TÜV SÜD Danmark ApS MDR Conformity Assessment Procedures

Add value.
Inspire trust.

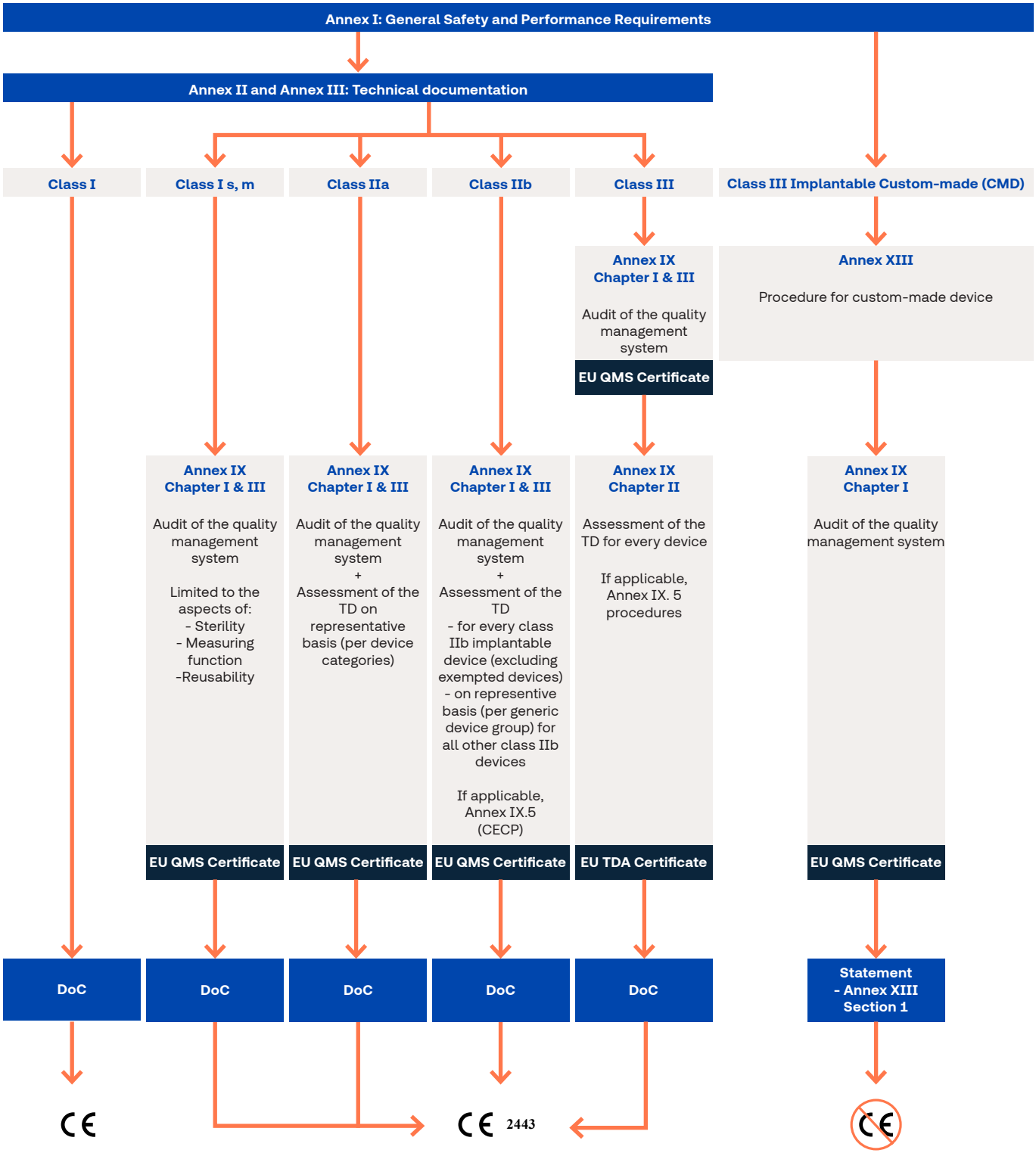
Be confident of medical device market approval

MDR 2017/745 Application Procedure
TÜV SÜD has developed an online service registration form to allow us to systematically process your request. If you would like to request MDR services from TÜV SÜD, please use this form to register your interest.

Step-by-step information of the conformity assessment procedures of TÜV SÜD Denmark MHS highlighted below.

English is the only acceptable language for the submission of documentation and any related correspondence.

Conformity Assessment Procedures under MDR 2017/745 for TÜV SÜD Denmark MHS



Glossary

Class Is sterile	**Class Im** measuring function	**DoC** Declaration of conformity	**QMS** Quality management system	**EU TDA Cert.** EU technical documentation assessment certificate	**CECP** Clinical Evaluation Consultation Procedure

Annex IX
Conformity assessment based on a Quality Management System and on the assessment of Technical Documentation

Chapter I: Quality Management System (QMS)
1. Pre-Application Management
- Pre-application form submitted by potential client
- Pre-application completeness check
- Acceptance / Rejection of Pre-application
- Establish framework agreement and conformity assessment order incl. quotation
- Confirmation of conformity assessment order
- Self-assessment forms and other necessary forms for client to review and fill in

2. Application Management
- Signed application to be submitted together with QMS and Technical Documentation package per agreement in the conformity assessment order. (In case application is submitted beforehand of the QMS and Technical Documentation, the application is only considered final when the documentation listed in the QMS and Technical Documentation checklists has been reviewed)
- Administrative Review
- Acceptance / Rejection of Application (If rejected application steps below will not proceed)
- Client submission of QMS and Technical Documentation
- Application complete
- Registration in EUDAMED

3. Technical Documentation
(Assessment of the Technical Documentation is performed prior or parallel to on-site audits)
- The Technical Documentation + completed checklist submitted by client together with application, will go through a completeness check to ensure all documents are submitted.
- Client will be informed if any documents are missing and will be asked to provide the missing documents. If these are not provided this may lead to a delayed review as the initiation of conformity assessment cannot start or result in non-conformities being raised during the conformity assessment for missing documentation.
- When completeness check has been successfully completed, initiation of conformity assessment activities will commence.
- The submitted technical documentation will be split into a pre-clinical and clinical assessment.
- If non-conformities are identified within the documentation, the client will receive a non-conformity report. We will perform agile reviews with close contact with the client during the review.
- Client addresses non-conformities.
- If the client cannot close the non-conformities within 3 rounds of responses, the application will be rejected and the client requested to file a new application.
- Technical documentation assessment report issued.

4. Auditing
- The QMS documentation + completed Client QMS Documentation Self-Assessment Evaluation Form submitted by client, will go through a off-site audit process.
- Client will be informed about the output of the process by the Off-site Audit Report. If any non-conformities will be issued, they will be forwarded to the client as a non-conformity report. Based on successful completion of the off-site audit, the auditor will dispatch to the client a plan for the on-site audit.
- On-site audit will be conducted at the client premises. The on-site audit may be expanded to include critical subcontractors and suppliers based on company setup.
- During the closing meeting of the audit, the client will be informed about the non-conformities (if any).
- The client will receive a full audit report containing the non-conformities within 14 working days from the audit. The client shall submit plans for corrections and corrective actions according to specified time frames based on the criticality of the identified nonconformities.

5. Certification
- QMS certificate(s) issued

Chapter II: Assessment of Technical Documentation (additional for classes III, IIb impl.)

1. Pre-Application Management
- Pre-application form submitted by potential client
- Pre-application completeness check
- Pre-application review
- Acceptance / Rejection of Pre-application
- Establish non-binding quotation and framework agreement
- Order confirmation

2. Application Management
- Filled in application form from client
- Administrative Review
- Acceptance / Rejection of Application (If rejected application steps below will not proceed)
- Client submission of QMS and Technical Documentation
- Application complete
- Registration in EUDAMED

3. Technical Documentation Assessment
- The technical documentation + completed checklist submitted by client together with application, will go through a completeness check.
- Client will be informed on missing documentation (if any). If client fails to provide documentation within two request rounds, non-conformities will be issued for the missing documents.
- When completeness check has been successfully completed, initiation of conformity assessment activities will commence.
- The submitted technical documentation will be split into a pre-clinical and clinical assessment.
- If non-conformities are identified within the documentation, the client will receive a non-conformity report.
- Client addresses non-conformities
- If non-conformities cannot be closed within 3 rounds of response, the application will be rejected and the client is asked to file a new application.
- Technical Documentation assessment report issued.

4. Audit
- The QMS documentation + completed checklist submitted by client together with application, will go through a completeness check.
- Client will be informed on missing documentation (if any). If client fail to provide documentation within two request rounds, non-conformities will be issued for the missing documents.
- When completeness check has been successfully completed, initiation of off-site audit will commence.
- Based on successful completion of the off-site audit, the auditor will dispatch to the client an audit plan for the onsite audit.
- On-Site audit will be conducted at the client premises. Audit may be expanded to include critical subcontractors and suppliers based on company setup.
- During the closing meeting of the audit, the client will receive a list of nonconformities (if any).
- The client will receive a full audit report within 14 days from the audit.
- The client shall submit plans for corrections and corrective actions according to specified time frames based on the criticality of the identified nonconformities.

5. Certification
- Product certificate(s) issued

Specific Procedures within the MDR

Un-announced Audits

An unannounced audit of a client or a significant subcontractor or supplier to a client is conducted without any prior notice and with special focus on a sampled product(s) and production processes.

Besides being unannounced, the audit also differs from a regular audit in the audit objective.

- The unannounced audit shall be initiated without undue delay e.g. there shall be no opening meeting or company presentation and on-site auditors shall be able to move around the production and test facilities during the audit.
- Where possible, the audit team shall select tests to be conducted on an adequate sample of the devices produced or an adequate sample from the manufacturing process during their presence to confirm the conformity to specifications in the technical documentation.
- The unannounced audit shall verify that the ongoing manufacturing activities at the time of the unannounced audit is according to the manufacturer's documentation and that it is in conformity with legal requirements.
- The requirements specified in Medical Device Regulation (MDR) 2017/745 annex VII (4.5.1 and 4.10) and applies to all unannounced on-site audits.

Product Testing
The requirements specified in the Medical Device Regulation (MDR) 2017/745 Annex IX 3.3, Annex IX 3.5, includes that the notified body shall, where necessary carry out or ask for tests in order to check the quality management system is working correctly.

During Surveillance on-site audits or unannounced audits we will prepare and identify the devices to be sampled and tested prior to a QMS audit, depending on the device classification.

Testing should be undertaken in accordance with the testing procedure defined by the client in the technical documentation which has to be assessed by TÜV SÜD Denmark Medical Health Services (TS DK MHS). The test may be performed by the client, its critical subcontractor or crucial supplier and shall be witnessed by TS DK MHS.

Device type	Additional assessment
Class III implantable devices	Subject to the Clinical Evaluation Consultation procedure, an additional assessment by an expert panel under the European Medicines Agency (EMA).
Class IIb active devices under rule 12	Subject to the Clinical Evaluation Consultation procedure, an additional assessment by an expert panel under the European Medicines Agency (EMA).
Devices incorporating a medicinal substance	Additional assessment by a Product Reviewer with medicinal substance expertise and consultation with a Competent Authority, as per Directive 2001/83/EC, is required.
Devices incorporating human blood derivatives	Additional assessment by a Product Reviewer with human blood derivatives expertise and consultation with the European Medicines Agency, as per Directive 2001/83/EC, is required. (Note: Manufacturers need upfront an official certificate from the Medicines Control Laboratory (OMCL) for batch release).
Devices utilising non-viable animal tissue/cells/derivatives	Additional assessment by a Product Reviewer with expertise in animal tissue is required, before the coordinating Competent Authority gains feedback from EU Member States, as per Regulation (EU) No 722/2012.
Devices utilising non-viable human derivatives	Additional assessment by a Product Reviewer with expertise in human derivatives and consultation with a human tissues and cells Competent Authority, as per Directive 2004/23/EC, is required.
Devices that are composed of substances, or of combinations of substances, that are absorbed by, or locally dispersed in, the human body (rule 21)	For Class III devices under rule 21, additional assessment by a Product reviewer with expertise within substances and consultation with Competent Authority, as per Directive 2001/83/EC, is required.

Clinical Audits
The MDR has put even more emphasis on requirements related to clinical aspects. Clinical audit is included as part of the initial certification audit and subsequently, once during a conformity assessment cycle of 5 years. 4 hours will be dedicated to the topic of clinical processes and the interlink between risk management.

In addition, irrespective of the medical device class, audits on clinical processes can be triggered in response to information that raises concerns about the compliance and/or effectiveness of clinical processes of a medical device manufacturer. Our dedicated experts on clinical MDR requirements – our Internal Clinicians – are accompanying the lead auditor and will perform this special part of the audit.

Periodic Safety Update Report (PSUR) – Article 86

	Contents	Updated (at least)	NB assessment	Notes
Class III + implantables	• Analysis of PMS data (results & conclusions) • Preventive & corrective actions • Risk-benefit determination • Main findings of PMCF • Volumn of sales + estimate of user population + frequency of use	1 year (III, IIb) 2 years (IIa)	At each update (via EUDAMED)	Supporting Technical Documentation might be requested, such as Clinical Evaluation Report
Class IIb		1 year	When necessary	
Class IIa		2 years	When necessary	

Summary of Safety and Clinical Performance (SSCP) – Article 32

Class III and implantable devices

(no custom-made or investigational devices)

Content

- Identification of the device and the manufacturer (including UDI-DI, SRN)
- Intended purpose, including indications, contra-indications and target populations
- Description of the device, including a reference to previous generation(s) or variants, and description of the differences
- Description of the accessories, or other devices/products intended to be used in combination with the device
- Possible diagnostic or therapeutic alternatives
- Reference to harmonised standards and common specifications
- Summary of clinical evaluation and relevant information on the Post-market Clinical Follow-up (PMCF) - for guidance please see MDCG 2019-9, section 5
- Suggested profile and training for users
- Information on any residual risks and any undesirable effects, warnings and precautions - for guidance please see MDCG 2019-9, section 4

Format / Update

- Updated at least annually and submitted for Notified Body (NB) validation
- Submitted in combination with an updated CER + technical documentation summary
- Submitted in language accepted by NB + confirmation of certified translation
- Written in a language clear to the final use (potentially a lay person)
- Publicly available through EUDAMED and referenced in labels or instructions for use (IFU)

Related services

TÜV SÜD provides the following related services:

- Denmark MDR declaration of interest
- Guidance for summary of MDR Technical Documentation
- MDR frequently asked questions
- MDR request for service registration
- MDR Technical Documentation assessment procedure
- Medical devices and IVDs testing
- Medical device market approval & certification
- Medical device regulation
- Questionnaires and application forms for medical devices
- Transfer to TÜV SÜD

TÜV SÜD AG Westendstr. 199, 80686 Munich, Germany
+49 89 5791-0, medicaldevice@tuvsud.com, www.tuvsud.com/en