Service description, conformity assessment procedures according to the Medical Devices Regulation (EU) 2017/745

TÜV NORD Certification

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This document is prepared to provide our clients a description of the conformity assessment and application procedure under the (EU)2017/745 (MDR Annex VII, 4.2 a). As such it forms an integral part of the contract between the notified body and the manufacturer.

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 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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TÜV NORD CERT clients applying for 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 CONFORMITY ASSESSMENT PROCEDURE (CAP)

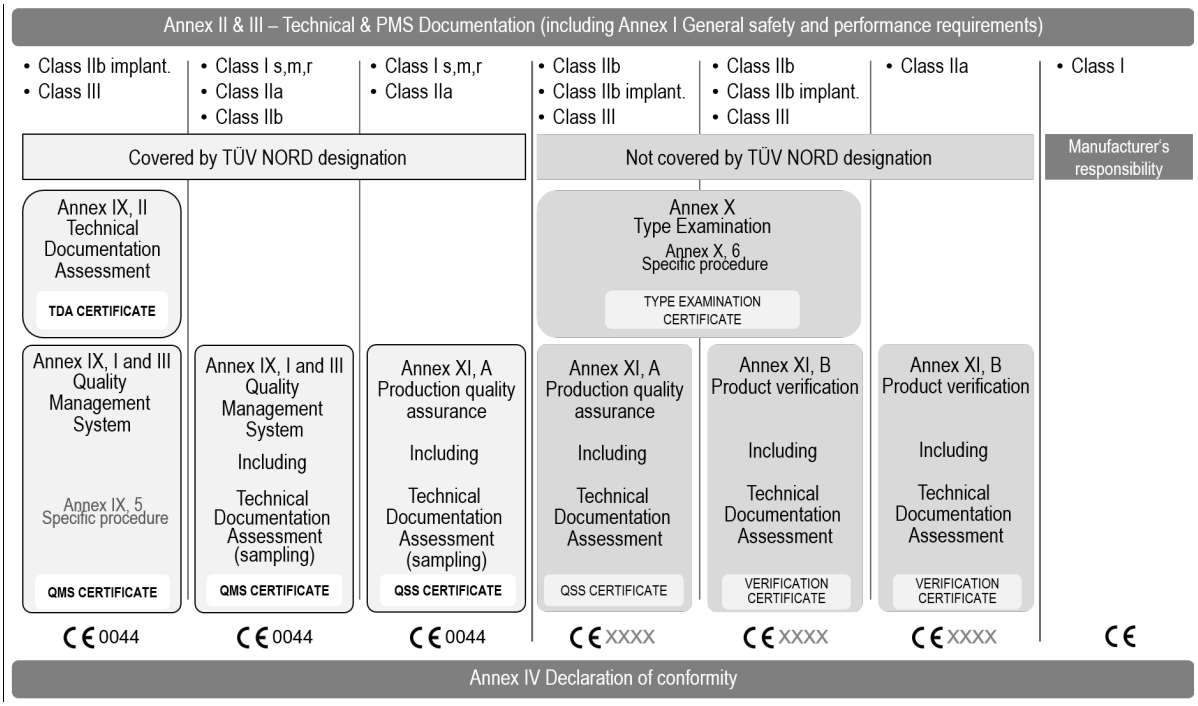
Under MDR, the manufacturer has to identify the appropriate CAP(s) depending on the classification of the device(s) that they intend to bring to market. The CAP performed by the notified body TÜV NORD CERT GmbH comprises the following main stages that are to be followed in the below order:

- 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 manufacturer can apply for the suitable MDR CAP after implementation of MDR requirements into the Technical Documentation according to Annex II and III of the MDR.

The technical documentation will be assessed regarding the compliance to the general safety and performance requirements (stipulated in the Annex I of the MDR), and the full implementation of the requirements concerning the quality system. The latter can be based on EN ISO 13485 to demonstrate compliance.

TÜV NORD CERT will focus on CAP(s) 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 grey.



Annex IX, Quality Management System

The conformity assessment procedure according to annex IX is called the “quality management system assessment”. The quality management system assessment will cover design, manufacture and/or final verification and testing of the devices. Along with the audit, the technical documentation will be assessed. After a successful conformity assessment an “EU quality management system certificate” will be issued.

Annex XI, A Production quality assurance

The conformity assessment procedure to annex XI, A is called “production quality assurance”. The quality assurance system is approved for 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 following a separate conformity assessment procedure according to Annex X by the notified body.

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.

1.1 Initial contact and pre-application Information

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

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) utilising the “clients questionnaire” P111F012. The pre-application documentation is preliminary verified. At the end of this stage TÜV NORD CERT will prepare an offer for the application review. If the manufacturer accepts the offer, they will submit the required application form P111F013 and related documentation as described in chapter 1.2 as well as the signed offer including the acceptance of the “Terms and conditions” P111F002 under the MDR.

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 per annexes IX 2.1 using the “Application form” P111F013. The application and related documentation (including an overview of the entities covered under the quality system and a separate comprehensive product list using the form P111F007 provided by the notified body) are subject to a chargeable application review. This includes a sample of the technical documentation using the “Technical Documentation Transfer Form” P111F008.

Manufacturers receive the application review result in writing.

1.3 Information on rejected or discontinued contracts

In case the application is refused, discontinued or withdrawn from this stage onwards 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(MDR Annex 4.3).

1.4 Finalizing the application process and planning the CAP

Based on the review result and the information provided, the notified body will plan the audit program and the technical documentation assessment program for the full 5 year-certification cycle under the MDR, if required in combination with other management system standards such as EN ISO13485 or EN ISO 9001 (see section 3.5).

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.

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 perform the Technical Documentation[1] assessment(s) based on the Technical Documentation Assessment (TDA) program developed prior to any assessment for the full certification period (result application review). The TDA program shall be updated as required. For all class III and the implantable class IIb products, the Technical Documentation for every product shall be assessed. 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 Art. 52,4, the Technical Documentation for every product must be assessed as well, but no additional certificate is issued. For all other class IIb products and all class IIa products the assessment of the Technical Documentation will be limited to a sampling according to the principles as laid out in the 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 class IIb products, representative samples are determined based on “generic product groups”. The “generic product group” is identified by a EMDN[2] code composing of at least 1 letter followed by 6 digits suitable for the 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[3] code for the devices.

For the class I products that are either sold with measuring functions, or sold sterile, or as reusable surgical instruments, the assessment will be based on sampling again, at least one representative sample for each method will be assessed.

The technical documentation assessment (TDA) results are communicated to the client in the form of an assessment report that includes the results of the clinical evaluation assessment and further assessments for specific aspects such as biocompatibility, software validation, etc..

1) Technical Documentation as used in this context always includes the clinical evaluation
2) European Medical device Nomenclature
3) MDA MDN codes are published

If the assessment result identifies non-conformities the client will have to prepare updates to the technical documentation within the indicated time frame. The updated documentation shall be presented again for the assessment subject to additional charges. Failing the TD assessment three times consecutively will lead to rejection of the project. Consequently, the manufacturer may re-apply.

If the assessment shows discrepancies regarding the product's qualification as a medical device or the classification between the client and the notified body, 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 requires 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.

Special procedures under the MDR covered by TÜV NORD CERT designation		
MDR ART	PRODUCT	ADDITIONAL SPECIAL PROCEDURE
54	Class III Implantable	Clinical evaluation consultation procedure (CECP) performed by the experts of the MDCG
54	Class IIb according rule 12	Clinical evaluation consultation procedure (CECP) performed by the experts of the MDCG
52,9	Devices incorporating pharmaceutical substances	Consultation with competent authorities according pharmaceutical substances 2001/83/EC
Special procedures under the MDR not covered by TÜV NORD CERT designation		
MDR ART	PRODUCT	ADDITIONAL SPECIAL PROCEDURE
52,9	Devices incorporating pharmaceutical substances derived from Human Blood or tissue	Consultation with EMA according to 2001/83/EC
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	Devices to be metabolized rule 21	Consultation with EMA according 2001/83/EC

The technical documentation shall be assessed prior to the performance of a quality system audit. 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 with the Surveillance audits

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

2.3 For the 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”.

These activities initiated in the post certification period 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 that are employed by the organization. The audit team is responsible for planning the 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 MD9). For MDR procedures, the technical documentation assessment is required prior to the audit (see chapter 2.1).

3.2 Audit Stage 1

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 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 cannot be resolved, or the audit shall be 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 Audit Stage 2 – 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 supplier audits. 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. 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, 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

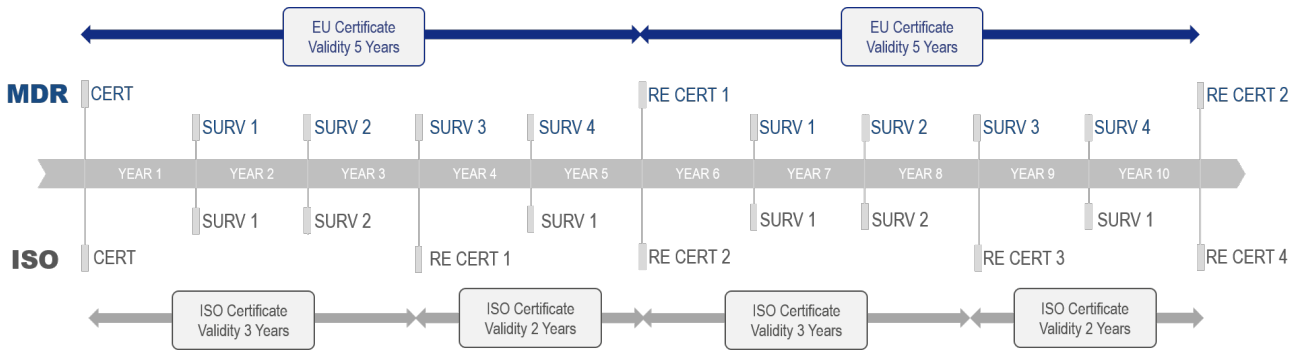
Surveillance audits must be conducted at least every 12 month during the period of validity of the certificate (3 years EN ISO 13485, 5 years MDR). The sequence of audited processes during each surveillance audit is equal to stage 2 (section 2.3). Effectiveness of corrective actions in regards to non-conformities 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. The sequence of audited processes during each surveillance audit is equal to stage 2 (section 3.3). 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.



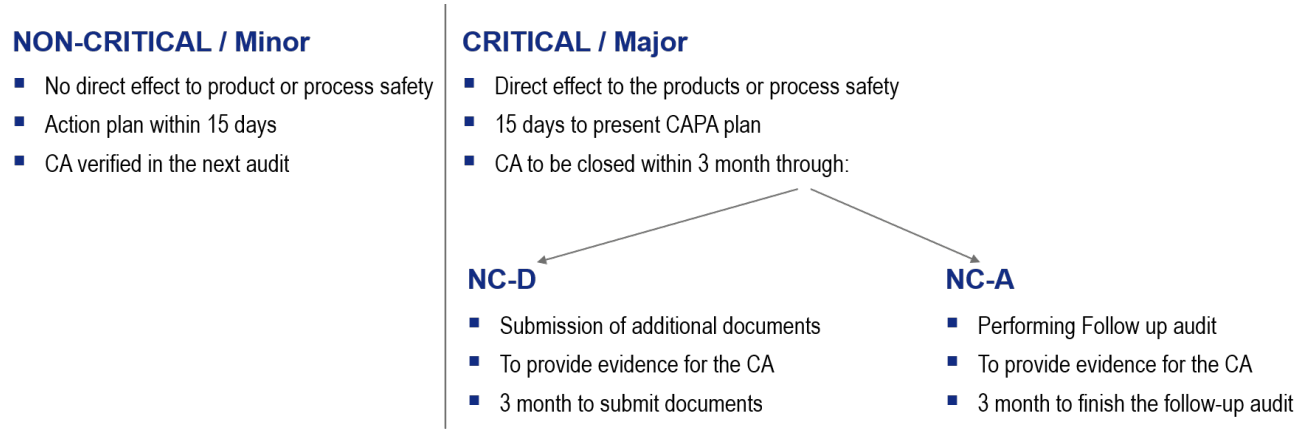
3.6 Unannounced audits

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 non-conformity 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 Non-conformity management, Audit

For the non-conformities identified during any of the audits the client has to perform a root cause analysis, implement corrections and propose corrective actions. In case of major or critical non-conformities 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 non-conformity shall be increased in the subsequent audit. The effort for the review or reassessment of the non-conformity 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). Non-conformity 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 Non-conformity management, Technical Documentation

In the assessment of the technical documentation, in contrast to the non-conformities in the audit, no gradation is made with regard to the required measures.

For all non-conformities 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 non-conformity

will be eliminated, may include new evidence of how compliance with the Essential Safety and Performance Requirements will be ensured.

The (re)evaluation of the revised technical documentation including the new evidence for the identified non-conformities will be carried out in due time after submission by the experts.. The time between the preparation of the non-conformities and the resubmission of the revised Technical Documentation should not exceed a period of 30 days.

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

3.9 Non-conformity management, closure

Failure to close all non-conformities 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 certificate(s).

4 CERTIFICATION PROCEDURE

All certificates are issued in a multiple-step procedure. The assessment results including the accompanying documentation is formally pre-reviewed and evaluated in depth with regard to content followed by the certification decision.

The person who reviews and releases the procedure may not have participated in the assessment procedure. The EU certificate / 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 technical documentation assessment and certification audit. The EU certificate may also be issued with obligations for the manufacturer. The quality management certificates under EN ISO 13485 are valid for 3 years. MDR certificates have a validity of 5 years. The notified body will transfer relevant details of the EU certificate to European databases. After approval and certification audit reports, technical documentation assessment reports (including the clinical evaluation reports, and other reports) and – if applicable – non-conformity 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.

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 CERTIFICATION SCOPE

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 DIN 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 non-conformities 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 the chapter 1-3 are 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, consequently multi-site audits cannot be performed under the MDR.