MDR conformity assessment procedures

Add value.
Inspire trust.

Be confident of medical device market approval (TS DE 0123)

MDR 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.

Based on the product classification, the manufacturer must apply for an applicable conformity assessment procedure.

Step-by-step information for each of the conformity assessment procedures (using the relevant Annex) is highlighted below. The graphics also provide an overview of the procedures for different device classes and types as well as relevant surveillance activities. Specific device types require additional assessments, which are listed in the tables below.

English and/or German are the only acceptable languages for the submission of documentation and any related correspondence.

The certification costs are based on hourly rates and take into account factors such as the size of company, sites, number and complexity of devices, etc.

The standard fees for the conformity assessment activities delivered by TÜV SÜD Product Service GmbH are as follows:

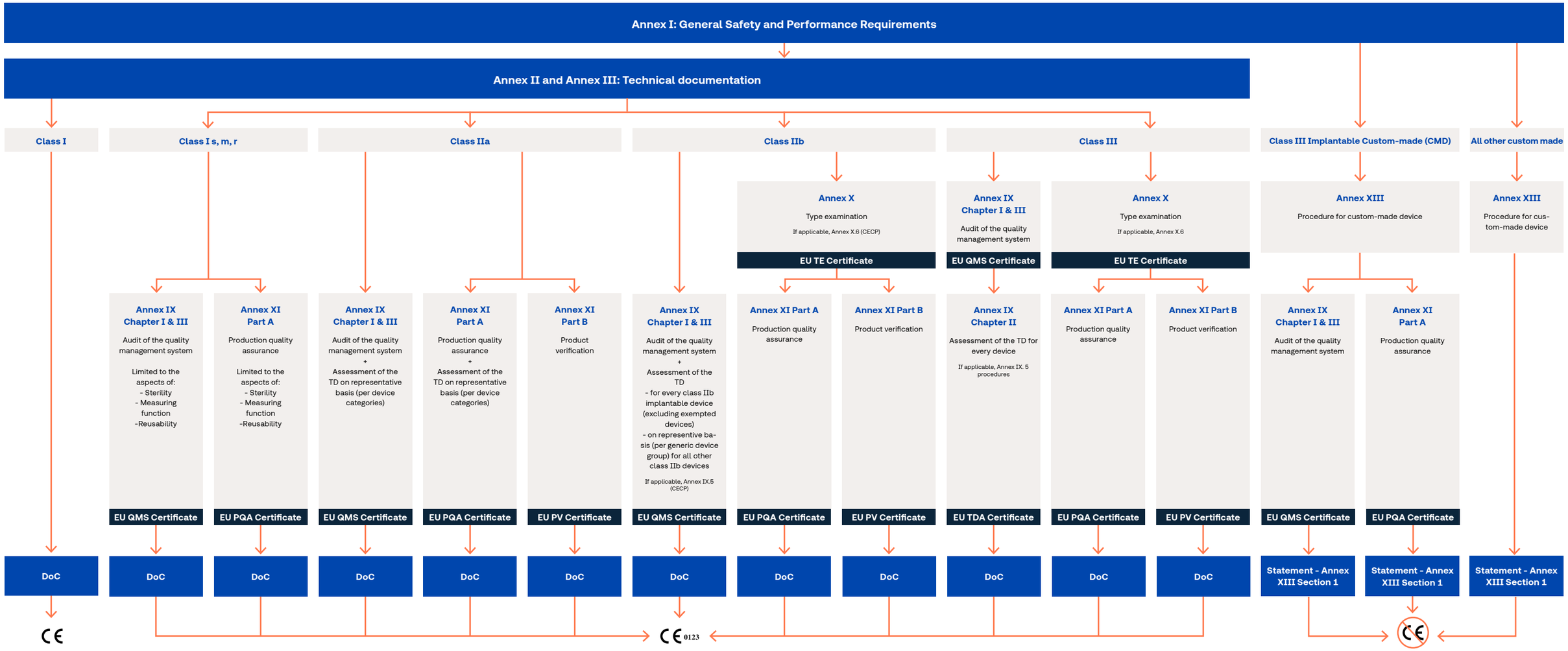
	Hourly Rate*
Audit and QM System Assessment Services	
Audit	320 €
Assessment of Change Notifications and Extensions for Quality Systems, MDR, IVDR	320 €
Technical Documentation Assessment Service	
Technical Documentation Assessment Offsite	430 €
Clinical Assessment	430 €
Application Management Fee	
Per case	2550 €
Initial Assessment of Vigilance Information	
Each case count 1 - 200	400 €
Each case count > 200	80 €

*Depending on the location of the manufacturer and possibility to include local experts or auditors in the conformity assessment procedure, prices may vary, and fees may be invoiced in local currency.

TÜV SÜD Product Service GmbH takes into account the interests of SMEs by basing its entire fee structure mainly on effort-related criteria rather than fixed steps, thus enabling SMEs in particular for a precise and individual cost calculation based on the effort involved in each individual case.

Conformity assessment procedures under MDR

TÜV SÜD Product Service GmbH provides conformity assessment services according to MDR Annex IX, Annex X and Annex XI Part A or Part B as described below, and according to the notification details officially published in the EU NANDO Information System. Manufacturers can select an appropriate conformity assessment procedure depending on the risk class of the device. Depending on the applicable conformity assessment procedures, the MDR certification can result in either one or more combined types of EU Certificates (five different types available). 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 year periods, based on an assessment according to Annex VII, 4.11 on Re-certification.



Glossary

Class Is
sterile

Class Im
measuring function

Class Ir
reusable surgical instrument

DoC
Declaration of conformity

QMS
Quality management system

EU PQA Cert.
EU production quality assurance certificate

EU PV Cert.
EU product verification certificate

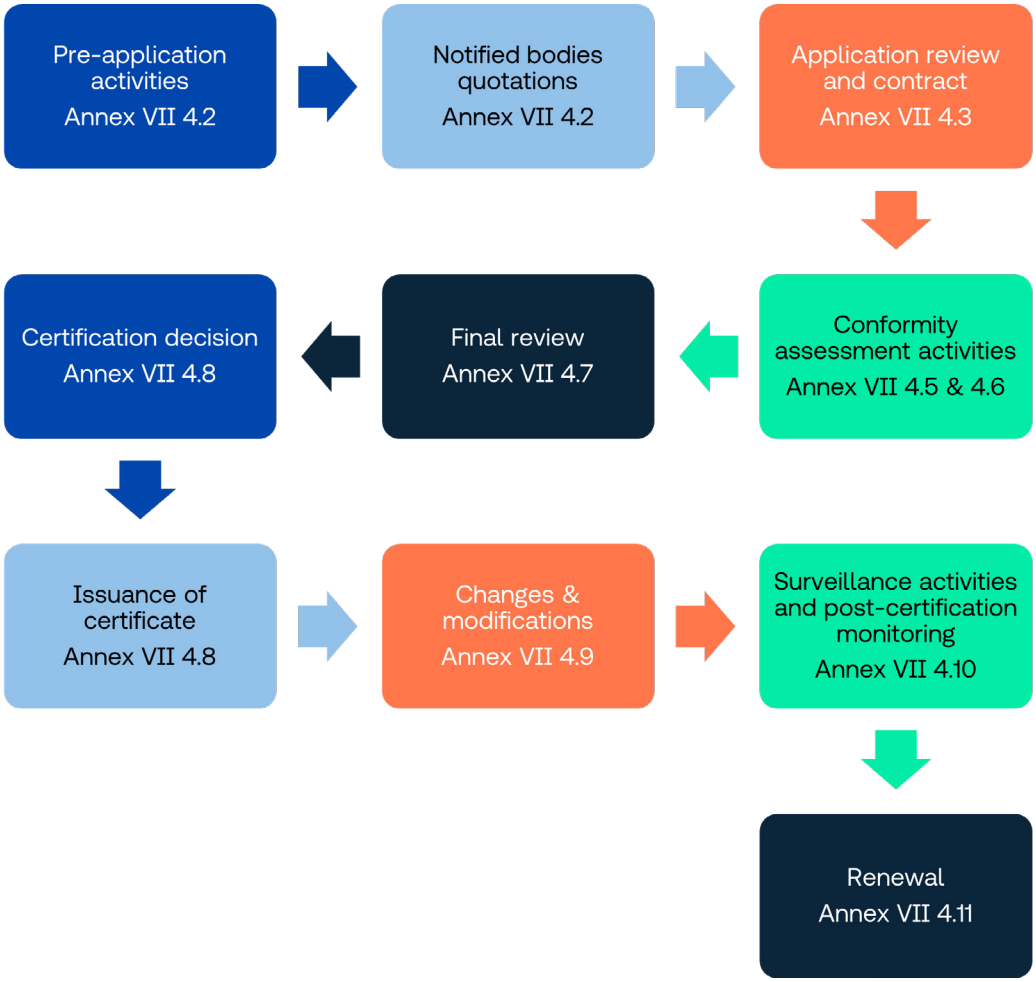
EU TE Cert.
EU type-examination certificate

EU TDA Cert.
EU technical documentation assessment certificate

CECP
Clinical Evaluation Consultation Procedure

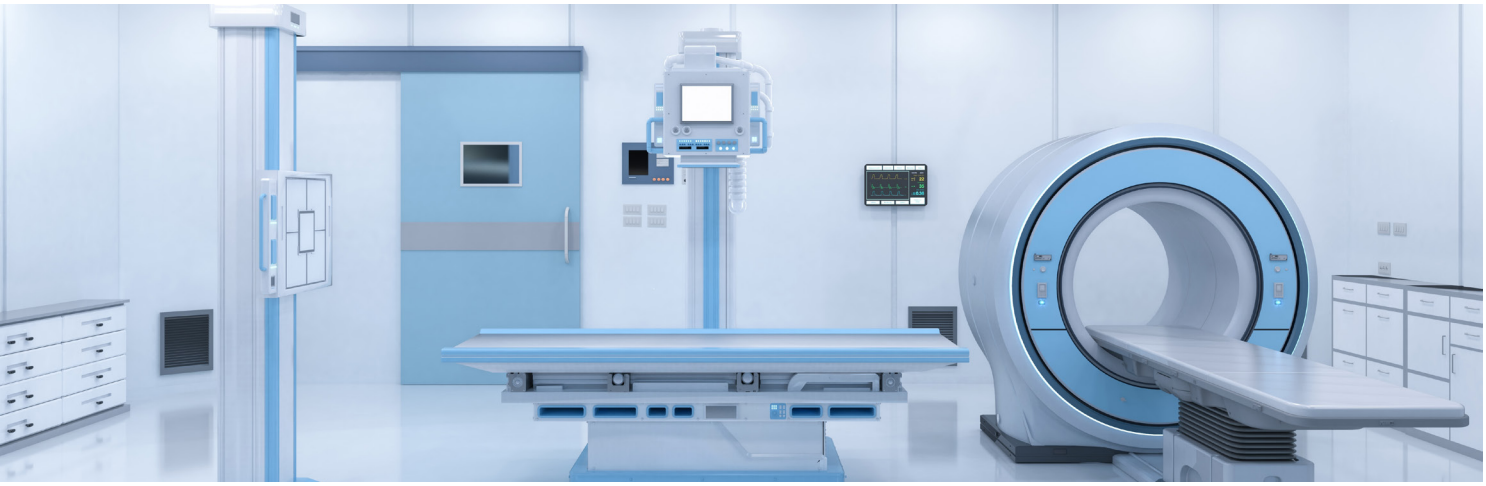
General overview on certification process

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, X, XI Part A or Part B) 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.



Our Service Description provides a detailed overview of the individual conformity assessment procedure according MDR Annex IX, X, XI Part A or XI Part B.

Download the MDR Service Description (NB 0123)



Specific procedures within the MDR

Device type	Additional assessment
 MDR Article 54 Class III implantable devices	Subject to the Clinical Evaluation Consultation procedure, an additional assessment by the expert panel.
 MDR Article 54 Class IIb active devices under rule 12	Subject to the Clinical Evaluation Consultation procedure, an additional assessment by the expert panel.
 MDR Article 52 (9) Devices incorporating a medicinal substance	Additional assessment by a TÜV SÜD medicinal substance expert and consultation with a Competent Authority, as per Directive 2001/83/EC, is required.
 MDR Article 52 (9) Devices incorporating human blood derivatives	Additional assessment by a TÜV SÜD human blood derivatives expert 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).
 MDR Article 52 (10) Devices utilising non-viable animal tissue/cells/derivatives	Additional assessment by a TÜV SÜD animal tissue expert is required, before the coordinating Competent Authority gains feedback from EU Member States, as per Regulation (EU) No 722/2012.
 MDR Article 52 (10) Devices utilising non-viable human derivatives	Additional assessment by a TÜV SÜD human tissue expert and consultation with a human tissues and cells Competent Authority, as per Directive 2004/23/EC, is required.
 MDR Article 52 (11) 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 TÜV SÜD expert and consultation with Competent Authority, as per Directive 2001/83/EC, is required.

Audits on clinical aspects

Auditing clinical processes is an integral part of our QMS audits for all medical device manufacturers. Clinical processes shall be audited as part of every QMS audit and is a part of the conformity assessment activities for medical device manufacturers. Under MDR, clinical processes such as clinical evaluation, pre-clinical evaluation and clinical investigations where applicable are covered during QMS audits. Audits on clinical aspects are performed by an authorized and qualified auditor.

Periodic Safety Update Report (PSUR) – Article 86

Device class	Frequency of data collection period	Upload EUDAMED*	Notified Body evaluation	Contents	Notes
Class III device + all implantable device	Every 12 months (III, IIb) Every 24 months (IIa)	Manufacturer uploads PSUR without undue delay	Notified Body to add its evaluation to EUDAMED	• Analysis of PMS data (results & conclusions) • Preventive & corrective actions • Risk-benefit determination • Main findings of PMCF • Volume of sales + estimate of user population + frequency of use	* In the absence of EUDAMED manufacturers should deliver the PSURs to the relevant Notified Bodies **PSUR (shall be part of the technical documentation acc. MDR Annex II + III)
Class IIb device	Every 12 months	N/A	Available upon request**		
Class IIa device	Every 24 months	N/A	Available upon request**		

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

Class III and all 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 the clinical evaluation and relevant information on the Post-market Clinical Follow-up (PMCF)
- Suggested profile and training for users
- Information on any residual risks and any undesirable effects, warnings and precautions

Format / Update

- The SSCP shall be kept updated (in EUDAMED). When the PMCF evaluation report and the PSUR are updated at least annually (IIa implantable devices every two years), the SSCP shall be reviewed and updated if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete.
- Submitted in English and/or German in combination with an updated PSUR or technical documentation
- Written in a way that is clear to the intended user and, if relevant, to the patient
- Publicly available (through EUDAMED) and the instructions for use (IFU) shall contain all that is needed to directly find the SSCP in EUDAMED.

Related services

TÜV SÜD provides the following related services:

- Clinical services
- Guidance for summary of MDR Technical Documentation
- MDR request for service registration
- Medical device regulation
- Medical device market approval & certification
- Medical devices and IVDs testing
- 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