TÜVNORD

DESCRIPTION OF THE CONFORMITY ASSESSMENT PROCEDURE
Medical Device Regulation (EU) 2017/745

CONTENT

1. CERTIFICATION PROCEDURE 3

1.1. Initial contact and pre-application Information 4
1.2. Application review and contract 5
1.3. Information on rejected or discontinued applications 5
1.4. Finalizing the application process and planning the CAP 5

2. TECHNICAL DOCUMENTATION ASSESSMENT 6

2.1. Technical documentation assessment prior to initial audit 6
2.2. Technical documentation assessment in conjunction with surveillance audits 9
2.3. For-cause assessments 9

3. QUALITY SYSTEM ASSESSMENT 9

3.1. Audit preparation 9
3.2. Stage 1 audit 9
3.3. Stage 2 audit – certification audit 10
3.4. Surveillance Audit 10
3.5. Re-certification Audit 11
3.6. Unannounced audits 11
3.7. Nonconformity management, general 12
3.8. Nonconformity management, technical documentation 12
3.9. Nonconformity management, closure 13

4. CERTIFICATION PROCEDURE 13

5. SPECIFIC ACTIVITIES 14

5.1. Notification of significant changes 14
5.2. Vigilance 14
5.3. Sampling from the market 14

6. EXTENSION OF SCOPE OF CERTIFICATION 15

7. POST CERTIFICATION MONITORING 15

8. TRANSFER OF CERTIFICATION FROM OTHER BODIES 15

9. CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE) 15

DESCRIPTION OF THE CONFORMITY ASSESSMENT PROCEDURE
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This document is prepared to provide our clients a description of the conformity assessment and application procedure under the EU Medical Device Regulation (MDR)[1] (Annex VII, 4.2 a)[2]. As such it forms an integral part of the contract between the notified body and the manufacturer.

The current version of the standard fees (Article 50 and Annex VII, 4.2 b) applicable for the conformity assessment activities can be obtained from the TÜV NORD CERT GmbH website.

The documentation provided by our clients for the conformity assessment procedures (MDR Annex VII 4.2 a) shall be provided monolingual throughout, 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 text searchable.

If you should require any further information, please do not hesitate to contact us. We will be glad to support you.

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[1] **EU Medical Device Regulation (MDR)**: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[2] References to articles and annexes without further indication of the source are all referring to MDR. Where a reference is to another source, the source is explicitly stated.

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TÜV NORD CERT clients applying for a conformity assessment procedure (CAP) under the Medical Device Regulation (MDR) must go through a multi-stage process. The individual stages are outlined in detail in this document.

The two main pillars of the conformity assessment procedure are the assessment of the technical documentation (TDA) including relevant clinical data, and the audit of the quality system implemented by the manufacturer.

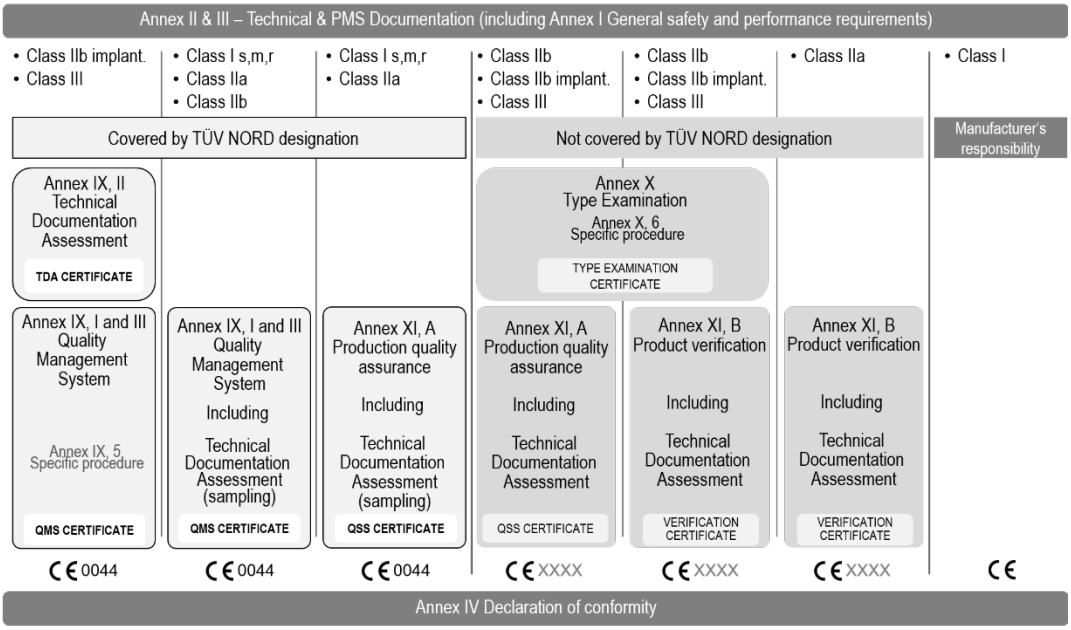
1. CERTIFICATION PROCEDURE

Under MDR, the manufacturer has to identify the appropriate CAP(s) depending on the classification of the device(s) that they intend to bring to market. The CAP performed by the notified body TÜV NORD CERT GmbH comprises the following main stages that are to be followed in the below order:

- Application review
- Technical documentation assessments
- Quality system audit

The extent of the individual process steps differs slightly depending on the classification of the device and the decision in regards to CAP and application. The CAP is performed after the compliance with the General Safety and Performance Requirements of Annex I has been recorded into the technical documentation according to Annex II and III, and the requirements for the quality system, which can be based, for example, on EN ISO 13485, have been implemented.

TÜV NORD CERT decided to focus on the CAPs based on the implementation of an appropriate quality system. The following graphics identify the available options for conformity assessment by class. The procedures not covered by TÜV NORD CERT notification are marked in grey.



Annex IX, Quality Management System

The conformity assessment procedure according to Annex IX, Chapters I and III, is called the "quality management system assessment". The quality management system assessment will cover the design, manufacture and/or final verification and testing of the devices. In conjunction with the audit, the technical documentation will be assessed. After a successful conformity assessment, an "EU quality management system certificate" will be issued.

For class III devices, the assessment of technical documentation according to Annex IX, Chapter II, is performed for each device and concluded with the issuance of an "EU technical documentation assessment certificate".

Annex XI, A Production quality assurance

The conformity assessment procedure to Annex XI, Part A, is called "production quality assurance". The quality assurance system covers the manufacture and final verification of the devices concerned.

For class IIb and III devices, the manufacturer's quality assurance system shall ensure the compliance with the type described in the "EU type examination certificate" that was previously issued by the notified body in a separate conformity assessment procedure according to Annex X.

For Class IIa devices, this verification of compliance to the Annex X "EU type examination certificate" is substituted by the technical documentation assessment performed together with the audit for representative samples. After a successful conformity assessment, the "EU quality assurance certificate" will be issued.

Scope of designation

The scope of designation of a notified body is determined using codes in accordance with the Implementing Regulation (EU) 2017/2085 and covers the corresponding types of devices.

The current designation of TÜV NORD CERT does not cover active implantable devices, nor the following device codes: MDA 0303, 0304, 0314, MDN 1212. The following horizontal codes are also excluded: MDS 1002, 1003, 1008[3], 1012, 1013, MDT 2009. (For details, refer to NANDO information system).

Further Information in addition to this service description outlining certification and conformity assessment procedures can be obtained on the of TUV NORD CERT webpage.

1.1. Initial contact and pre-application Information

Prior to the preparation of a quotation for the application review, potential clients must provide certain mandatory pre-application information to TÜV NORD CERT (Annex VII 4.2 d) using the "clients questionnaire" P111-F-012. The pre-application documentation is preliminarily verified. At the end of this stage, TÜV NORD CERT will prepare an offer for the conformity assessment starting with the application review. Inconsistencies with regard to the qualification and classification of devices are communicated to the applicant, and an additional chargeable review may be necessary. In case there is an indication that

[3] The designation for the code MDS 1008 has been applied for. The corresponding devices can only undergo conformity assessment after the designation has been completed and published in the NANDO information system.

the devices are not covered in the notified body's scope of designation, the applicant is informed accordingly, and the request declined.

If the requestant accepts the offer, they will submit the signed offer including the acceptance of the "General Terms and conditions", of the special certification conditions for MDR P111-F-003, and of this service description, followed by applying for the conformity assessment procedure as described in section 1.2.

1.2. Application review and contract

Acceptance of the offer for application review concludes the contract between prospect/client and notified body. The client shall submit the required documentation as per Annex IX 2.1 using the "Application form" P111-F-013. The application and related documentation including a list of devices covered by the quality system (P111-F-007) are subject to a chargeable application review. Together with these documents, the applicable provides a representative technical documentation using the "Technical Documentation Transfer Form" P111-F-008, which is also screened during the application review.

Manufacturers receive the application review result in writing.

1.3. Information on rejected or discontinued applications

In case the application is rejected, discontinued or withdrawn by either the notified body or the client, the relevant information will be notified to the electronic system referred to in Article 57 (EUDAMED database) and will be accessible to other notified bodies (Annex 4.3).

1.4. Finalizing the application process and planning the CAP

Based on the application review result and the information provided, the notified body will plan the audit program and the technical documentation assessment program for the initial certrification.

The notified body informs the applicant about the necessary volume of audits and technical documentation assessments. At the same time the notified body will prepare the quotation for performing the conformity assessment procedure the client applied for based on the information provided together with the application.

Conformity assessment procedures are carried out by qualified internal and external personnel that is contractually bound to the notified body and comply with the principles of confidentiality, independence, impartiality and objectivity.

The audit program of the complete 5-year certification cycle under the MDR is planned after the positive initial certification; if required, this includes certification to other management system standards, such as EN ISO 13485 or EN ISO 9001 (see section 3.5).

2. TECHNICAL DOCUMENTATION ASSESSMENT

2.1. Technical documentation assessment prior to initial audit

Prior to any initial audit of the quality management system, the notified body shall initiate the technical documentation[4] assessment(s) based on the Technical Documentation Assessment (TDA) program. The TDA program shall be updated as required.

If the manufacturer is not able to provide technical documentation for the selected representative device within the announced deadline, the certification cannot be successfully completed or expanded.

For all class III and all implantable class IIb devices, the technical documentation shall be assessed for every device. A separate EU technical documentation assessment certificate will be issued upon successfully passing the assessment. The validity of the certificate will not exceed 5 years.

For class IIb implantable devices exempted according to Article 52,4, the technical documentation must be also assessed for every device, but no additional EU certificate is issued.

For all other class IIb devices and all class IIa devices, the assessment of the technical documentation will be limited to a sample of devices according to the principles of Article 52 as laid out in MDCG 2019-13 and summarized in the following graph.

	○ Class I s,m,r	○ Class IIa	○ Class IIb	○ Class IIb, implant.	○ Class III.
	Documentation assessment per METHODE	Art. 52(x) TD assessment per PRODUCT CATEGORY	Art. 52(4) TD assessment per GENERIC PROUCTGROUP	Art. 52(4) TD assessment but for EVERY PRODUCT	Art. 52(3) TD certification for EVERY PRODUCT
		MDA /MDN Codes	**EMDN Codes**	**100%**	**100%**
PRIOR TO INITIAL CERTIFICATION	Min. 1	Min. 1	Min. 1	All	All
FIRST CERTIFICATION CYCLE	5%	5%	5%	New: all Existing: Focus PMS	New: all Existing: Focus PMS
OTHER CERTIFICATION CYCLES	15%	15%	15%	New: all Existing: Focus PMS	New: all Existing: Focus PMS

Further Details see: MDCG 2019-13

For non-implantable class IIb devices, and for implantable class IIb devices exempted according to Article 52,4, representative samples are determined based on “generic product groups”. The “generic product group” is identified by an EMDN code[5] comprised of at least 1 letter followed by 6 digits suitable for determination of devices.

For class IIa products, representative samples are determined based on relevant “product categories”. The “product category” is identified by a suitable MDA or MDN code[6] for the devices.

[4] Technical documentation used in this context always also includes the clinical evaluation.

[5] EMDN: European Medical Device Nomenclature.

[6] MDA and MDN codes are published in the Implementing Regulation (EU) 2017/2185 – also see subsection Scope of designation in section 1.

For the class I products that either have a measuring function, or are placed on the market in a sterile condition, or are reusable surgical instruments, the assessment of the corresponding documentation on the aspects related to metrological requirements, establishing, securing and maintaining sterile conditions, and/or the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional texting and the related instructions for use, will be performed outside the audits and also based on sampling again, at least one representative sample for each method will be assessed.

For sterile systems and procedure packs according to Article 22(3), the assessments are performed based on the documentation, provided by the person placing on the market the procedure pack, on the sterilisation process and relating to ensuring sterility until the sterile packaging is opened or damaged.

The results of technical documentation assessment (TDA) and assessment of documentation on aspects for class I devices and/or sterile systems and procedure packs[7] are communicated to the client in the form of an assessment report that includes, as applicable, the results of the clinical evaluation assessment and further assessments for specific aspects such as biocompatibility, software validation, etc..

If the assessment result identifies nonconformities the client will have to prepare updates to the technical documentation within the indicated time frame. The updated documentation shall be presented again for further assessment subject to additional charges. Failing the TD assessment three consecutive rounds will lead to rejection of the project. Consequently, the manufacturer may submit a new application.

If the assessment shows discrepancies between the client and the notified body regarding the product qualification as a medical device, its classification or coding, these projects shall be referred to the competent authority of the Member State in which the manufacturer or the authorized representative has it's registered places of business, for clarification and decision. The assessment process for that project will be rejected and require a re-application after receiving the member state's decision.

If a specific class of device requires an additional special procedure according to Annex IX Section 5, the final decision by the notified body cannot be made prior to receiving results of consultation from the expert panels mentioned in the chart below. These consultation procedures shall be considered chargeable projects. With TÜV NORD CERT GmbH as a notified body, only the consultation procedures written in the first part of the table may be selected, the special procedures in the second part are not covered by TÜV NORD CERT's designation.

[7] Hereinafter, the term "technical documentation" also includes to such documentation for class I devices and/or sterile systems and procedure packs.

Special procedures under MDR covered by TÜV NORD CERT 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 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

Special procedures under MDR not covered by TÜV NORD CERT designation		
MDR Article	Product	Additional special procedure
52,9	Devices incorporating pharmaceutical substances derived from human blood or tissue	Consultation with European Medicines Agency (EMA)
52,10	Devices incorporating non viable cells/ tissue derived from animal origin	Consultation with Coordination group for (EU) 722/2012
52,10	Devices incorporating non viable cells/ tissue derived from human origin	Consultation with competent authority for 2004/23/EG
52,11	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

The technical documentation assessment shall be initiated prior to the performance of a quality system audit, so that any necessary audit input can be elaborated. In cases where the technical documentation assessment results do not allow the quality system audit to be performed as planned the audit may be re-scheduled or canceled at the expense of the applicant.

2.2. Technical documentation assessment in conjunction with surveillance audits

During the surveillance phase, further technical documentation shall be assessed based on the TDA program as described above. For the non-implantable and implantable exempted (Article 52,4) class IIb devices, as well as for class IIa devices, the assessment continues to be based on sampling, however, a minimum of 5% (during the first certification cycle) or 15% (during subsequent certification cycles) of all devices of a generic product group or a product category are shall be assessed.

2.3. For-cause assessments

Based on information received from different sources such as, but not limited to, vigilance cases and complaints of classification issues, the notified body may decide to perform further chargeable assessments “for the cause”. (also see chapter 5).

3. QUALITY SYSTEM ASSESSMENT

The notified body, in addition to the technical documentation assessment, performs the assessment of the quality system in the form of different audit activities. The activities are based on the audit program that is developed prior to the initial audit for the entire certification period and modified when necessary and/or appropriate.

3.1. Audit preparation

Based on the audit program, the notified body assigns an audit team based on specific expertise for the products and technologies employed by the organization and covered in the scope of audit. The audit team is responsible for planning the concrete audit dates and for the preparation of the audit based on information provided by the client (information from short notice changes, quality documents, and quality procedures). Audit duration is based on international guidelines (e.g. IAF MD 9) and planned in the audit program. For MDR procedures, the technical documentation assessment is required prior to the audit (see chapter 2.1).

3.2. Stage 1 audit

The stage 1 audit is conducted in order to assess the “preparedness of the quality management system by evaluating the QMS documentation, the location of the organization, and site-specific conditions of the organization. Necessary information regarding the scope of the management system, the products, the processes and the location(s) of the organization, and the related legal and regulatory aspects and compliance are collected and analysed. Internal audits and management reviews as well as evidence to demonstrate effectiveness of the quality system, such as corrective and preventive actions, shall be evaluated during the stage 1 Audit. The lead auditor will collect evidence of implementation of the management system that demonstrates that the organization is ready for the stage 2 audit. Nonconformities identified in the stage 1 audit shall be corrected by the organization prior to the stage 2 audit. If nonconformities and/or concerns cannot be resolved, or the audit must be prematurely terminated, the certification process stops after stage 1. The lead auditor is responsible for the coordination of the activities of the stage 1 audit and, if necessary, for the coordination and cooperation of all auditors assigned

to the project. The time interval between the two audit stages shall be agreed with the client. In exceptional cases that require the permission of the specialist management, the stage 1 and 2 audit can be performed in close proximity in relation with the risk of discontinuation after stage 1. The maximum time between both audits shall generally not exceed 3 months.

3.3. Stage 2 audit – certification audit

The client should receive an audit plan 14 days prior to stage 2 audit. The plan is agreed with the client in advance. The audit program may include additional regular audits at other locations and/or suppliers and/or subcontractors. The audit begins with an opening meeting and introduction off the participants. The audit plan and process shall be explained. Within the framework of the audit at the organization's premises, the auditors review and assess the effectiveness of the introduced management system according to the applicable standard as applied for and the relevant MDR conformity assessment procedure, if applicable.

The task of the auditors is to compare the application of the management system with the documented processes and to assess them in relation to the requirements of the normative and regulatory framework. This is achieved by means of interviewing employees (who have management functions within the organization), examining the relevant documents, records, orders and guidelines and by visiting relevant areas of the organization. The audit follows the processes and subsystems in accordance with Annex VII 4.5.2 b. A final meeting takes place at the end of the onsite audit, which should include at least the employees from the organization with management responsibilities. The lead auditor reports on the individual elements and explains the positive and negative results. The lead auditor may or may not recommend issuance of the certificate(s).

In the case of nonconformities (also see sections 3.7-3.9), route cause analyses, corrections and corrective actions will be expected from the audited organization within a defined period of time depending on the severity of the nonconformities. In case of minor non-critical nonconformities, an action plan shall be established and approved by the notified body within 15 days after the audit. The implementation of the corrective actions will be followed up in the subsequent audit. In case of major nonconformities, immediate actions shall be taken by the organization. Additionally, a re-audit or additional documentation review by the notified body may be deemed necessary. If nonconformities cannot be resolved or the audit has to be prematurely terminated, the certification process stops after stage 2. The lead auditor is responsible for the coordination of the activities of the stage 2 audit and, if necessary, for coordination and cooperation of all auditors assigned to the project. The certification procedure is described in section 4.

3.4. Surveillance Audit

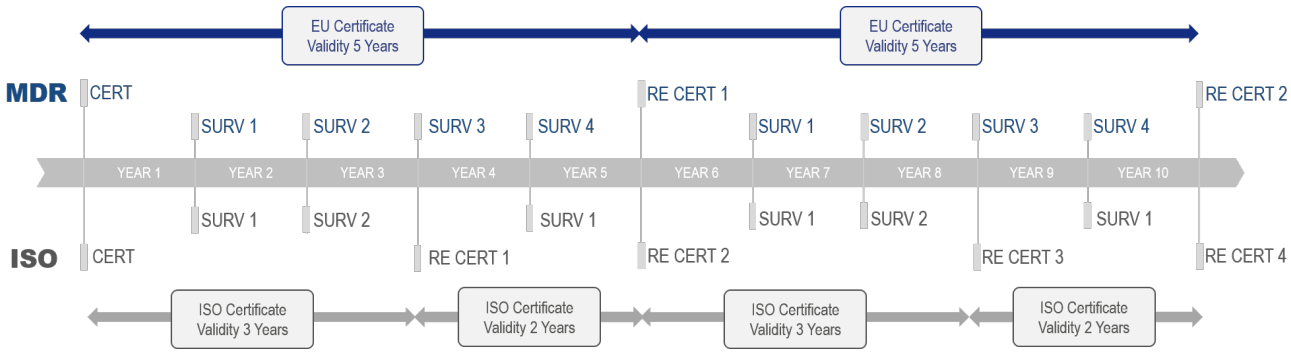
Surveillance audits must be conducted at least every 12 month during the period of validity of the certificate (3 years for EN ISO 13485, 5 years for MDR). The first surveillance audit following the initial certification must be performed within 12 months of the certification decision. Effectiveness of corrective actions in regards to nonconformities issued in the previous audit will be verified. Obligatory elements from the normative and regulatory elements have to be audited. In addition, each year the audit can focus on specific products, processes, or other current topics. After the audit, the lead auditor may or may not recommend the prolongation of the certification.

3.5. Re-certification Audit

At the end of the certification period and prior to a renewed issuance of an EU certificate (after 5 years) / EN ISO 13485 certificate (after 3 years) the notified body has to perform a re-certification audit. The recertification audit follows the procedure of a certification audit but may omitting the stage 1 audit.

Re-certification audits must be completed before the expiration date listed on the certificate. This should include a review of the corrections and corrective actions of nonconformities. Prior to the audit, a review of the organization's quality management system, and of the previous year's audit programs shall be conducted. All applicable normative and regulatory elements have to be audited. In addition, the audit can focus on specific products, processes or other current topics. After the audit, the lead auditor may recommend re-certification.

In case of combined certificates, TÜV NORD CERT GmbH aims to reduce the number of re-certification audits resulting from the different certification periods of the EU Certificates based on the MDR and EN ISO 13485 certificates. . In order to prevent divergent timelines for the re-certification audits, the validity of the EN ISO 13485 certificates may be reduced to 2 years as identified in the following graph.



3.6. Unannounced audits

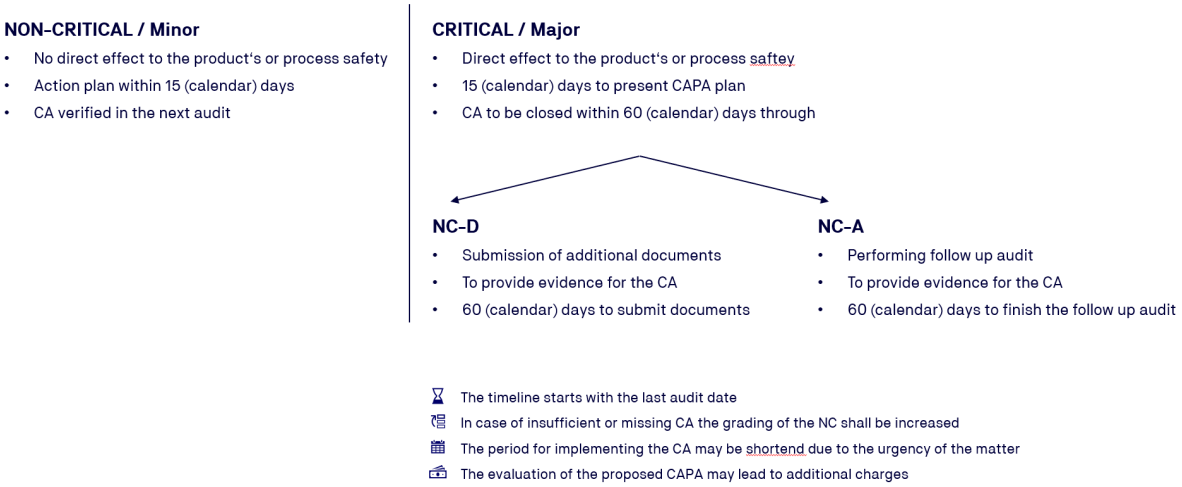
The notified body randomly performs unannounced audits at least once every five years on site at the manufacturer and, when appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment or be performed in addition to that surveillance assessment. These unannounced audits are planned in the audit program but are not disclosed to the manufacturer. In general a team of two auditors performs these unannounced audits for at least one day. The duration of the audit may be prolonged to also include subcontractors etc. in the audit. Any audit activity including audits at subcontractors including potential nonconformity management as well as travelling expenses are subject to charges as outlined in the quotation for the conformity assessment procedure.

The unannounced audit focuses on manufacturing and control of products. Samples of representative devices specified in the audit program are taken from production or warehouse and are verified against the specifications of the technical file. Alternatively, or in addition to the sampling, the notified body may take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation and have them tested in qualified laboratories. These device tests may require the submission of the test samples to a qualified test lab at the expense of the manufacturer. The audit report shall include both the audit results and the results of the sampling test. The organization is requested

to announce production free times for each calendar year for consideration when planning such unannounced audits by the notified body.

3.7. Nonconformity management, general

For the nonconformities identified during any of the audits and/or assessments of technical documentation, the client has to perform a root cause analysis, implement corrections and propose corrective actions. In case of major or critical nonconformities the client will have to submit the planned corrective actions to the notified body within the timeframe as indicated by the following graph:



The period for implementing the corrective action (CA) may be shortened if necessary by the notified body. In case of insufficient or missing corrective action, the grading of the nonconformity shall be increased in the subsequent audit. The effort for the review or reassessment of the nonconformity and the proposed corrections shall be charged separately. Failing to close all NC in the above mentioned time frame may have an impact on the conformity assessment procedure or the certification status. The notified body has the right to refuse certification or in case of surveillance audit to withdraw, restrict or suspend the existing certificate(s). Nonconformity management is subject to additional charges as outlined in the quotation for the conformity assessment procedure. A re-audit may be become due in order to review effectiveness of implementation of corrective actions an additional and chargeable re-audit may be become due.

3.8. Nonconformity management, technical documentation

In the assessment of the technical documentation, in contrast to the nonconformities in the audit, no grading is made with regard to the required measures.

For all nonconformities identified during the assessment of the technical documentation, the client must submit new documentation and evidence for correction which, in addition to explaining how the identified nonconformity will be eliminated, may include new evidence of how compliance with the General Safety and Performance Requirements will be ensured.

The (re)evaluation of the revised technical documentation including the new evidence for the identified nonconformities will be carried out in due time after submission by the experts.. The time between the preparation of the nonconformities and the resubmission of the revised technical documentation should not exceed a period of 30 days. Should more time be necessary for the correction of nonconformities, this should be aligned with the notified body. Deadlines exceeding 60 calendar days are generally not accepted.

The re-examination of the technical documentation, the nonconformity and the proposed corrections and remedial actions will be charged on an hourly basis.

3.9. Nonconformity management, closure

Failure to close all nonconformities within the above timeframes may affect the conformity assessment procedure or certification status. The notified body has the right to refuse certification or, in the case of a surveillance audit/technical documentation assessment, to withdraw, restrict or suspend the existing (EU) certificate(s).

4. CERTIFICATION PROCEDURE

A certification procedure consists of individual projects, each project comprised of multiple conformity assessment steps. The individual assessment results including the accompanying documentation is formally pre-reviewed and evaluated in depth with regard to content. After the conformity assessment steps of a project are all completed, the certification decision is made for the overall project.

The person who reviews and releases the procedure may not have participated in the conformity assessment step of the procedure subject to release. The (EU) certificate can only be issued when the nonconformities have been eliminated i.e. the corrective measures have been accepted or verified by the audit / assessment team. EU certificates under the MDR will only be issued after successful completion of technical documentation assessment and certification audit. The EU certificate may also be issued with conditions for the manufacturer. The quality management certificates under EN ISO 13485 are valid for 3 years. EU certificates have a validity of 5 years. The notified body will transfer relevant details of the EU certificate to European databases (EUDAMED)[8]. All audit reports, technical documentation assessment reports (including the clinical evaluation reports, and other reports) and – if applicable – nonconformity reports shall be made available to the organization and archived by the notified body according to the archiving regulations of TÜV NORD CERT GmbH. Noncompliance of the organization in regards to normative and regulatory requirements may lead to restriction, suspension and even withdrawal of (EU) certificates. This in turn may have consequences for the organization to place medical devices or deploy activities on the European market. Any rejection, restriction, suspension or withdrawal of EU certificates will be notified by TÜV NORD CERT to the EUDAMED database.

[8] Until EUDAMED is declared functional, the EU certificates, including any changes, are reported to the national database (DMIDS).

5. SPECIFIC ACTIVITIES

5.1. Notification of significant changes

The organization is obliged to notify specific changes to the notified body prior to their implementation:

- "Substantial" changes to the quality management system or the device-range covered by it (MDR Annex IX 2.4). Examples for substantial changes to the quality management system may include but are not limited to:
  - Relocation of the manufacturer, change of process equipment with impact to product quality or safety, change of responsible personnel
- Changes to the specific composition of medical devices incorporating a pharmaceutical substance, such as:
  - changes are made with regard to an excipient used in the medical device, in particular in relation to the manufacturing process (MDR Annex IX 5.2 f)
- Changes to the approved device for which an EU technical documentation assessment certificate has been issued that may compromise the safety and performance or affect the conditions of use prescribed for the device (MDR Annex IX 4.10).

The notified body shall assess the changes and their impact on the certificates in regards to quality management system and/or products of the organization at the expense of the manufacturer. This assessment may involve additional audit(s) or document assessment activities. The organization shall be notified of the decision and the justified conclusions of the assessment. The organization may continue with the implementation of the change only after receiving the approval and the supplement to the" EU quality management system certificate" by the notified body.

5.2. Vigilance

The organization is obliged to notify competent authorities and the notified body of all serious incidents and field safety corrective actions with their medical without undue delay upon becoming aware of them. As part of their surveillance tasks, the notified body investigates such vigilance cases either reported by the client, the market or competent authorities and may report details to relevant European databases and authorities. The assessment of such "for the cause" assessments is considered a separate chargeable project. The result of this assessment may affect the status of the certificate.

5.3. Sampling from the market

In accordance with specified criteria, the notified body may collect product samples from the market and subject them to analysis in a laboratory to investigate if they conform to the specifications provided by the manufacturer. This sampling and the subsequent assessment including laboratory test are considered as separate chargeable projects. The result of this investigation may affect the status of the certificate.

6. EXTENSION OF SCOPE OF CERTIFICATION

The client may request the extension of the certification scope by submitting the application form. Based on the requested extension the notified body may decide on the necessary conformity assessment activities required to extend the certification scope, which may include additional audits or additional technical documentation assessments as described in the previous chapters. The notified body will inform the client about the relevant chargeable procedures.

7. POST CERTIFICATION MONITORING

All clients are subject to post certification monitoring activities, which include the activities decribed in the previous chapters such as surveillance audits, assessments of the technical documentation including the Post market surveillance documentation and the related reports such as PSUR and SSCP, unannounced audits but also a proactive research and evaluation of the clinical literature and vigilance reports published during the surveillance period. The proactive evaluation of the data is performed as a separate chargeable project in preparation of the forthcoming surveillance audit by the clinical experts of the notified body. The results of the evaluation may impact the sampling of the products, the technical documentation, the audit focus, and (if applicable) the certification status.

8. TRANSFER OF CERTIFICATION FROM OTHER BODIES

In general, only certificates from accredited certification bodies (QM systems according to EN ISO 13485) or notified bodies or recognized bodies (conformity assessment procedures according to MDR) can be regarded as transfer from other bodies. Organizations requesting a transfer will in general be treated as new clients. As an initial step a "pre-transfer review" shall be carried out by a competent person to identify if the client is qualified for the “transfer from other bodies” usually consisting of a review of important documents and a visit to the customer. Suspended EU certificates or EU certificates that are in danger of being suspended will not qualify the client for the “transfer from other bodies”. Open nonconformities should be clarified with the previous notified body and the organization prior to acceptance.

If the client qualifies for a transfer from other bodies all of the activities identified in sections 1-3are applied with the exception of a stage 1 audit.

Furthermore, a tripartite contract between the organization, the outgoing notified body and the notified body of TÜV NORD CERT GmbH must be established in accordance with legal requirements as stipulated in Article 58 MDR.

9. CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

Conformity assessment procedures under the MDR cannot cover multiple locations using site sampling; consequently, audits of an organisation with multiple locations are generally performed at all locations involved in the design and manufacturing of products in the scope of certification. This also applies to EN ISO 13485 certification procedures.