removal of a critical supplier.** This needs to be reported to the notified body for information, as an administrative change that does not require prior approval (see Chapter 5.4).

5.2.1.2.3 Changes to processes

Substantial changes to processes regard alterations which could impact the final product's safety and / or performance.

Examples of substantial changes, which are reportable changes requiring prior approval, related to critical manufacturing processes include:

- Implementation of new or changes to **critical manufacturing processes** (e.g., changes from casting to 3D printing, changes from manual to automatic filling process, changes to surface treatment methods (e.g., from plasma to laser treatment), changes to washing / cleaning steps, changes to the welding process, changes in the viral inactivation process, changes in the drug coating process for the device, changes in the validated labelling process).
- Changes in a **manufacturing process** for a device that might **impact pre-sterilisation bioburden**.
- **Transfer of critical processes** (e.g., design, manufacture, storage) from one facility to another, within the company / group, unless already covered by the same QMS certificate, and not introducing a new technology code for the new facility.
- **Internalisation** (from supplier to manufacturer), **outsourcing** (from manufacturer to supplier), or **transfer** from one supplier to another **of a critical process** or part of it.
- **Addition or replacement of an equipment** which is involved in a **critical process**, unless it is an identical equipment.
- Changes in a **software system** which influences or controls device manufacturing equipment affecting the output of a critical process.
- Changes in **software distribution mechanisms** (e.g., change from distribution via physical media to distribution via “over the air” or vice versa, change from distribution via a consumer-grade “app store” to an EN ISO 13485-certified cloud platform or vice versa).
- Changes that impact **trackability or traceability** of components, processes or devices during or after device production (e.g., changes to software or critical processes assuring trackability or traceability).
- Changes from **paper to digital documentation and / or archiving**.

Examples of non-substantial changes, which **are non-reportable changes**, include:

- Implementation of a **new process or changes to a process** which is **not considered critical** (without changing the related device).
- **Upscale** of a manufacturing process or equipment **not impacting any process specifications**.
- **Replacing or adding an equipment** which is **not involved in a critical process** (including its validation, specifications or parameters).
- Replacing an **equipment in a critical process with an identical one**, without impacting validation parameters.
- **Moving manufacturing equipment within the same facility or to a new facility**, if the new location carries the same environmental specifications, and allows the same manufacturing process, and which results in the same process output.
- Changes in **electronic record storage application / programme**.
- Change of a **software system** that does not influence or control device manufacturing equipment and doesn’t affect the output of a critical process nor traceability (e.g., UDI).
- Changes to **equipment software** without changes to the process (e.g., update of operating system without changing the application specific software, regular software updates).

- Changes in **process data collection** (e.g., elimination of excessive data or data collection, change from manual to digital data collection).

5.2.1.2.4 Changes to sterilization processes

The sterilisation process is a critical process and one of the main components of the QMS, needing to be documented by the manufacturer for assessment. Thus, a change in such a process could impact the sterility hence, eventually, the overall safety of the device.

Examples of substantial changes, which are **reportable changes requiring prior approval**, related to sterilisation processes include:

- Changes in **sterilisation methods** (e.g., ethylene oxide (EO) to gamma, gamma to e-beam).
- Changes in the **sterilisation process** outside of the validated range (e.g., sterilant concentration or doses, sterilant exposure time).
- Changes in the **validation process** (e.g., overkill to product bioburden-based methods, VDMax to Method 1).
- Changes in the **quality control verification** (e.g., introduction of parametric release, for example changing form standard release, removal of biological indicator, changes to a dosimetry system used in an irradiation process requiring revalidation according to EN ISO 11137-3).
- Changes in the **density or configuration of the sterilisation load** (e.g., alternating breathable portions of the load for gas diffusion, changing density of absorbing materials, maximum load outside of validated range).
- Changes that **increase bioburden action levels**, introduce **organisms** that are **more difficult to eliminate** or **increase the risk** of the presence of **organisms that are more resistant** to sterilisation (e.g., increase in the D-value).
- **Changes in sterilisation equipment**, such as replacement (e.g., as a result of decommissioning) or **addition of a new equipment**, unless it is an identical equipment.
- Changes in the **sterilisation service provider**, such as the introduction of a **new sterilisation provider** or of a new sterilisation **facility**, the **relocation** of a sterilisation facility or the **transfer** of sterilisation processes in-house.
- Reductions in **conventional incubation duration**.
- Changes that may adversely affect the **levels of the residues of the sterilant** on the device.
- Changes and / or extension to **intended purpose** such as special populations with a more stringent residue level requirement.
- Changes impacting **aseptic processing** requiring revalidation according to EN ISO 13408 series or EudraLex Volume 4 Annex I (GMP) (e.g., change of zoning concept, relocation of equipment, changes to CIP / SIP process, changes to sterile filtration).

Additional information when assessing which changes may have impact on the effectiveness of the sterilisation process is provided in the respective sterilisation standards such as EN ISO 11135-series (Ethylene Oxide), EN ISO 11137- series (Radiation), EN ISO 17665-1 (Moist Heat), EN ISO 13408-series (Aseptic Process), EN ISO 20857 (Dry Heat). In case the relevant standards require a revalidation of the sterilisation process due to the planned change (provided it is not a substantial change, as per the examples listed above), the **change should be reported not requiring prior approval.**

5.2.1.2.5 Changes to packaging processes

Examples of substantial changes, which are **reportable changes requiring prior approval**, to the packaging process, this being a component of manufacturing include:

- Changes in the packaging process of **medical electrical equipment** requiring a **revalidation of packaging.**
- Changes in the packaging process affecting **transport validation** (e.g., modifications to the holding system that influence transport simulation outcomes, fluctuations of temperature and humidity, variations in packaging load).

In addition, for **sterile devices**, the following examples of changes to the packaging process are also **substantial** (reportable changes requiring prior approval):

- Changes in the packaging process requiring a **revalidation of packaging** according to EN ISO 11607.
- Changes in the packaging process (e.g., due to changes in packaging material, design, closure system) **affecting sterility and / or stability** of the device and that may require revalidation of the sterilisation process (e.g., adding an additional layer to the primary sterile barrier that alters the penetration or removal of the sterilisation agent).
- Changes in the packaging process affecting **aseptic handling**.
- Changes to **packaging equipment** introducing new technologies (e.g., switching from heat sealing to ultrasonic sealing).

5.2.1.2.6 Changes to reprocessing processes

Examples of substantial changes, which are **reportable changes requiring prior approval**, in the reprocessing of reusable devices include:

- Increase of **maximum number of reprocessing cycles** in the IFU. On a case-by-case basis, the manufacturer and the notified body may agree to include such changes within a PCCP.
- Addition of a **new reprocessing technology** in the IFU (e.g., hydrogen peroxide sterilisation), which was not previously assessed by the notified body.
- Removal and / or addition of **process steps** (cleaning / disinfection / sterilisation) or **parameters.**
- Changes in the **QMS critical procedures** relating to reuse including changes in:
    - Provisions for **validation of reprocessing** (e.g., cleaning, disinfection, sterilisation): endpoints, acceptance criteria, changes of the systematic grouping approach for the selection of the master device.
    - **Validation requirements**, such as:
        - New or changed device not covered by the reprocessing validation (e.g., novel worst-case geometry).
        - Changes in reprocessing chemistry (detergent, disinfectant, when a new cleanability study and lifetime test data is needed, e.g., if cleaning process is changed from enzymatic to highly alkaline cleaning, or if the concentration of the cleaning agent is

modified, this may impact both cleanability and biocompatibility and should be evaluated accordingly).
- Release criteria for implementation of changes relating to reuse.

5.2.1.2.7 Changes resulting from new or revised legislation

Example of substantial changes, which are **reportable changes requiring prior approval**, related to changes in legislation include:

- Changes from paper IFU to electronic IFU (eIFU), when the manufacturer has not previously implemented eIFU and compliance with the eIFU-Regulation has not yet been assessed by the notified body (i.e., introduction of a new process under the QMS certificate).

5.2.2 Changes to the device-range covered by the QMS certificate

The manufacturer is required to inform DQS MED of any planned substantial change(s) to the device-range covered by the QMS certificate using the Change Notification Form.

“Device-range covered” refers to the products that are in the scope of an approved QMS certificate. This expression is not defined in the MDR and IVDR. For the purposes of this document the device-range is to be understood as all “device categories" (for Class I m / r / s, IIa) and all “generic device groups” (for Class IIb Implantable WET, IIb Non-Implantable, III) covered by a certificate.

The regulatory requirements can be found in MDR Annex IX, Chapter I, Section 2.4, Chapter III, Section 7 and MDR Annex XI, Part A, Section 6.4 and 9.

Examples of substantial changes, which are **reportable changes requiring prior approval**, related to the device-range covered by the approved QMS certificate include:

- **Addition** of a **new device category** or a **new generic device group** not previously covered by the **scope of the QMS certificate.**
- Addition of a **new device** that introduces an **additional specific procedure** not previously covered by the **scope of the QMS certificate**, i.e., when no device requiring the same procedure was previously included, thereby introducing new manufacturer activities not yet contained in the approved QMS.

Examples of reportable changes not requiring prior approval include:

- Removal of a device category or a generic device group from the certificate. This needs to be reported to the notified body for information, as an administrative change that does not require prior approval.
- Addition of an individual device to an existing device category or generic device group covered by the certificate, as long as it is a type of device covered by the scope of the designation of the notified body. This needs to be reported to the notified body for information, as an administrative change that does not require prior approval, to allow updating relevant documentation (e.g., the sampling plan or, when applicable, the intended purpose stated on the certificate). Please note that if the device added to an existing device category or generic device group, introduces other substantial change (e.g., addition of a critical process), this should be reported requiring prior approval.

- Removal of an individual device from an existing device category or generic device group covered. This needs to be reported to the notified body for information, as an administrative change that does not require prior approval, to allow updating relevant documentation (e.g., the sampling plan).
- Changes in device nomenclature and coding (e.g., MDA, MDN, MDS, MDT, IVR, IVS, IVT, IVP, most granular EMDN) not affecting the device categories or generic device groups covered. This needs to be reported to the notified body for information, as an administrative change that does not require prior approval.

5.2.3 Administrative changes

For reportable changes requiring prior approval, the manufacturer is required to wait for the notified body approval before implementation. These include not only changes to the QMS, device-range covered or the approved device, but also administrative changes.

However, for administrative changes requiring prior approval, the type and extent of the assessment differ from the type and extent of the assessment required for non-administrative changes described in other sections. In such cases, the notified body grants approval following an administrative assessment (e.g., update of the content of the certificate), without the need for any technical assessment (e.g., review of the technical documentation).

All changes impacting the content of certificates need to be reported requiring prior approval of the notified body to allow timely update of the certificate (with the only exception of corrections as reported below).

Other administrative changes need to be reported not requiring prior approval to provide relevant information to the notified body to manage the certificate and related activities such as:

- **Corrections** of the content of certificates (e.g., correction of spelling or translation errors, formats, layout or printing failures or other editorial type of changes), which may be done by notified bodies as certificate supplement.
- Changes to **manufacturers' key organisational and managerial staff** (e.g., CEO signing the Declaration of Conformity), including organisation's **PRRC**.
- Changes affecting relevant information for **unannounced audits** (e.g., changes of entities to the list of manufacture facilities and related activities) if not falling under the category of substantial changes as per Chapter 5.2.1.
- Minor changes affecting the **audit program** (e.g., removal of a critical supplier, changes in critical supplier data). Substantial changes impacting the scope of the QMS are described in Chapter 5.2.1.
- **Changes to the intended purpose** not impacting the content of the certificate (if the intended purpose is included on the certificate, such changes are administrative changes requiring prior approval).
- Separation of a **single certificate into multiple individual certificates** or vice versa, the combination of multiple certificates into a single certificate, provided that the certificate content remains unchanged.
- **Discontinuation of certification** of one or more devices, if not impacting the content of the certificate.

Manufacturers may implement other administrative changes without need to report this information to the notified bodies, such as changing non-critical supplier data (e.g., address, name, legal form of the entity, trademark or tradename, ownership), changes in the number of employees not involved in the certification scope, or changes to the logo of the company.

5.3 Surveillance Activities and Post-Certification Monitoring for EU QMS Certificate

To maintain the EU QMS Certificate (Annex IX, chapter I), DQS MED must conduct regular surveillance audits of the manufacturer's QMS, unannounced audit(s), review of vigilance reports and if applicable, monitoring of any conditions for certifications to ensure ongoing compliance with the MDR requirements.

5.3.1 Surveillance Audits for EU QMS Certificate

The objective of a surveillance audit is to ensure that the manufacturer duly fulfils the obligations arising from the approved QMS. DQS MED periodically, at least once every 12 months, carries out surveillance audits and assessments to make sure that the manufacturer in question applies the QMS and the post-market surveillance plan according to MDR Annex VII 4.5.2, Annex IX 3. Those audits and assessments include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.

In case of Class IIa devices (incl. implantable), Class IIb devices, Class IIb exempted implantable devices the surveillance audits include an assessment of the technical documentation on representative basis as defined in sampling plan as described in section 5.1.1. In due time before the audit the Notified Body requests the manufacturer to submit the technical documentation of a selected sample device (acc. MDCG 2019-13).

The first surveillance audit is performed within and not later than 12 months after the issuance date of EU QMS certificate, unless DQS MED considers a shorter period more appropriate. All subsequent, surveillance audits are performed 12 months after the issuance date of the EU QMS certificate plus/minus 3 months. The recertification audit is conducted early enough to be able to renew the certificate prior to expiration of the previous version.

During the surveillance audits, the audit team reviews the manufacturer’s system for vigilance, post-market surveillance, post-market clinical follow-up (PMCF) and risk management as well as all open non-conformities from previous audits. Additionally, DQS MED considers results of its evaluation of additional scientific and clinical data and clinical evaluations and post-market information as well as the outcome of latest technical documentation assessments on sampling basis and product tests. The audit team gather sufficient information to determine if the QMS continues to comply with the MDR requirements. if non-conformities are detected, audit team requires manufacturer to provide corrections, corrective actions, and where applicable preventive actions as described in section 5.1.3.4.

In case the manufacturer does not allow DQS MED to carry out all the necessary audit or the response to non-conformities from surveillance assessment are inappropriate, DQS MED can impose specific restrictions on the relevant certificate or suspend or withdraw it.

5.3.2 Unannounced Audits

DQS MED randomly performs at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, on the site of the manufacturer's suppliers and/or subcontractors. The unannounced audit may be combined with the periodic surveillance assessment or be performed in addition to that surveillance assessment according to established audit programme. The unannounced audits are typically completed by two auditors with a duration of one day.

Within the context of such unannounced on-site audits, DQS MED tests an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation.

Instead of, or in addition to sampling, DQS MED can take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. DQS MED provides the manufacturer in question with an on-site audit report including if applicable, the result of the sample test.

5.3.3 Review of Vigilance Cases

The manufacturer is obligated to notify DQS MED of vigilance reports related to any serious incidents and field safety corrective actions. DQS MED reviews the vigilance cases upon receipt of information from the manufacturer or competent authorities as part of post-certification monitoring in order to estimate its impact, if any, on the validity of existing certificates. The result of review might require DQS MED to take action such as detail review of manufacturer´s investigation, extraordinary surveillance measures, increase the frequency of surveillance audits, review specific products or processes on the next audit of the manufacturer, or take any other relevant measure (MDR Annex VII 4.11). The action resulted from review may impact relevant EU certifications.

5.3.4 Validation of Summary of Safety and Clinical Performance

The manufacturer is required to draw up a summary of safety and clinical performance (SSCP) for all implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance (MDR Art. 32). All SSCPs must be validated by DQS MED, depending on the class before initial certification or the certification cycle (5 years). The validated SSCPs are made available to the public via EUDAMED by DQS MED.

5.3.5 Assessment of Period Safety Update Report

Based on MDR, Article 86 manufacturers of devices only covered under a EU QMS certificate namely Class IIa devices (incl. implantables),non-implantable Class IIb devices and Class IIb “exempted” implantable devices shall prepare a periodic safety update report (‘PSUR’) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in MDR Article 84. For implantable Class IIa devices and implantable Class IIb devices, manufacturers shall submit the PSUR at least annually/biannually as agreed with DQS MED or if the EUDAMED module is available, by means of EUDAMED. Such PSURs and the DQS MED evaluation are made available to competent authorities through that electronic system or by alternative means. For devices other than class IIa devices and class IIb implantable devices, manufacturers shall make PSURs available upon requires to DQS MED.

5.4 Renewal of EU QMS Certificate

On application by the manufacturer, the validity of the EU QMS certificate may be extended for further periods, each not exceeding five years, based on a renewal review in accordance with the applicable conformity assessment procedures (MDR, Annex VII, 4.11).

The manufacturer must submit the request for renewal of the EU QMS certification to DQS MED no later than twelve months before the expiry date of the respective certificate. The renewal submission includes the signed renewal application with required documentation according to the application information.

The renewal review for the EU QMS certificate includes the verification if all relevant regulation requirements for conducting audits (MDR Annex VII 4.5.3 and Annex IX 2.2 and 2.3) in its entirety were met. In addition, DQS MED assesses the results of the surveillance audits carried out during the period of validity of the certificate in accordance MDR Annex VII 4.10, also including any unannounced audits and all audits carried out at subcontractors and suppliers. The review includes manufacturer´s system for vigilance, post-market surveillance, PMPF and risk management as well as all open non-conformities. Furthermore, results of the Notified Body´s evaluation of additional scientific and clinical data and clinical evaluations and post-market information as well as the outcome of latest technical documentation assessments on sampling basis and product tests are considered (MDCG 2019-6).

Upon a successful positive review, the EU QMS certificate is renewed for a further period not exceeding five years and registered in EUDAMED or respective alternative. If the renewal of EU QMS certificate is not performed and/or completed and/or does not have a positive outcome within the expiry date, it will lose the validity at date of expiry and the respective certification contract is terminated from the day after expiry of certificate.

6 EU Technical Documentation Assessment Certificate – Assessment of the TD according to MDR Annex IX Chapter II

For class III devices and to the class IIb devices referred to in the second subparagraph of MDR Article 52(4) the MDR requires the certification along the technical documentation assessment according to MDR Annex IX Ch. II, which is required in addition to the QMS certification according to Annex IX Ch. I. The assessment of the technical documentation as referred to in Annexes II and III covers the design, manufacture and performance of the device in question.

Specific characteristics and classes of medical devices require one or more additional special consultation procedures with the assessment of the technical documentation. These procedures are outlined in Annex IX Section 5 or Section 6. Section 5 addresses consultations for:

- the clinical evidence for class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product
- devices incorporating a medicinal substance
- devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable
- devices composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

Section 6 addresses the batch verification of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in Article 1(8).

If the consultation/verification results are evaluated positive and the technical documentation confirms the requirement of the MDR, the EU Technical Documentation Assessment (TDA) certificate is issued by DQS MED.

DQS MED scope of designation does not include devices incorporating tissues or cells of human origin as well as medicinal products derived from human blood or human plasma.

6.1 Initial EU Technical Documentation Certification

6.1.1 Conformity Assessment Planning

In case of class III devices and to the class IIb devices referred to in the second subparagraph of MDR Article 52(4), manufacturer shall lodge an application for an EU technical documentation assessment according to MDR Annex IX chapter II. With that the manufacturer provides the technical documentation according to MDR Annex II and III to DQS MED. A completeness check of the application and the supporting documentation is performed as part of the application review. The scheduler assigns appropriate resources to assess the technical documentation.

6.1.2 Assessment of the Technical Documentation

The technical documentation includes the elements described in Annexes II and III of the MDR and evidence of compliance with the General Safety and Performance Requirements (Annex I) applicable to the relevant device(s). The technical documentation also includes test reports, which encompass the results of studies conducted with intended users, as well as data demonstrating the device's suitability for its intended purpose.

During the assessment of the TD and depending on the complexity of the device(s) one or more differently qualified TD Assessors verify how the aspects described in Annex II and III of MDR are addressed, as well as how the fulfilment of the General Safety and Performance Requirements according to Annex I are demonstrated. Personnel with appropriate clinical expertise specifically assesses the clinical evidence presented by the manufacturer in the clinical evaluation report and the related performance evaluations in respect to the clinical performance.

In case of assessments according to MDR Annex IX Section 5 and Section 6, additional specific procedures are required. DQS MED gives due consideration to the views expressed in the consultation reports when making its decision. DQS MED does not deliver the certificate if the consultation report is unfavourable and/or a deviation from the result is not justifiable.

6.1.3 Specific Procedures

If a specific class of medical device requires an additional special procedure as outlined in Annex IX Section 5, the notified body cannot make a final decision until it receives consultation results from the expert panels. These consultation procedures are chargeable projects. With DQS MED being your Notified Body, only the special procedures listed below can be applied.

Special Procedures under MDR covered by DQS MED designation		
MDR Article	Product	Additional Special Procedure
54	Class III Implantable	Clinical evaluation consultation procedure (CECP), performed by expert panels according to Article 106
54	Class IIb according to rule 12	Clinical evaluation consultation procedure (CECP), performed by expert panels according to Article 106
52 (9)	Devices incorporating pharmaceutical substances	Consultation with a competent authority for medicinal products according to Directive 2001/83/EG
52 (10)	Devices incorporating non-viable cells/ tissue derived from animal origin	Consultation with Coordination group for (EU) 722/2012

52 (10)	Substances that are intended to be introduced into the human body and that are absorbed by the body or distributed locally in the body and Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body – which qualify as such, in particular through the application of Rule 3, 14 or 21 or the claim of product characteristics	Consultation with a competent authority for medicinal products according to Directive 2001/83/EG

If consultation results are evaluated positive and the technical documentation confirms the requirement of MDR, EU Technical Documentation Assessment (TDA) certificate is issued by the DQS MED.

6.1.4 Management of the Technical Documentation Deficiencies

If the technical documentation assessment has a positive outcome, the assessment procedure continues with final review and certification decision. If non-conformities are identified during the technical document assessment, the product reviewer involved provides the manufacturer a deficiency report and requests the resolution of identified non-conformities. The manufacturer is required to send the response including the required updated technical documentation in a timely manner to DQS MED. Upon receival of manufacturer's response, the TD Assessor involved reviews the response including the required technical documentation and provides written feedback on the closure or additional clarification using an updated deficiency report.

If the manufacturer doesn't respond within agreed timelines or fails to close all non-conformities after three additional assessment rounds, DQS MED can terminate the evaluation and refuse the EU TDA certification. The initial quotation of technical documentation assessment includes the cost of two deficiency rounds. The costs associated with additional deficiency rounds are borne by the manufacturer and notified through a dedicated quotation, according to the DQS MED's price list.

6.1.5 Final Review and Certification Decision

DQS MED assigns authorized personnel who are different from those who conducted the technical documentation assessment. This independent personnel reviews all the relevant documentation and evidence related to the applicable conformity assessment procedure and verifies that the assessment reports are complete and sufficient with respect to the scope of the application. They ensure that the conclusions of the assessments are clearly documented, regulatory requirements are met and that the assessments were conducted impartially and thoroughly.

Based on the comprehensive evaluation of the documentation and evidence, DQS MED decides to either approve the certification to the applicable conformity assessment procedure, request additional information, or reject the application if it does not meet the necessary requirements.

If there are no unresolved deficiencies preventing issuance of a certificate, the final review and final decision is completed by issuing an EU TDA certificate with a maximum of five years validity. DQS MED informs the manufacturer of the outcome of the assessment and the decision to issue the EU TDA certificate, along with relevant technical documentation and clinical evaluation assessment report. Information about the EU TDA certificate is registered into EUDAMED (MDR Art. 52) if the EUDAMED certificate module is functional. In the absence of the EUDAMED module, the EU TDA certificate data is registered according to the corresponding provisions of Directives 90/385/EEC and 93/42/EEC (MDR Art. 123).

If the EU TDA certification is not approved, DQS MED informs the manufacturer of its decision in writing including the reason for rejection of certification. DQS MED notifies any rejection, restriction, suspension or withdrawal of EU TDA certificates to the EUDAMED database (MDR Art. 57), or the respective alternative national database.

6.2 Changes and Modifications to EU TDA Certificate

This section only applies to changes to the approved device(s) covered by an EU Technical Documentation Assessment certificate.

The manufacturer is required to inform DQS MED using the Change Notification Form.

The regulatory requirements can be found in MDR Annex VII, Section 4.5.6, 4.9 and MDR Annex IX, Chapter II, Section 4.10, 5.2, 5.3.

DQS MED assesses the planned design changes and decides whether the planned changes require a new conformity assessment in accordance with MDR Article 52 or whether they could be addressed by means of an amendment or a supplement to the existing EU TDA certificate. In the latter case, DQS MED assesses the substantial changes, notifies the manufacturer of its decision and, where the changes are approved, provides it with a supplement to the EU TDA certificate. Once the substantial changes are approved by the Notified Body, they can be implemented by the manufacturer.

The notified body should have documented procedures and contractual arrangements with the manufacturer for the assessment of the following changes related to the approved device:

- Design of a device
- Intended purpose or claims made for the device
- Any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific additional procedures in accordance with Annex VII, Section 4.5.6 MDR

Changes to an approved device assessed by the notified body may require an amendment to the product certificate or a new conformity assessment in accordance with Article 52 MDR.

There are reportable changes requiring prior approval and non-reportable changes, as well as, where relevant, reportable changes not requiring prior approval/administrative changes. These are grouped into the following categories:

- Changes to intended purpose or conditions prescribed for use

- Changes to the PMCF / PMPF plan
- Changes to device design and performance specifications / characteristics
- Changes to materials or ingredients
- Changes to software
- Changes to sterilisation
- Changes to packaging
- Changes to reprocessing
- Changes affecting specific additional procedures
- Changes to labelling and / or instructions for use (IFU)

It should be noted that these distinctions are made solely for the purposes of this document, and a single change may impact multiple aspects of the approved device.

Substantial changes to **critical processes, equipment, facilities, and critical supplier** listed in Chapter 5.2 also apply to devices with a product certificate.

It is important to note that all the changes to an approved device implemented as a result of field safety corrective actions need to be reported and require prior approval. Notified bodies should assess these changes in cooperation with the Competent Authority without undue delay.

6.2.1 Changes to intended purpose or conditions prescribed for use

Examples of **reportable changes requiring prior approval** related to the device intended purpose, as defined in Article 2(12) MDR or clinical application include:

- Extensions and / or additions to the **indications for use or claims**, unless they are editorial changes.
- Restrictions and / or removal of **indications for use or claims** due to **safety and / or performance reasons** (e.g., post-market surveillance findings, or safety concerns).
- Restrictions and / or removal of the **contra-indications for use**, unless they are editorial changes.
- Extensions and / or additions to the **contra-indications** for use due to **safety and / or performance reasons.**
- Extensions and / or additions to the **medical conditions** (e.g., changes in disease or condition / clinical form, stage, severity / symptoms or aspects to be diagnosed, treated and / or monitored, risk factors of interest).
- Restrictions and / or removal of **medical conditions** due to **safety or performance reasons**.
- Changes in the **instructions to use the device** (e.g., changes in the duration or lifetime use, delivery pathway or deployment method, number or duration of applications, clinical process or implantation technique, shift from single use to reusable, operation from automatic to manual).
- Changes and / or additions to the **anatomical site** approved for intended purpose of the device.
- Changes and / or additions to the **target population or vulnerable groups and / or testing population** (e.g., change from adult to paediatric population).
- Changes in **patient selection criteria**.
- Changes and / or additions to the **intended user** (e.g., change from professional use to lay person use).

- Restrictions and / or removal of **intended user** due to **safety and / or performance reasons**.
- Changes to and / or removal of **warnings and precautions for a device**, unless they are editorial changes.
- Extensions and / or additions to **warnings and precautions for a device**, due to safety and / or performance reasons.
- Changes in **function** such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic.

Please note that when the intended purpose is included in the **content of the certificate**, changes to the intended purpose need to be **reported as administrative changes requiring prior approval**.

The reportable changes to the intended purpose of the device should be supported by a demonstration of the **clinical and / or analytical evidence** and should be the subject of an analysis relating to the safety of the device in view of the proposed change.

Examples of **reportable changes not requiring prior approval**:

- Restrictions and / or removal of **indications for use or claims**, when such changes are made for other reasons not related to safety and / or performance of the device.
- Extensions and / or additions to **contra-indications** when such changes are made for other reasons not related to safety and / or performance of the device.
- Restrictions and / or removal of **medical conditions** when such changes are made for other reasons not related to safety and / or performance of the device.
- Restrictions and / or removal of the **target population or vulnerable groups** (e.g., exclusion of patients of a certain age, sex or race, stage or severity of disease).
- Restrictions and / or removal of the **intended user** (e.g., removal of lay person use and restriction to use by professionals (MDR only), elevation of the level of professional or device specific training), when such changes are made for other reasons not related to safety and / or performance of the device.
- Extensions and / or additions to **warnings and precautions for a device**, when such changes are made for other reasons not related to safety and / or performance of the device.
- Restrictions of **environmental settings** required for use of a device (e.g., practice of a general practitioner no longer considered appropriate, only hospital setting remains as previously specified).

6.2.2 Changes to the PMCF / PMPF plan

Examples of **reportable changes requiring prior approval** related to PMCF / PMPF plan include:

- Changes to PMCF / PMPF plan associated with **certification decisions / conditions**, such as updates to clinical data at defined intervals or changes in the type of study or population.
- Changes in the **need for conducting PMCF / PMPF** (e.g., PMCF / PMPF plans are changed in response to issues identified in the CER / PER, risk management, safety related concerns).
- **Delays or deviations** (e.g., protocol, timelines) from the plan such as:
    - Removal or ceasing of any **ongoing or planned specific / proactive activities**.

  - Changes to **specific methods and procedures** that could impact the overall quantity and quality of clinical data such as reduction in sample sizes, the number of sites or number of respondents.
  - Changes to **objectives or endpoints**.
  - Changes to **statistical analysis plans**.

6.2.3 Changes to device design and performance specifications / characteristics

Examples of **reportable changes requiring prior approval** related to device design or performance specification / characteristics (such as modifications in technology, engineering, or performance) include:

- Changes in the **design of the device critical components / key functional elements**, such as changes to shape or dimension and characteristics outside current specifications.
- Extensions to **claimed shelf life**.
- Changes impacting **built-in control mechanism** (e.g., change from analogue to digital control, software driven instead of manually driven, from pneumatic to electronic controls).
- Changes in **principles of operation** of the device such as:
  - modifying or moving from mechanical to electronic and / or software implementation of a control mechanism (e.g., when setting flow control in a hydrocephalus shunt),
  - Changes or replacement of a linear algorithm with a deterministic algorithm or adaptive AI (e.g. in monitoring, diagnosis, or treatment),
  - Changes in measurement type / measurand / calculation, e.g., moving from Specific Absorption Rate (SAR) to B1 + rms i.e., the time-weighted average of the applied radio frequency field (relevant to MRI and AIMDs),
  - Changes in communications method, e.g., from Inductive Coupling to Bluetooth Low Energy (BLE) or WiFi HaLow (in AIMD and medical device communication).
- Changes in the device **mode of action** such as:
  - Changes in the frequency of radiation, e.g., of Ultraviolet light (e.g., for disinfection).
  - Changes in the type of radiation, e.g., from thermal to ultrasonic (e.g., for ablation).
  - Changes in the mode of interaction, e.g., from mechanical to radiation (e.g., for dissection).
  - Changes in the type, intensity, or length of action, e.g., by changing radioactive isotope (for treatment of a tumour), or electric shock timing, intensity or duration (e.g., for cardioversion).
  - Changes in the mechanism of action, e.g., from silver impregnation to antibiotics (e.g., for infection control).
- Changes in **type of energy source** (e.g., change of a battery type from AA to 6LR61, changes of battery chemistry from Alkaline to Lithium Manganese Dioxide or from lead acid batteries to lithium iron phosphate (LiFePo4) batteries, change from a battery to a rechargeable accumulator, if recharging takes place outside of the device).
- Changes in **critical Bluetooth connections** (e.g., RS485, DF-1, IS-4), including updates to newer Bluetooth versions, that affect device safety and / or performance.

- Changes in the **alarm system** of the device (e.g., changing colours, frequency and conditions of visual alarms, changing frequency or sequence of tones of audio alarms or their volume, changing conditions to trigger, silence or quit an alarm).
- Changes to **state-of-the-art evidence** impacting scientific technical validity of the batch verification (e.g., new variant strain for microbiological assays or knowledge of new interfering or cross-reacting substances).
- Changes to device performance due to changes in the **harmonised standards or common specifications (CS)**, by reference to which the conformity of a device is declared and which are affecting performance specifications or require additional testing / verification activities.

Examples of reportable changes not requiring prior approval include:

- Reductions of **claimed shelf life**.

6.2.4 Changes to materials or ingredients

Examples of **reportable changes requiring prior approval**, related to type of material, formulation or ingredients include:

- Changes to a **critical ingredient or material** requiring performing **design / performance validation or verification activities**, including additional testing, e.g., changes that could affect:
    - biological safety, chemical, physical, electrical properties of the device.
    - other device safety and / or performance characteristics, including stability studies.
- Changes to **formulation** affecting **specifications, stability or biocompatibility** of the device (e.g., increase or decrease of protein concentration).
- Changes of a **material or ingredient** which carries a **higher toxicological or biological risk** than before the change, especially those containing substances carcinogenic, mutagenic or toxic to reproduction or substances having endocrine-disrupting properties.
- Substitution of a **chemical substance, material or component** in order to comply with other applicable laws and regulations such as the REACH Regulation.
- Changes to an ingredient or material of an **implantable device** intended for **contact with body tissue or fluid**.
- Changes to a critical **accessory** supplied with the device.

For changes to materials or ingredients affecting specific additional procedures refer to Chapter 6.2.9.

For changes to packaging materials, refer to Chapter 6.2.7.

For changes to labelling materials, refer to Chapter 6.2.10.

6.2.5 Changes to software

Examples of **reportable changes requiring prior approval** related to a software include:

- Software changes that impact the **control of the device** and may alter the **diagnosis or therapy** delivered to the patient.

- New or modification of **software architecture** (e.g., software changes to support modified or new hardware with impact on diagnosis or therapy delivery, addition of telemetry components).
- **Rewrite of the software** to utilise a different **programming language** or use **new compilers**.
- Software changes that **modify an algorithm** and may alter the **diagnosis or therapy** delivered to the patient.
- Software changes that alter **operating principles** (e.g., replacement of a deterministic algorithm with an artificial intelligence (AI) / machine learning-based algorithm).
- Software changes that replace **previously required user input to a closed loop system** changing the **degree of automation** in clinical decision making.
- Software changes that alter the **control mechanism of the device** (e.g., changes from manual input to AI-controlled component in a surgical robot).
- **New version of an operating system**, which is not considered an update (e.g., Windows 10 to Windows 11), if modification to the application software is required.
- Porting an application from one **operating system to another** operating system (e.g., Linux to Windows or iOS or Android).
- Addition of a **new feature or functionality to the software** that may alter **the diagnosis or therapy** delivered to the patient (e.g., addition of a measuring function).
- **New user interface impacting usability** (e.g., presentation of medical data in a new format, dimension or measuring unit, from keyboard input to touchscreen or wireless remote control) or software **changes that impact the way data is read or interpreted** by the user.
- **New channel of interoperability** (e.g., software changes that allow for wireless communication with compatible -continuous- monitoring systems).
- Introduction or removal of an **alarm function** in the software such that a response to the new configuration may change the treatment of the patient in comparison to the previous version of the software (e.g., changing the number of alarm).
- Inclusion of **AI** with relevance to the **diagnosis or therapy** delivered to the patient or **safety risk control measure.**
- Changes to **cybersecurity** that **increase the attack surface of the device** (e.g., implementation of remote monitoring capabilities or change in authentication mechanism affecting the use of the device).

In addition to these examples of product level changes affecting software, certain software-related changes may also impact the QMS certificate, as described in Chapter 5.2.1.2 (e.g., changes to software distribution mechanism, change of supplier of cybersecurity service).

6.2.6 Changes to sterilization

In addition to QMS certificate modification, other changes related to sterilisation of devices, where a product certificate is issued, may require a product-level assessment and prior approval.

Examples of **reportable changes requiring prior approval** related to sterilisation include:

- Changes from **non-sterile to sterile device** or vice versa.

- Changes of **sterilisation methods or parameters** (e.g., from a device sterilised by irradiation to sterilisation with ethylene oxide, or from gamma to e-beam).
- Changes in the **resistance profile** of the product bioburden.
- Adding **resterilisation or increasing the validated number** of resterilisation.
- Changes in the **design** of the device having an impact on the sterilisation (e.g., change of lumen dimension for an aspiration catheter or a drip chamber for an infusion set).
- Changes of **material** of the device having an impact on sterilisation (e.g., adding a new material that retains a larger quantity of residues of EO, adding polymers with chlorine residues generating new residues with EO sterilant).
- Other changes that result in a relevant **impact on sterilisation** as defined in other sections of this document (e.g., changes to IFU (Chapter 5.3.10), or changes to packaging (Chapter 5.3.7)).

Additional information when assessing which changes may have impact on the effectiveness of the sterilisation process is provided in the respective sterilisation standards such as EN ISO 11135-series (Ethylene Oxide), EN ISO 11137-series (Radiation), EN ISO 17665-1 (Moist Heat), EN ISO 13408-series (Aseptic Process), EN ISO 20857 (Dry Heat). In case the relevant standards require a revalidation of the sterilisation process due to the planned change (provided it doesn't require prior approval, as per the examples listed above), the change should be **reported not requiring prior approval**.

6.2.7 Changes to packaging

In addition to QMS certificate modification, other changes related to packaging, where a product certificate is issued, may require a product-level assessment and prior approval.

Examples of **reportable changes requiring prior approval** related to device packaging include:

- Changes in **packaging system** that constitute a reason for **sterilisation revalidation**, such as changes adversely affecting the permeability of the packaging to sterilising agents (e.g., from single sterile to double sterile packaging), the presentation of the load to the steriliser, the irradiation pathway or product density.
- Changes in **packaging design or material** which affects sterility, biocompatibility, stability or microbiological state of the device, including seal integrity.
- Changes of **internal layout of packaging** (e.g., change from cardboard holders to plastic trays), unless the manufacturer can demonstrate that other devices already approved had this type of new packaging, the device subject to the change could be considered similar to them and within the worst-case of the specific sterilisation validation already approved.
- Changes to **storage or transportation conditions** that could impact sterility, stability, or the microbiological state of the device, outside the approved specification range, and for which existing studies do not suffice.
- Changes of the **quantity of the devices** in the package affecting the transport validation.

6.2.8 Changes to reprocessing

In addition to QMS certificate modification, other changes related to reprocessing of devices, where a product certificate is issued, may require a product-level assessment and prior approval.

Examples of **reportable changes requiring prior approval** related to reprocessing include:

- Changes to **detergent type or concentration as described in the IFU** (e.g., impacting prion decontamination).
- Changes in the **design of the device not covered by reprocessing validation** (e.g., new product design requiring a new cleaning validation, new worst-case product).

6.2.9 Changes affecting specific additional procedures

Examples of **reportable changes requiring prior approval** affecting specific additional procedures under MDR include:

- Changes related to a **medicinal substance, as an integral part of the device**, which, if used separately, may be considered to be a medicinal product within the meaning of Article 1(2) of Directive 2001 / 83 / EC. This includes:
  - Changes related to **ancillary medicinal substances**, including those **derived from human blood or human plasma** that may impact the quality, safety, or usefulness of the substance.
  - Changes to a **material, component or ingredient containing a medicinal substance** (e.g., excipient or carrier material that may impact the quality, safety, purity or release kinetics).
- Changes related to **tissues or cells of human origin and their derivatives** as an integral part of the device covered by Directive 2004 / 23 / EC, and changes relating to their donation, testing or procurement.
- Additions and / or changes to **tissues or cells of animal origin or their derivatives** (e.g., changes in geographical origin of animals, raw materials, or processes such as selection, collection, handling, control, and viral inactivation / elimination), as referred to in Regulation (EU) No 722 / 2012 that may impact the quality, safety or usefulness of the tissues or cells.
- Changes related to **devices composed of substances or combination of substances that are absorbed or locally dispersed in the body** that affect the quality and safety of devices in accordance with requirements covered by Annex I of the Directive 2001 / 83 / EC.

Please note specific additional procedures also include clinical consultation procedures (Annex IX Section 5.1), and in case of changes that require a new conformity assessment Article 54 of the MDR applies.

6.2.10 Changes to labelling and / or instructions for use (IFU)

Examples of **reportable changes requiring prior approval** related to labelling and / or instructions for use (IFU) include:

- Changes to the **IFU impacting packaging and / or sterilisation validation** (e.g., increase of IFU size or volume affecting packaging configuration, sterile barrier integrity, gas permeability or moisture retention).

- Changes to the **IFU / instructions** impacting reprocessing validation (e.g., consolidation of different instructions for (re)processing into one general instruction).
- Changes to label from **single use to multiple use** and vice versa.
- Changes to label from **non-sterile to sterile** and vice versa.
- Changes to label to display "**sterilisation prior use required**" and removal of such statement.
- Changes to the **label material** which may adversely influence readability or endurance or resistance against deterioration of printing (e.g., bleeding, removability with usual solvents such as water or alcohol, abrasion) or the performance of the device.

A single change can impact multiple aspects related to the approved device.

In particular, changes to labelling and / or IFU are often triggered by reportable changes to the **intended purpose** (see Chapter 6.2.1, e.g., removal of warnings), **packaging** (see Chapter 6.2.7, e.g., changes of the quantity of the devices in the package or changes to transport or storage conditions), **materials** (see Chapter 6.2.4, e.g., changes to materials of the device that impact performance characteristics reflected on the label), or **design and performance characteristics** (see Chapter 6.2.3, e.g., extension of shelf life). In such cases, when the manufacturer submits a change for prior approval, it should also inform the notified body of the related impact on labelling and / or IFU.

6.2.11 Administrative changes

See chapter 5.2.3.

6.3 Surveillance Activities and Post-Certification Monitoring for EU TFA Certificate

6.3.1 Evaluation of PSUR

Manufacturers class III devices and class IIb devices referred to in the second subparagraph of MDR Article 52 (4) shall prepare a periodic safety update report (PSUR) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in MDR Article 84 together with a rationale and description of any preventive and corrective actions taken. Manufacturers of class III devices and class IIb devices referred to in the second subparagraph of MDR Article 52 (4) shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. The manufacturer submits the PSUR at least annually as agreed with DQS MED or if the EUDAMED module is available, by means of EUDAMED. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. DQS MED assesses the PSURs considering the guidance MDCG 2022-21.

6.3.2 Validation of Updated SSCP

The manufacturer is required to draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance (MDR Art. 32). The SSCP must be validated prior issuing the certificate by the DQS MED involved in the conformity assessment and made available to the public via EUDAMED. The validated SSCPs are registered in EUDAMED by the DQS MED, in general during the issued certificate registration, and keep up to date in EUDAMED. In absence of EUDAMED, validated SSCP are provided to manufacturer and stored at DQS MED until it can be uploaded to EUDAMED.

6.3.3 Batch Verification of Devices that Incorporate, as Integral Part, a Medicinal Substance

To verify conformity of manufactured devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in the first subparagraph of MDR Article 1 (8), the manufacturer shall inform the NB of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114 (2) of Directive 2001/83/EC, according to Annex IX, Section 6.

Attention: DQS MED does not include devices incorporating medicinal products derived from human blood or human blood in its scope of designation as Notified Body.

6.4 Renewal of EU TDA Certificate

On application by the manufacturer, the validity of the EU TDA certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures (MDR Art. 56(2)).

The manufacturer must submit the request for renewal of the EU TDA certification to DQS MED no later than twelve months before the expiry date of respective certificate. The renewal submission includes signed renewal application with a summary of changes and scientific findings of the Device(s), containing at least the following elements:

- all changes to the originally approved device, including changes not yet notified
- experience gained from post-market surveillance
- experience from risk management, d. experience from updating the proof of compliance with the general safety and performance requirements set out in 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 harmonised 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.

During the review of renewal of EU TDA certificate, DQS MED performs targeted conformity assessment according to MDR Annex VII, 4.11, which focuses on certain elements of the technical documentation review, in particular clinical data from post-market surveillance and post-market clinical follow-up activities undertaken since the previous certification or recertification, including appropriate updates to manufacturers' clinical evaluation reports.

Upon a successful positive review, the EU TDA certificate is renewed for a further period but not exceeding five years and registered in EUDAMED. If the renewal of EU TDA certificate is not performed and/or completed and/or does not have a positive outcome within the expiry date, it will lose the validity at date of expiry and the respective certification contract is terminated from the day after expiry of certificate.

7 Conformity Assessment based on Product Conformity Verification, Annex XI Part A

For class IIa devices either Annex XI, Part A or B can be coupled with the drawing up of technical documentation as set out in Annexes II and III, without the need of an Annex X, EU type-examination certificate.

For Class Is, m, r devices the conformity assessment procedure Annex XI, Part A can be applied. There is no additional conformity assessment according to MDR Annex X required.

DQS MED can only perform conformity assessment procedures acc. to Part A of Annex XI and not Part B.

7.1 Initial Conformity Assessment for EU PQA Certificate

For class IIa devices the conformity assessment procedure to MDR Annex XI, Part A is based on the assessment of Production Quality Assurance system concerning the type of device, whether the technical documentation as referred to in Annexes II and III for the devices selected on a representative basis is compliant with this Regulation. For class III devices, and applicable IIb devices, the conformity assessment procedure to MDR Annex XI, Part A is based on an assessment of the Production Quality Assurance system concerning the type of device described in the “EU TE certificate” that is issued following conformity assessment according to MDR Annex X. prior the application of MDR Annex XI and applicable class IIb and class III devices.

If the Production Quality Assurance system is such that it ensures that the devices conform to the type described in the EU TE certificate and conforms to the relevant provisions of the MDR, an Annex IX, Part A EU Production Quality Assurance (PQA) certificate is issued by DQS MED.

7.1.1 Conformity Assessment Planning

In contrast to MDR Annex IX Ch. I, for Annex XI, Part A the manufacturer is required to describe all elements of Annex IX, 2.2a), b), d) and e), except c).

For all Class III and IIb devices, the type-examination according to MDR Annex X is required to be performed first, then the assessment of Production Quality Assurance according to MDR Annex XI, Part A can be initiated. While lodging the application, the manufacturer provides the technical documentation for the types approved, a copy of EU TE certificate and QMS documentation according to MDR Annex, IX 2.1 to the Notified Body.

Attention: DQS MED can’t issue EU Type-Examination certificates according to MDR Annex X.

For Class IIa (incl. implantable), DQS MED upon receival of the application draws up the sampling plan for the assessment of technical documentation on representative basis covering the range of devices (MDCG 2019-13) covered by the manufacturer's application. Prior to the audit, DQS MED will request the submission of technical documentation as referred to in MDR Annexes II and III.

For Class Is, m, r the assessment of the production quality assurance by DQS MED as Notified Body is limited to aspects relating to establishing, securing and maintaining sterile conditions, to the aspects relating to the conformity of the devices with the metrological requirements and to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use, respectively.

The principles of the assessment planning as outlined under section 5.1.1. and Annex IX above are equivalently applied to the Production Quality Assurance certification.

7.1.2 Assessment of Technical Documentation on Representative Basis

DQS MED requests for the initial certification of Class IIa (incl. implantable) the technical documentation of at least 1 representative device per device category. The technical documentation assessment follows the same principle as described in section 5.1.2.

7.1.3 Assessment of Production Quality Assurance

The assessment of production quality assurance focuses on implementation of the QMS to ensure that there is compliance with either the type described in the EU TE certificate (class III/IIb), the technical documentation (class IIa) or parts of the technical documentation (class Is, m, r), and the manufacturer conforms to the relevant provisions of the MDR. The initial audit consists of Stage 1 and Stage 2. The audit planning, audit performance, audit closure, final review and certification decision follows the same principle as described in section 5.1.3. If there are no unresolved non-conformities preventing issuance of a certificate, the final review and final decision is completed by issuing an EU PQA certificate with maximum five years validity. DQS MED informs the manufacturer of the outcome of the assessment and the decision to issue the EU PQA certificate, along with relevant audit and assessment reports. Information of the EU PQA certificate is entered into EUDAMED (MDR Art. 57), if the EUDAMED module is functional. In the absence of the EUDAMED module, the EU PQA certificate data is registered according to the corresponding provisions of Directives 90/385/EEC and 93/42/EEC (MDR Art. 123). If the EU PQA certification is not approved, DQS MED informs the manufacturer of its decision in writing including the reason for rejection of certification. DQS MED notifies any rejection, restriction, suspension or withdrawal of EU PQA certificates to the EUDAMED database (MDR Art. 57), or respective national alternative.

7.2 Changes and Modifications to EU PQA Certificate

The manufacturer must report any planned changes to the approved QMS to DQS MED.

The reporting of substantial changes under an EU PQA certificate follows the same principles as described under section 5.2, anyhow since under Annex XI, Part A the procedures for design and development (Annex IX, 2.2c)) is excluded. Therefore, the reporting criteria of design changes are stricter, and the manufacturer has to report every design change for the devices covered under Annex XI, Part A.

7.3 Surveillance Activities and Post-Certification Monitoring for EU PQA Certificate

To maintain the EU PQA certificate (Annex XI, Part A), DQS MED must conduct regular surveillance audits of the manufacturer's QMS incl. technical documentation assessment for Class IIa devices, unannounced audit, review of vigilance reports and perform batch verification (where applicable).

7.3.1 Surveillance Audits for EU PQA Certificate

The surveillance audits follow same principle as described above in section 5.1.3 and includes technical documentation assessment on representative basis for class IIa as described above in section 5.1.2.

7.3.2 Unannounced Audits

The unannounced audit follows same principle as described above in section 5.3.2.

7.3.3 Review of Vigilance Cases

The review of vigilance cases follows same principle as described above in section 5.3.3.

7.3.4 Batch Verification

The batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, follows same principle as described above in section 6.3.3.

7.3.5 Validation of SSCP

In the circumstance that more than one Class IIa Implantable devices are covered by the EU PQA certificate, DQS MED validates at least one SSCP against relevant documents in the technical documentation during the initial conformity assessment, prior to issuing the certificate. Non-validated SSCP at the initial conformity assessment are uploaded in EUDAMED. DQS MED will validate non-validated SSCP at least once during the period of validity of the certificate and upload it after its validation in EUDAMED. In absence of EUDAMED, validated SSCP are provided to manufacturer and stored at DQS MED until it can be uploaded to EUDAMED.

7.3.6 Review of PSUR

For Class IIa Implantable device, the manufacturer submits the PSUR at least bi-annually as agreed with DQS MED or if the EUDAMED module is available, by means of EUDAMED. The product reviewer of DQS MED evaluates the PSUR and adds it to EUDAMED with details of any action taken. For Class IIa non-Implantable devices, the manufacturer makes PSURs available to DQS MED and competent authorities upon request. DQS MED verifies the content of the PSUR for at least one device for which it has issued the EU Certification. This verification can be performed during periodic surveillance activities for EU PQA certificate.

7.4 Renewal of EU PQA Certificate

The renewal of the EU PQA certificate follows the principle as described above in section 5.4.