



# 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.

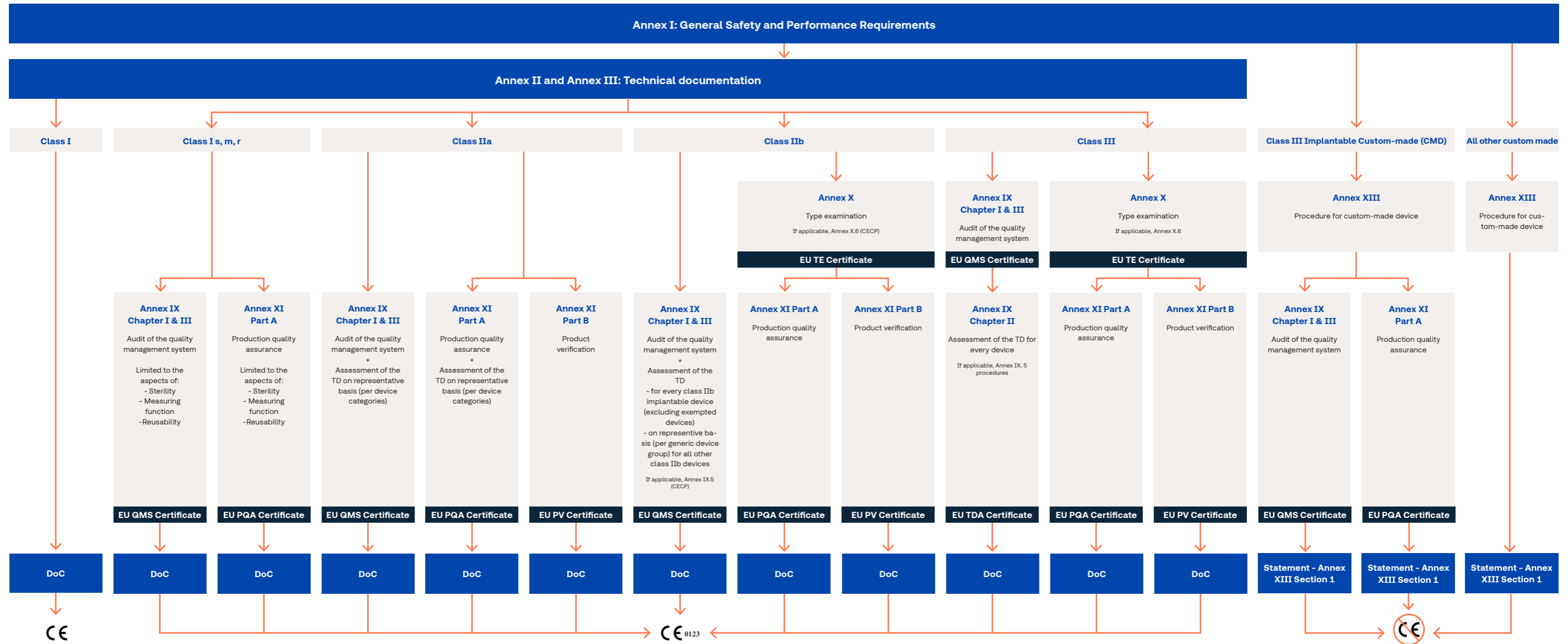
The standard fees for the conformity assessment activities delivered by TÜV SÜD Product Service GmbH are as follows:

|  | Hourly Rate* |
|--|--------------|
| <b>Audit and QM System Assessment Services</b>                                   |              |
| Audit  | 320 €        |
| Assessment of Change Notifications and Extensions for Quality Systems, MDR, IVDR | 320 €        |
| <b>Technical Documentation Assessment Service</b>                                |              |
| Technical Documentation Assessment Offsite                                       | 430 €        |
| Clinical Assessment  | 430 €        |
| <b>Application Management Fee</b>  |              |
| Per case   | 2550 €       |
| <b>Initial Assessment of Vigilance Information</b>                               |              |
| 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.

## 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.

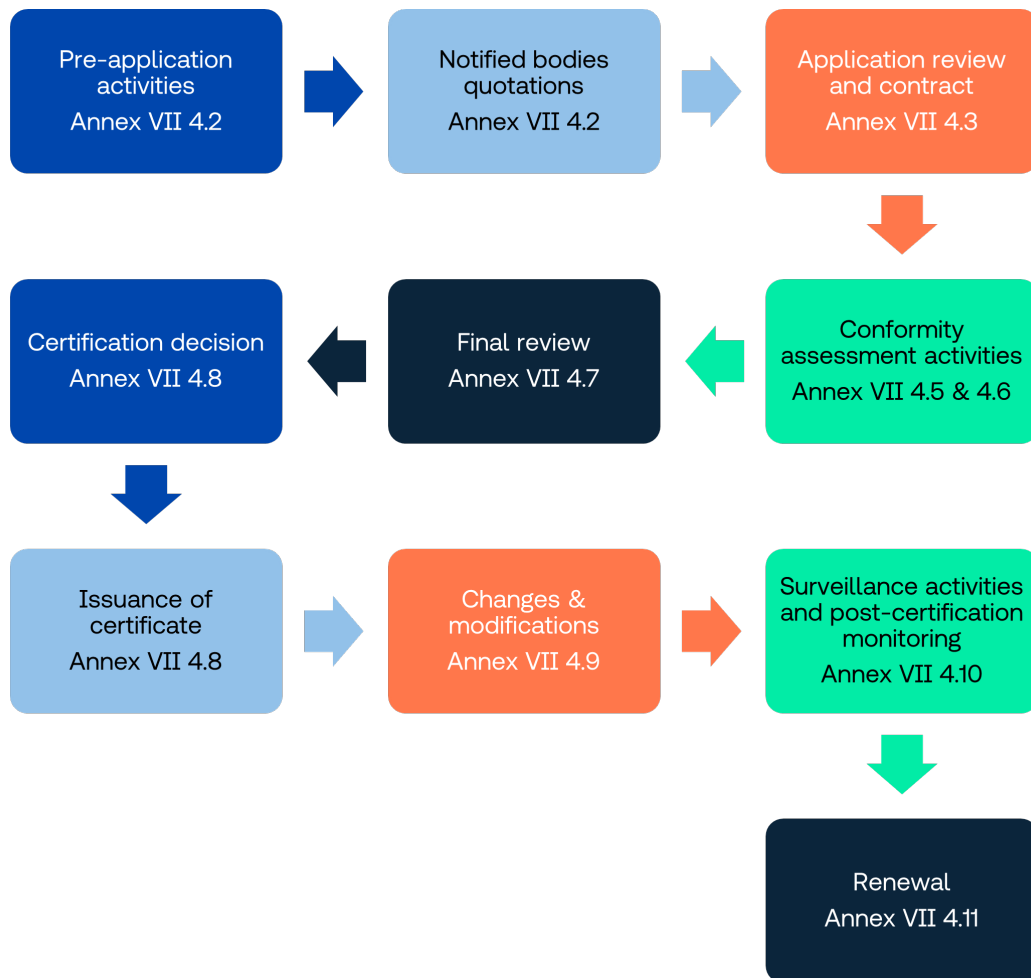


### Glossary

|                                       |   |  |   |  |
|---------------------------------------|---|--|---|--|
| <b>Class Is</b><br>sterile            | <b>Class Ir</b><br>reusable surgical instrument | <b>QMS</b><br>Quality management system                            | <b>EU PV Cert.</b><br>EU product verification certificate | <b>EU TDA Cert.</b><br>EU technical documentation assessment certificate |
| <b>Class Im</b><br>measuring function | <b>DoC</b><br>Declaration of conformity         | <b>EU PQA Cert.</b><br>EU production quality assurance certificate | <b>EU TE Cert.</b><br>EU type-examination certificate     | <b>CECP</b><br>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   |
|--|---|
|  <p>MDR Article 54<br/>Class III implantable devices</p>  | Subject to the Clinical Evaluation Consultation procedure, an additional assessment by the expert panel.  |
|  <p>MDR Article 54<br/>Class IIb active devices under rule 12</p>   | Subject to the Clinical Evaluation Consultation procedure, an additional assessment by the expert panel.  |
|  <p>MDR Article 52 (9)<br/>Devices incorporating a medicinal substance</p>  | Additional assessment by a TÜV SÜD medicinal substance expert and consultation with a Competent Authority, as per Directive 2001/83/EC, is required.  |
|  <p>MDR Article 52 (9)<br/>Devices incorporating human blood derivatives</p>  | 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). |
|  <p>MDR Article 52 (10)<br/>Devices utilising non-viable animal tissue/cells/derivatives</p>  | 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.  |
|  <p>MDR Article 52 (10)<br/>Devices utilising non-viable human derivatives</p>  | 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.   |
|  <p>MDR Article 52 (11)<br/>Devices that are composed of substances, or of combinations of substances, that are absorbed by, or locally dispersed in, the human body (rule 21)</p> | 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.   |

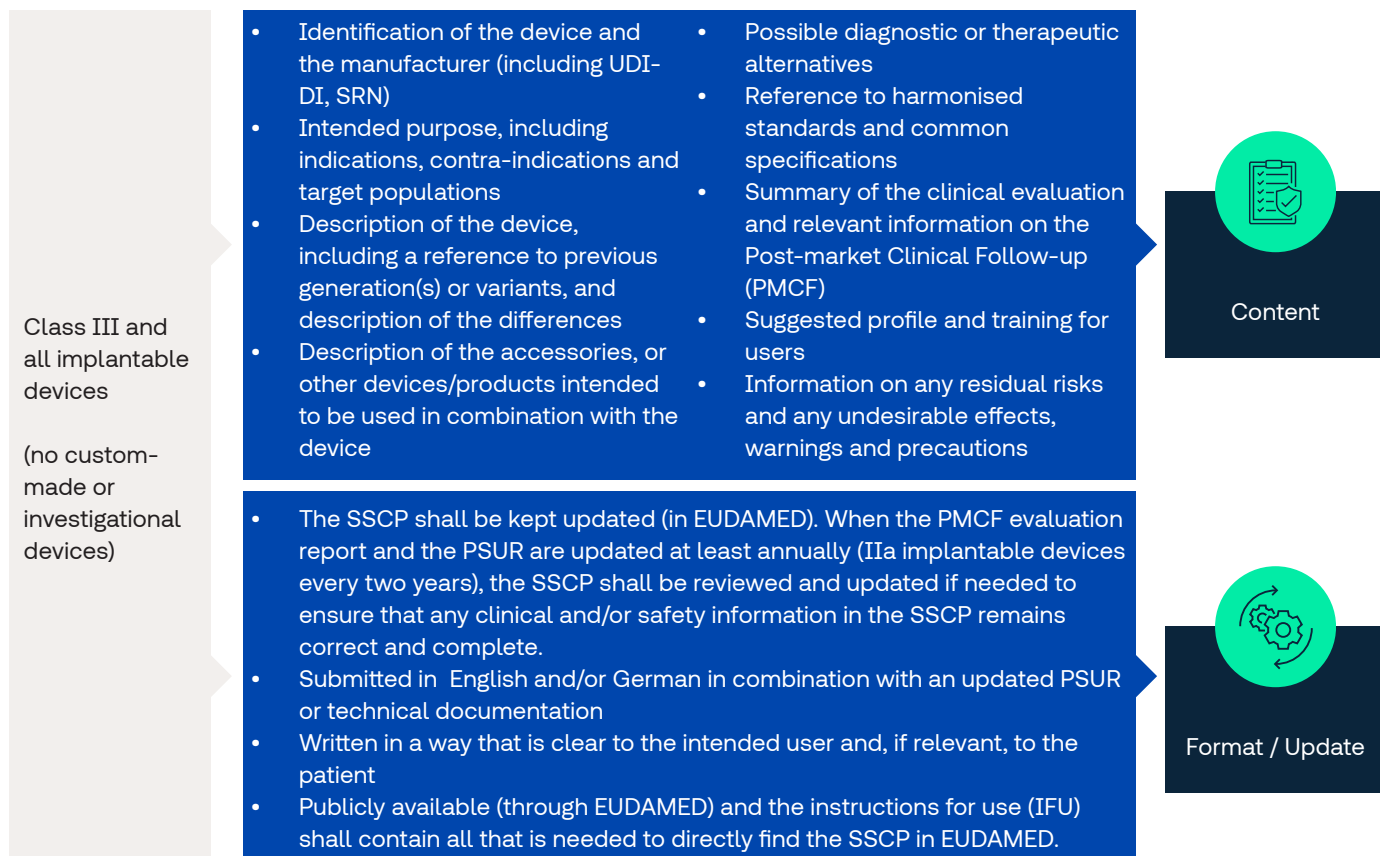
## Audits on clinical aspects

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)<br>Every 24 months (IIa) | Manufacturer uploads PSUR without undue delay | Notified Body to add its evaluation to EUDAMED | <ul style="list-style-type: none"> <li>Analysis of PMS data (results &amp; conclusions)</li> <li>Preventive &amp; corrective actions</li> <li>Risk-benefit determination</li> <li>Main findings of PMCF</li> <li>Volume of sales + estimate of user population + frequency of use</li> </ul> | * In the absence of EUDAMED manufacturers should deliver the PSURs to the relevant Notified Bodies |
| Class IIb device                          | Every 12 months                                     | N/A   | Available upon request**                       |  | **PSUR (shall be part of the technical documentation acc. MDR Annex II + III)                      |
| Class IIa device                          | Every 24 months                                     | N/A   | Available upon request**                       |  |  |

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



### 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