Your partner
in progress

# MDR Conformity Assessment Routes

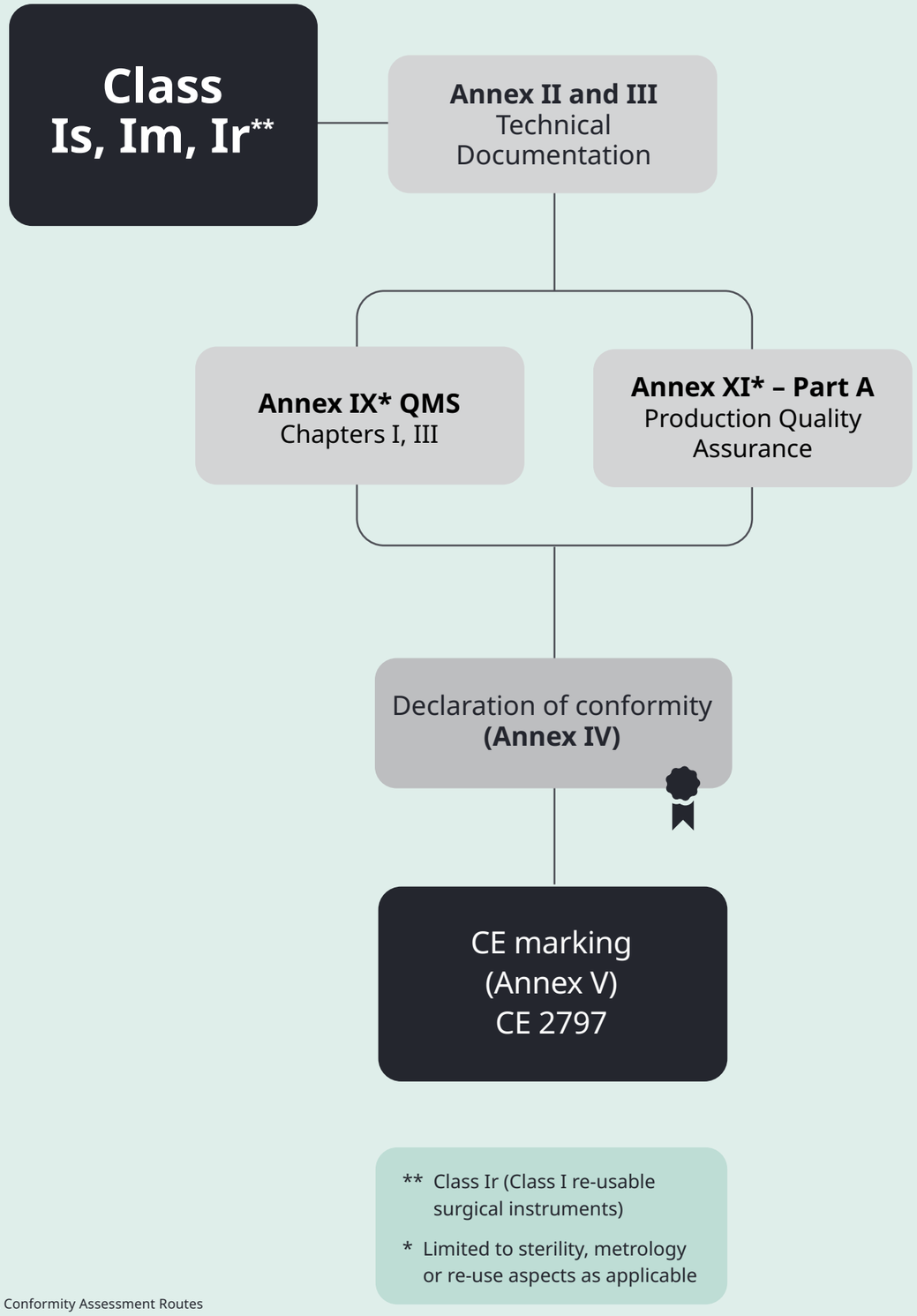
# Contents



**DISCLAIMER:**

Information presented in the conformity assessment flow charts and tables below is based on our current understanding of the MDR requirements at the time of publishing this document; subject to change. The tables do not cover assessments under the conformity routes Annex X (Type Examination) and Annex XI, Part B (Product Verification) which may require additional tests or examinations of the devices. The tables present a generalization of the requirements based on the classification of devices and some exceptions may apply.

# Class Is/Im/Ir devices




** Class Ir (Class I re-usable surgical instruments)

* Limited to sterility, metrology or re-use aspects as applicable

## Applicable audits, assessments and requirements

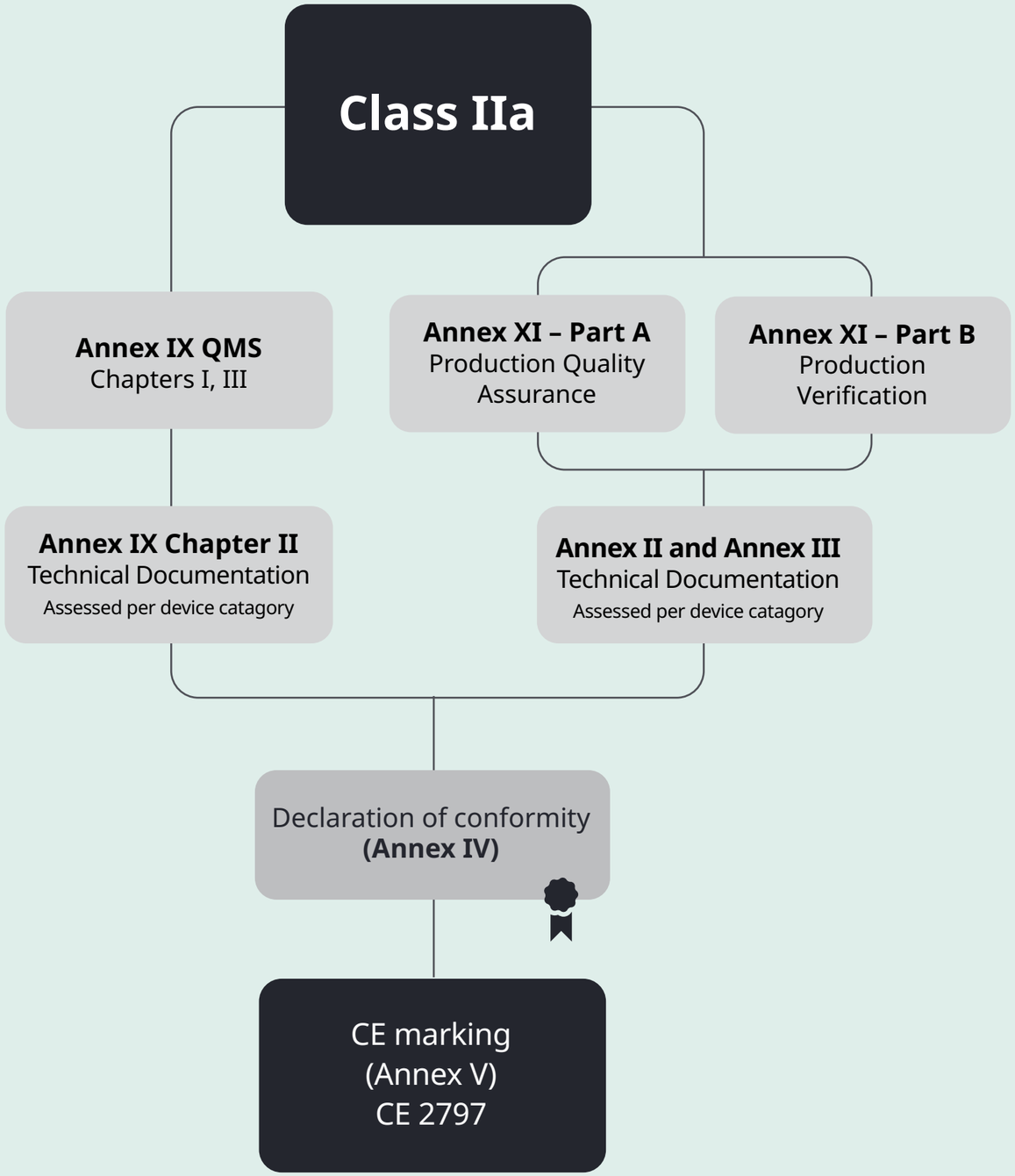
Class Is/Im/Ir devices

| **Class Is/Im/Ir** devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | No stand-alone Technical Documentation assessment. However, parts of Technical Documentation relevant to sterilization/metrology/re-use aspects may be audited as part of QMS/Microbiology audits. | | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Report updates** | Updated as per manufacturer's clinical evaluation plan. | | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | Updated as per manufacturer's PMS, PMCF plans. Notified Body QMS audits to verify implementation of the plan by sampling complaints, vigilance information etc. | | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | Updated when necessary and made available to the Notified Body upon request. | | | | | |
| **Periodic Safety Update Report (Article 86)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Unannounced Audits** | At least once every 5 years. | | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class IIa devices




## Applicable audits, assessments and requirements

Class IIa non-implantable devices

| **Class IIa** non-implantable devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per category of devices | At least one Technical Documentation surveillance assessment is required every year. Assessments carried out as per the Technical Documentation Sampling Plan. | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Report updates** | Updated as per manufacturer's clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan. | | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | Updated as per manufacturer's PMS, PMCF plans. Notified Body to review as per Technical Documentation Sampling Plan. | | | | | |
| **Periodic Safety Update Report (Article 86)** | PSUR update required at least once every 2 years. Notified Body to review as per Technical Documentation Sampling Plan. | | | | | |
| **Unannounced Audits** | At least once every 5 years. | | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

Continues on page 4

# Applicable audits, assessments and requirements

## Class IIa implantable devices

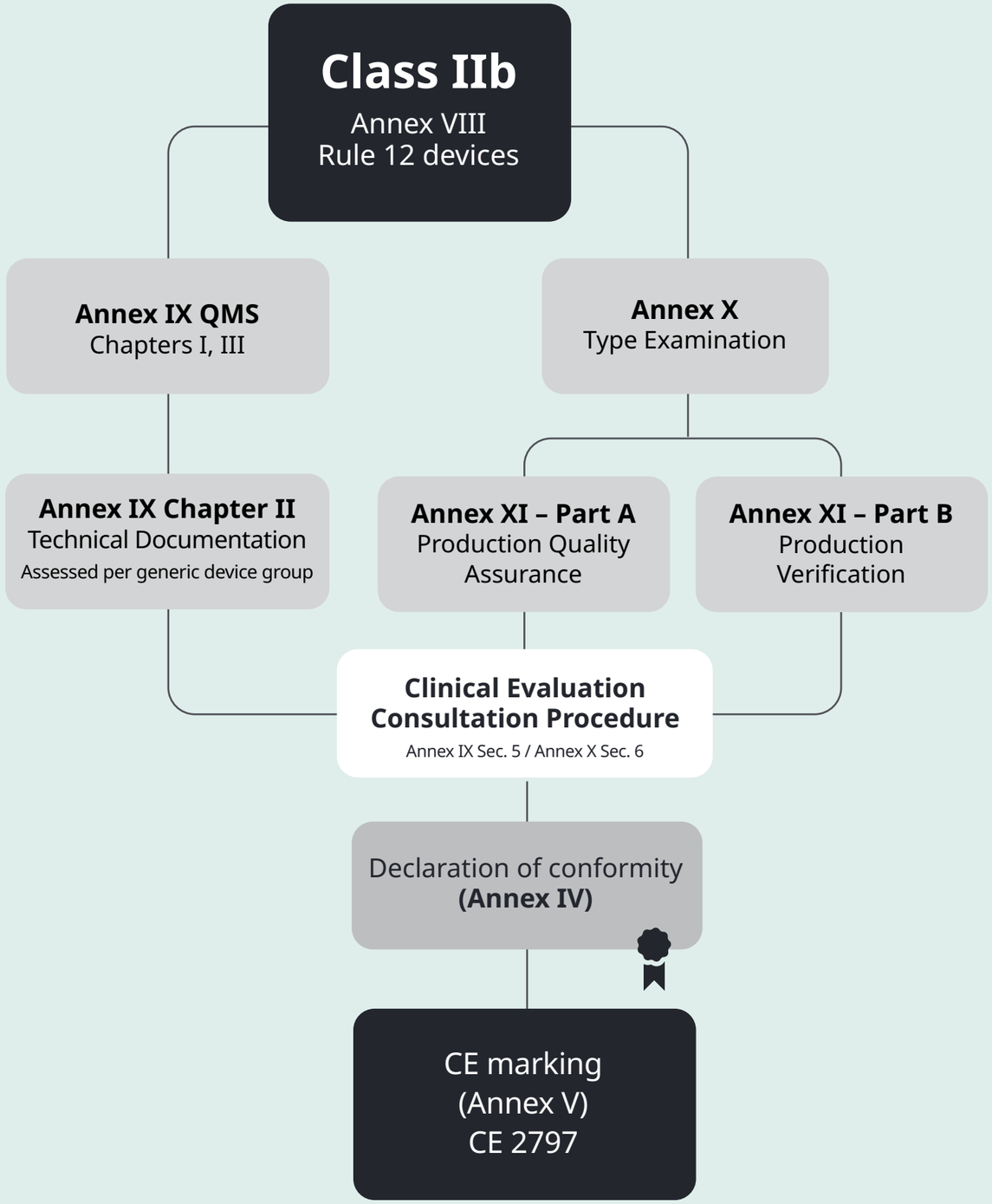
| **Class IIa** implantable devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per category of devices | At least one Technical Documentation surveillance assessment is required every year. Assessments carried out as per the Technical Documentation Sampling Plan. | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | Yes | Updated at least annually "if indicated". Notified Body to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments. | | | | |

| | |
|---|---|
| **Clinical Evaluation Report updates** | Updated as per manufacturer's clinical evaluation plan. Notified Body to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments. |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | Updated at least annually. Notified Body to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments. |
| **Periodic Safety Update Report (Article 86)** | Updated when necessary and at least every two years. submitted to Notified Body via EUDAMED for Notified Body review. |
| **Unannounced Audits** | At least once every 5 years. |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class IIb Annex VIII Rule 12 devices




## Applicable audits, assessments and requirements

Class IIb Annex VIII Rule 12 devices

Annex VIII Rule 12 devices – All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body.

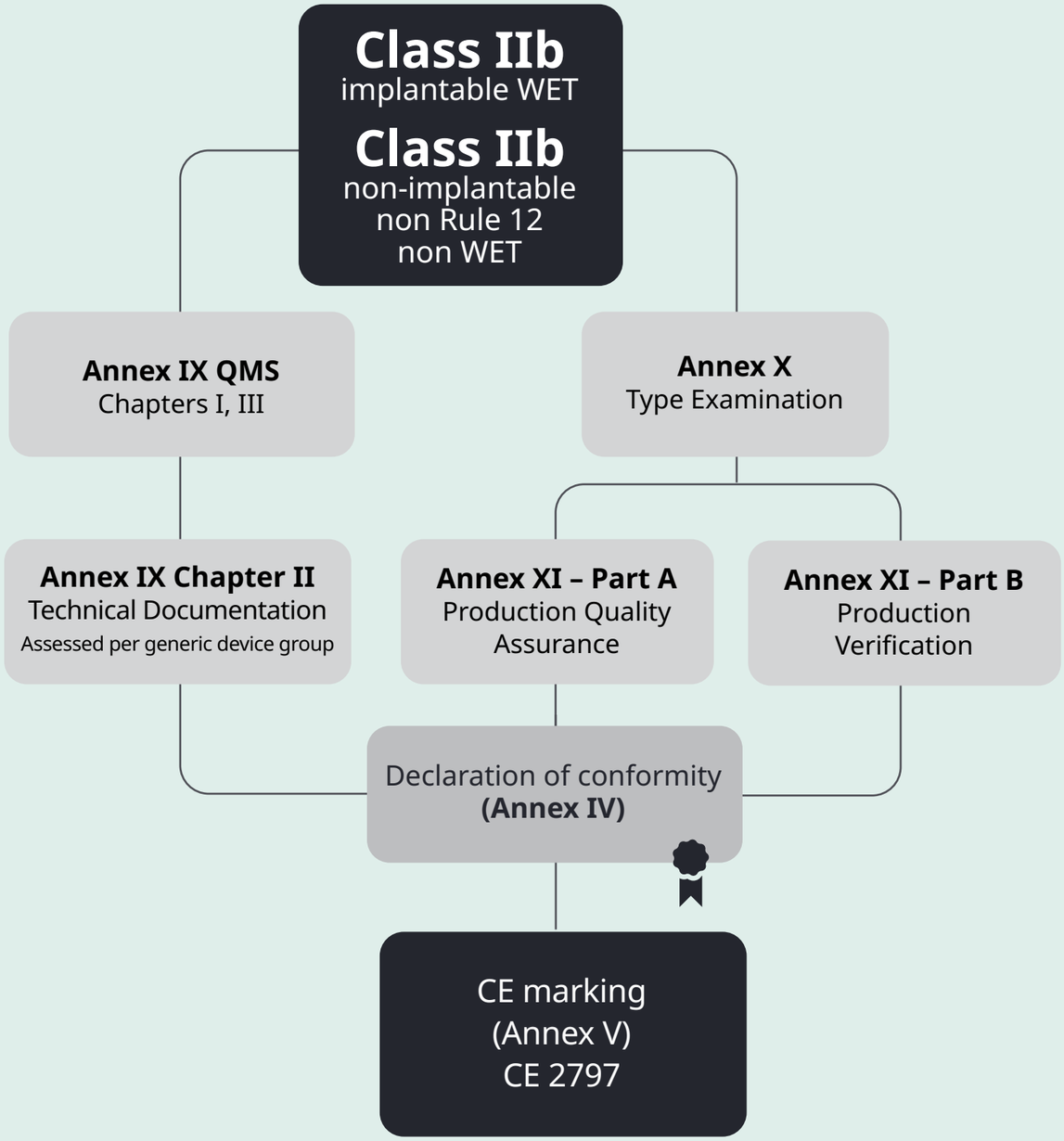
| **Class IIb** Annex VIII Rule 12 devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per generic device group | At least one Technical Documentation surveillance assessment is required every year. Assessments carried out as per the Technical Documentation Sampling Plan. | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | Yes, but exemptions may apply as per Article 54.2 | May be required if any modifications to the device adversely affect the risk-benefit ratio. | | | | |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | N/A | N/A | N/A | N/A | N/A | N/A |

| | |
|---|---|
| **Clinical Evaluation Report updates** | Updated as per manufacturer's clinical evaluation plan. Notified Body to review updates as per Technical Documentation Sampling Plan. |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | Updated as per manufacturer's PMCF plan Notified Body to review updates as per Technical Documentation Sampling Plan. |
| **Periodic Safety Update Report (Article 86)** | Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan. |
| **Unannounced Audits** | At least once every 5 years. |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class IIb implantable WET
# Class IIb non-implantable non Rule 12 non WET




MDR Conformity Assessment Routes

## Applicable audits, assessments and requirements

Class IIb implantable WET, ClassIIb non-implantable non Rule 12 non WET

Well-Established Technologies (WET) - sutures, staples, dental fillings and braces, tooth crowns, screws, wedges, plates, wires, pins, clips & connectors as per Article 52 of MDR.

| **Class IIb** implantable WET devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per generic device group | At least one Technical Documentation surveillance assessment is required every year. Assessments carried out as per the Technical Documentation Sampling Plan. | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | Yes | Updated at least annually “if indicated”. Notified Body to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments. | | | | |
| **Clinical Evaluation Report updates** | | Updated as per manufacturer’s clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan. | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | | Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments. | | | | |
| **Periodic Safety Update Report (Article 86)** | | Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review (assuming WET devices are implantable devices). | | | | |
| **Unannounced Audits** | | At least once every 5 years. | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 “Recert” indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

Continues on page 7

# Applicable audits, assessments and requirements

Class IIb non-implantable non WET non Rule 12 devices

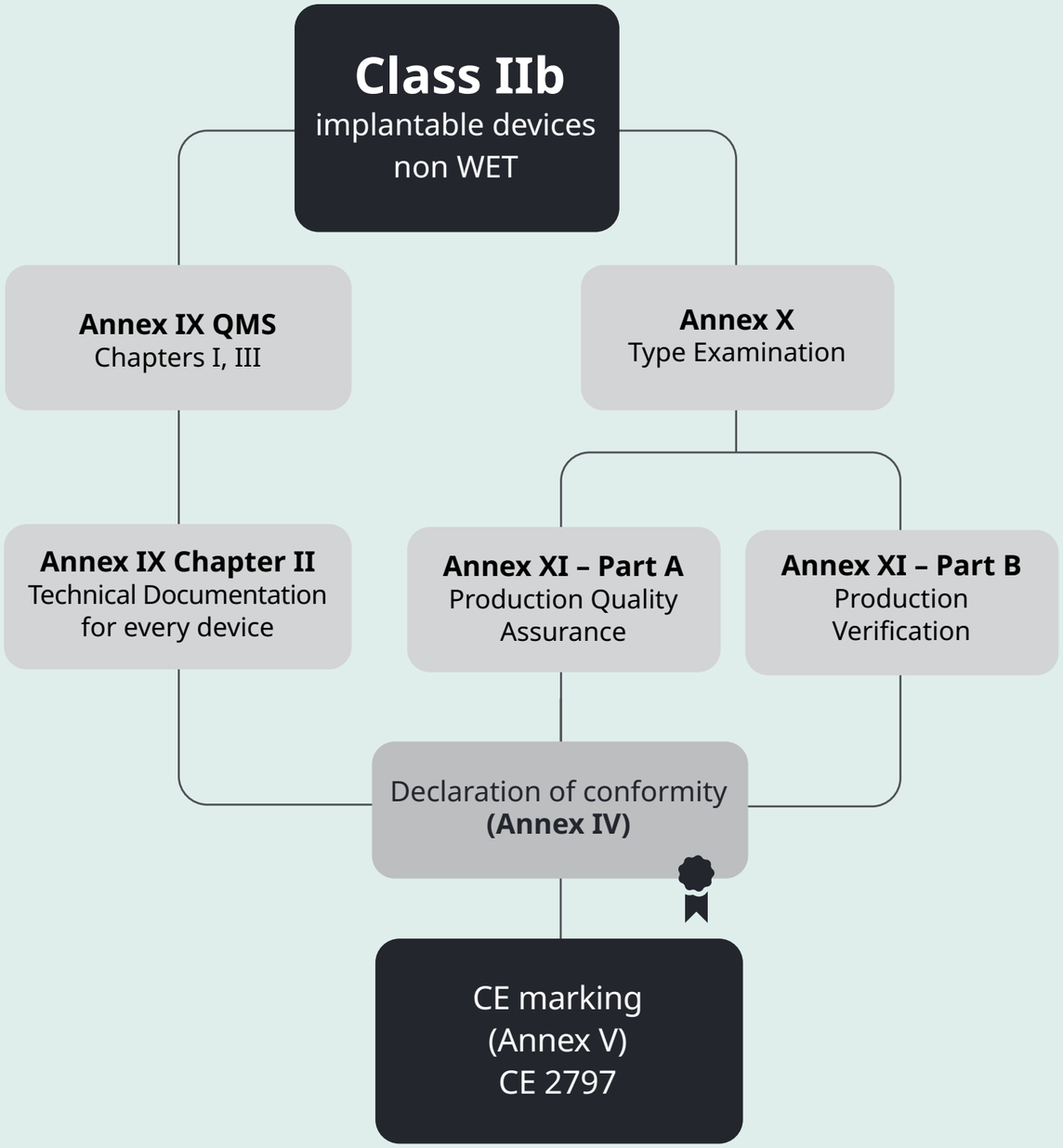
| **Class IIb** non-implantable non-WET non-Rule 12 devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per generic device group | At least one Technical Documentation surveillance assessment is required every year. Assessments carried out as per the Technical Documentation Sampling Plan. | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | N/A | N/A | N/A | N/A | N/A | N/A |

| | |
|---|---|
| **Clinical Evaluation Report updates** | Updated as per manufacturer's clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan. |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | Updated as per manufacturer's PMCF plan. Notified Body to review updates as per Technical Documentation Sampling Plan. |
| **Periodic Safety Update Report (Article 86)** | Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan. |
| **Unannounced Audits** | At least once every 5 years. |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class IIb implantable devices
Excluding WET




## Applicable audits, assessments and requirements

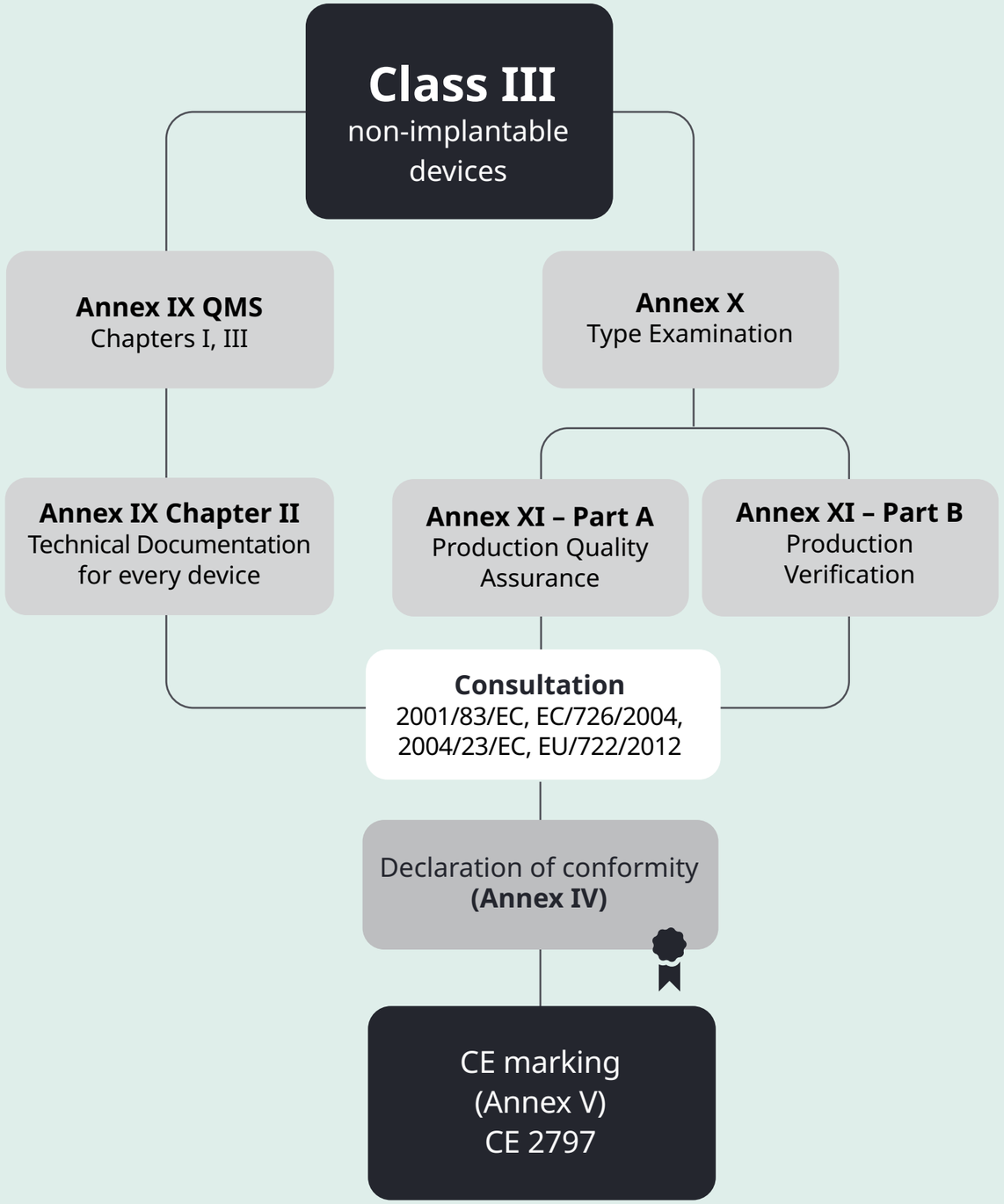
Class IIb implantable non-WET devices

| **Class IIb** implantable non-WET devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | Yes | Updated at least annually "if indicated". Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Clinical Evaluation Report updates** | | Updated as per manufacturer's clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Periodic Safety Update Report (Article 86)** | | Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review. | | | | |
| **Unannounced Audits** | | At least once every 5 years. | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class III non-implantable devices




## Applicable audits, assessments and requirements

Class III non-implantable devices

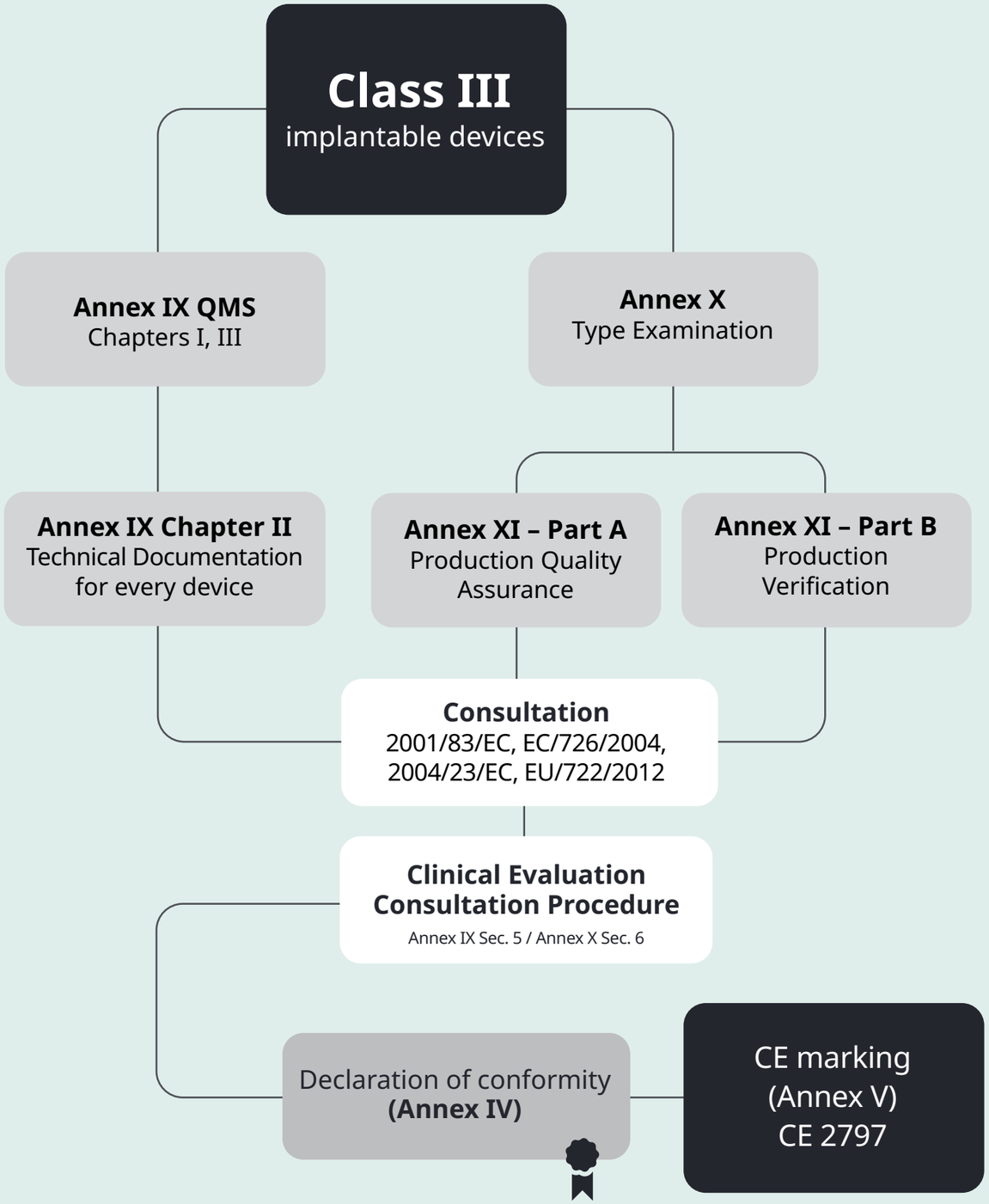
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

| **Class III** non-implantable devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | If applicable | Modifications to the devices may need supplementary consultations; determined on a case-by-case basis taking into account the nature of the changes proposed. | | | | |
| **Summary of Safety and Clinical Performance (Article 32)** | Yes | Updated at least annually “if indicated”. Notified Body to review at the time of PSUR reviews or substantial change reviews | | | | |
| **Clinical Evaluation Report updates** | | Updated as per manufacturer’s clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Periodic Safety Update Report (Article 86)** | | Updated at least annually. Submitted to Noitified Body via EUDAMED for Notified Body review. | | | | |
| **Unannounced Audits** | | At least once every 5 years. | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 “Recert” indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Class III implantable devices




## Applicable audits, assessments and requirements

Class III implantable devices

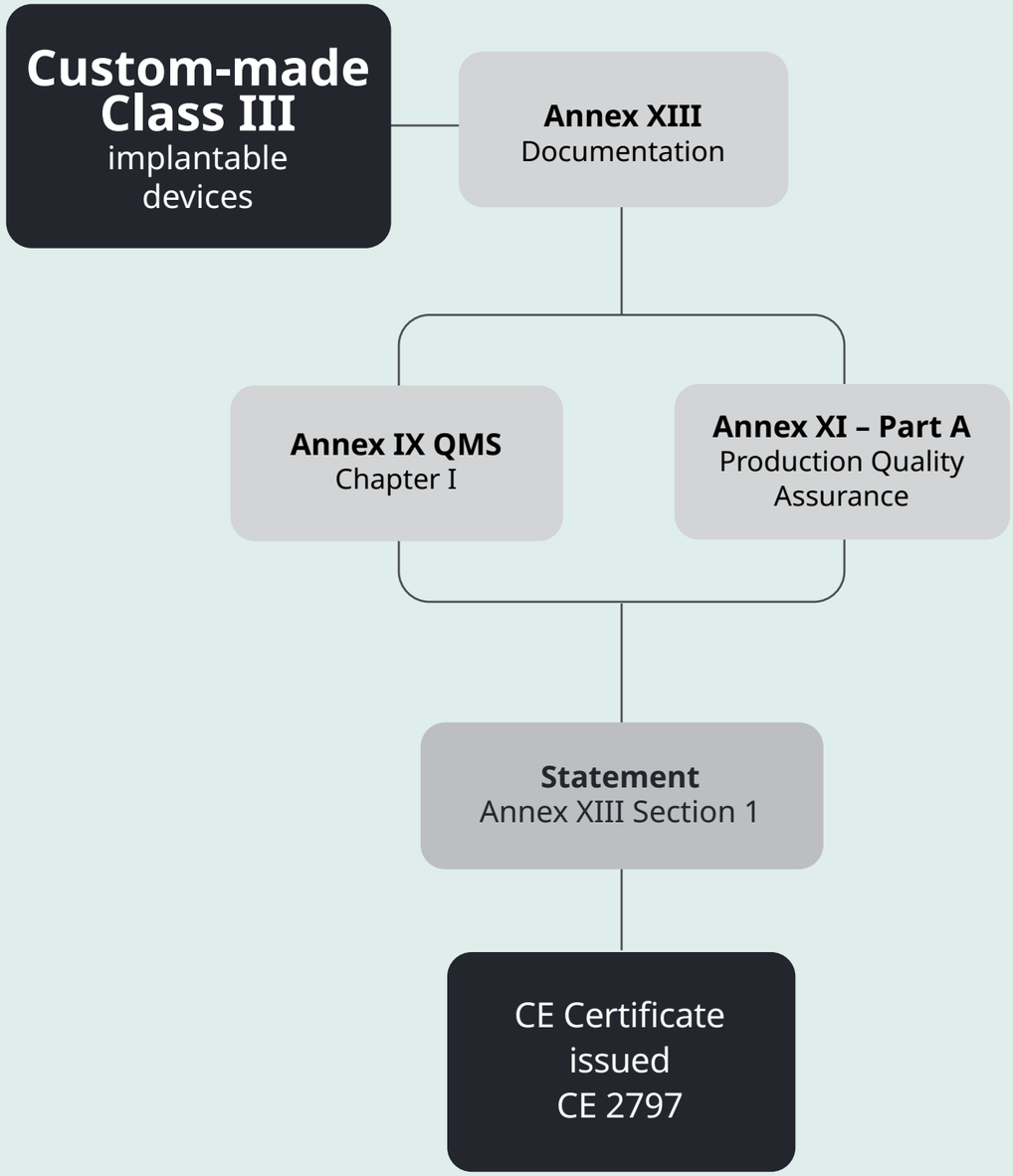
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

| **Class III** implantable devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Consultation Procedure (Article 54)** | Yes, but exemptions may apply as per Article 54.2 | May be required if any modifications to the device adversely affect the risk-benefit ratio. | | | | |
| **Consultations (Rule 14, Rule 18, Rule 21)** | If applicable | Modifications to the devices may need supplementary consultations; determined on a case-by-case basis taking into account the nature of the changes proposed. | | | | |
| **Summary of Safety and Clinical Performance (Article 32)** | Yes | Updated at least annually 'if indicated'. Notified Body to review at the time of PSUR assessments or substantial change reviews. | | | | |
| **Clinical Evaluation Report updates** | | Updated as per manufacturer's clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | | Updated at least annually. Notified Body review at the time of PSUR reviews or substantial change reviews. | | | | |
| **Periodic Safety Update Report (Article 86)** | | Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review. | | | | |
| **Unannounced Audits** | | At least once every 5 years. | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Custom-made Class III implantable devices




## Applicable audits, assessments and requirements
Custom-made Class III implantable devices

| Custom-made Class III implantable devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | No stand-alone Technical Documentation assessment. However, relevant parts of Technical Documentation may be audited as part of QMS/ Microbiology audits. | | | | | |
| **Clinical Evaluation Consultation Procedure (Article 54)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Consultations (Rule 14, Rule 18, Rule 21)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Clinical Performance (Article 32)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Clinical Evaluation Report updates** | | N/A | N/A | N/A | N/A | N/A |
| **Post Market Clinical Follow-Up Update Report (Article 61)** | | As per manufacturer's PMS, PMCF plans. Notified Body QMS audits to verify implementation of the plan. | | | | |
| **Periodic Safety Update Report (Article 86)** | | Updated at least annually. Not required to be submitted to EUDAMED for Notified Body review. Notified Body to verify updates at the time of surveillance QMS audits. | | | | |
| **Unannounced Audits** | | At least once every 5 years. | | | | |

* If sterile or re-usable surgical instruments.

** The Y3 "Recert" indicated in the table refers to the recertification audit related to EN ISO 13485:2016 certificate cycle which is typically three years. Most manufacturers with MDR/IVDR certificates also hold EN ISO 13485 certificate.

# Custom-made devices

Excluding custom-made Class III implantable devices

**Custom-made**

**Annex XIII**
Documentation

**Collect PMS, PMCF data** as per Part B of Annex XIV

**Statement**
Annex XIII Section 1

**Note:** No Notified Body involvement except for custom-made Class III implantable devices

# Class I devices

Excluding Class Is, Ir, Im devices

**Class I**

**Annex II and III**
Technical Documentation

Declaration of conformity **(Annex IV)**

CE marking (Annex V)

**Note:** No Notified Body involvement

# How BSI supports your Medical Device launch

### Readiness

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We support you through the application and certification process.

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We offer a wide range of regulatory and quality management programs that work cohesively for international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

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### BSI Transfer

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### Additional Services

- **Access to more than 34,000 standards** and related products, as well as online guidance documents.
- **Expert training** online or face-to-face through our public training courses.
- **Regulatory updates and newsletters** focusing on industry changes, helping you to plan for the future.
- **Webinars** delivered by our experts on regulatory issues.
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## Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

**Request a quote**

# CE Excellence

BSI CE-Exellence Programs are designed to support manufacturers seeking timely and effective market access. Our services combine efficiency with the integrity, independence, and thoroughness you expect from BSI.

### CE-Standard

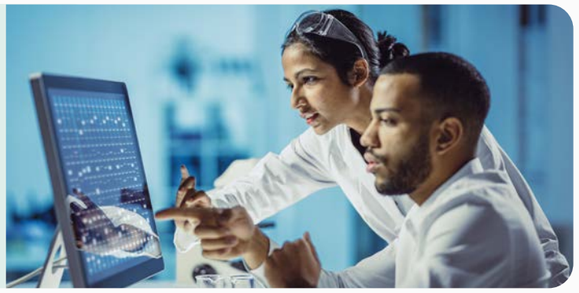
The Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert via phone and email as required.

### CE-Dedicated

The Dedicated review service allows a technical document review to be booked in advance. It is conducted remotely with your BSI Product Expert, who uses your allocated time, to conduct a focused review of your technical documentation. This allows you to interact with your BSI Product Expert, and provide information during the review. By improving the efficiency of the process, this service provides predictability in your review planning.

For more information on our Excellence services

Call BSI on +44 345 080 9000, visit our **CE marking webpage** and read our **Excellence Pathways brochure**



**Note:** Our services do not guarantee an EU/UKCA certificate will be issued or that it will be issued within a certain number of working days but they are based on completeing the review process with either a positive or negative recommendation. CE and UKCA Dedicated Review service is not available for devices utilizing animal issue derivatives or medicinal substances.

# Your partner in progress


**BSI Assurance UK Ltd (0086)**

Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

**BSI Group The Netherlands B.V. (2797)**

Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

**BSI Group America Inc.**

12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find our services at **bsigroup.com/medical**

Email us at **medicaldevices@bsigroup.com**

Find us on **LinkedIn**