# IVDR Conformity Assessment Routes

## Notified Body Assessments

bsi.

By Royal Charter

bsi

# Contents



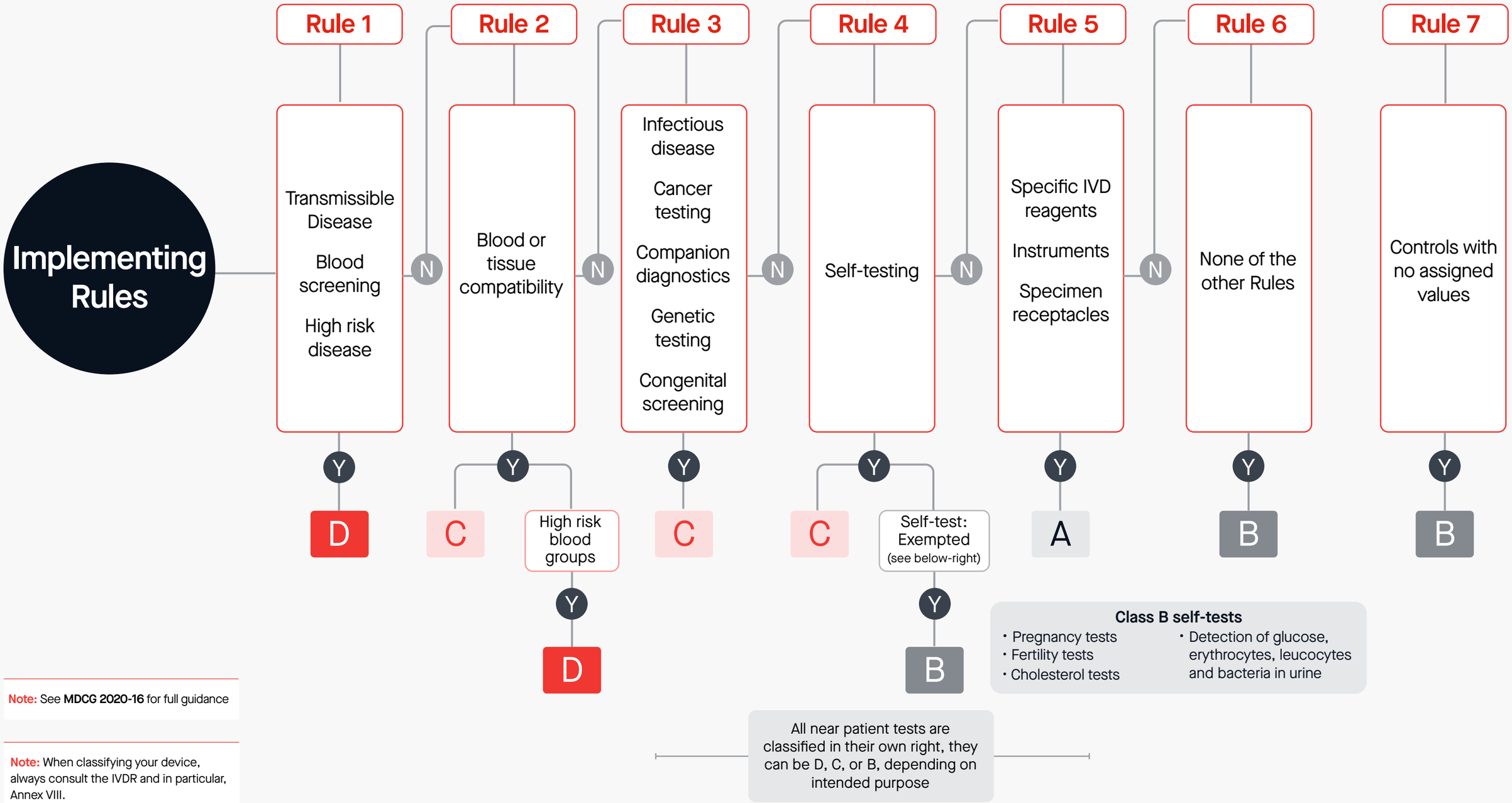
**DISCLAIMER:**

- The information presented in this brochure is based on our current understanding of the IVDR requirements at the time of publishing and is subject to change
- The tables do not cover assessments under the conformity route of Annex XI (Production Quality Assurance). BSI is not designated to Annex X (Type Examination)
- The Competent Authority may ask for verification testing by the EU Reference Laboratory for devices other than Class D

Hover over each letter to see the examples

# IVD Classification Rules under the IVDR

All devices need to be divided into classes, A, B, C, or D, taking into account their their intended purpose and inherent risks. The Classification map below allows you to allocate your device correctly. Application of the Classification Rules shall be governed by intended purpose, novelty, complexity and inherent risk of the devices.




**Note:** See **MDCG 2020-16** for full guidance

**Note:** When classifying your device, always consult the IVDR and in particular, Annex VIII.

# Useful information

### Notified Body (NB)

The role of BSI as a Notified Body is to conduct a conformity assessment under the IVDR. This usually requires an audit of the manufacturer's quality management system and, depending on the particular classification of the device, a review of the relevant Technical Documentation in support of the safety and performance claims for the device. The Technical Documentation is assessed against the General Safety and Performance Requirements (GSPR) within the IVDR.

### CE 2797

Throughout this guide, our Notified Body is referenced using its assigned Notified Body number: BSI The Netherlands (2797).

### Common Specifications

The European Commission provides Common Specifications to the IVDR as a means of complying with the legal obligations applicable to a device, process or system, such as the General Safety and Performance Requirements (GSPRs), the requirements for performance studies and performance evaluation, and/or post-market surveillance.

### CA and EMA

In the case of companion diagnostics, the Competent Authority (CA) or the European Medicines Agency (EMA) will be consulted regarding the associated medicinal product.

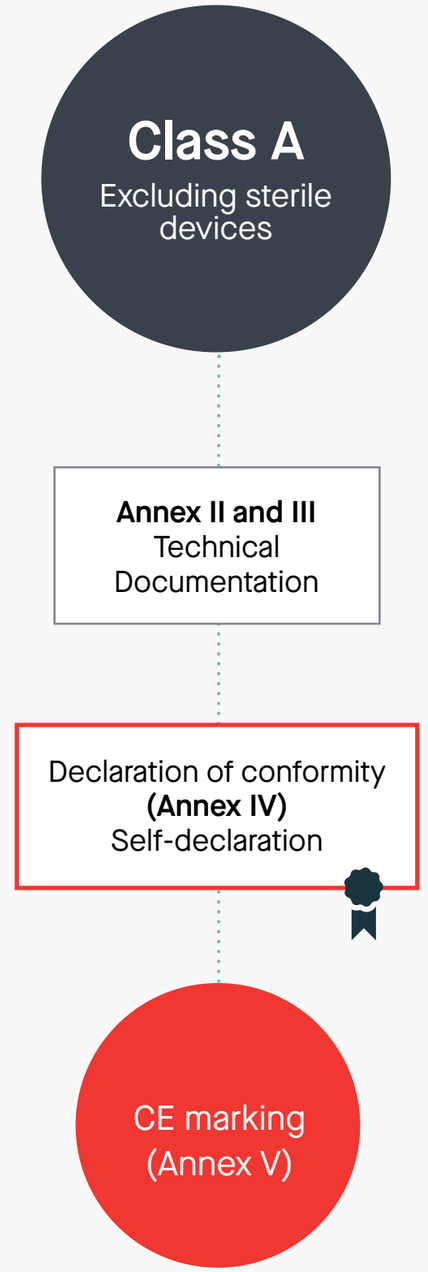
### EU Reference Laboratory

These have been introduced under the IVDR and are laboratories designated by the European Commission to support with the assessment of Class D IVD devices. An EU Reference Laboratory is responsible for verifying the performance of Class D IVD devices and the ongoing verification of manufactured devices.

The Competent Authority may ask for verification testing by the EU Reference Laboratory for devices other than Class D.

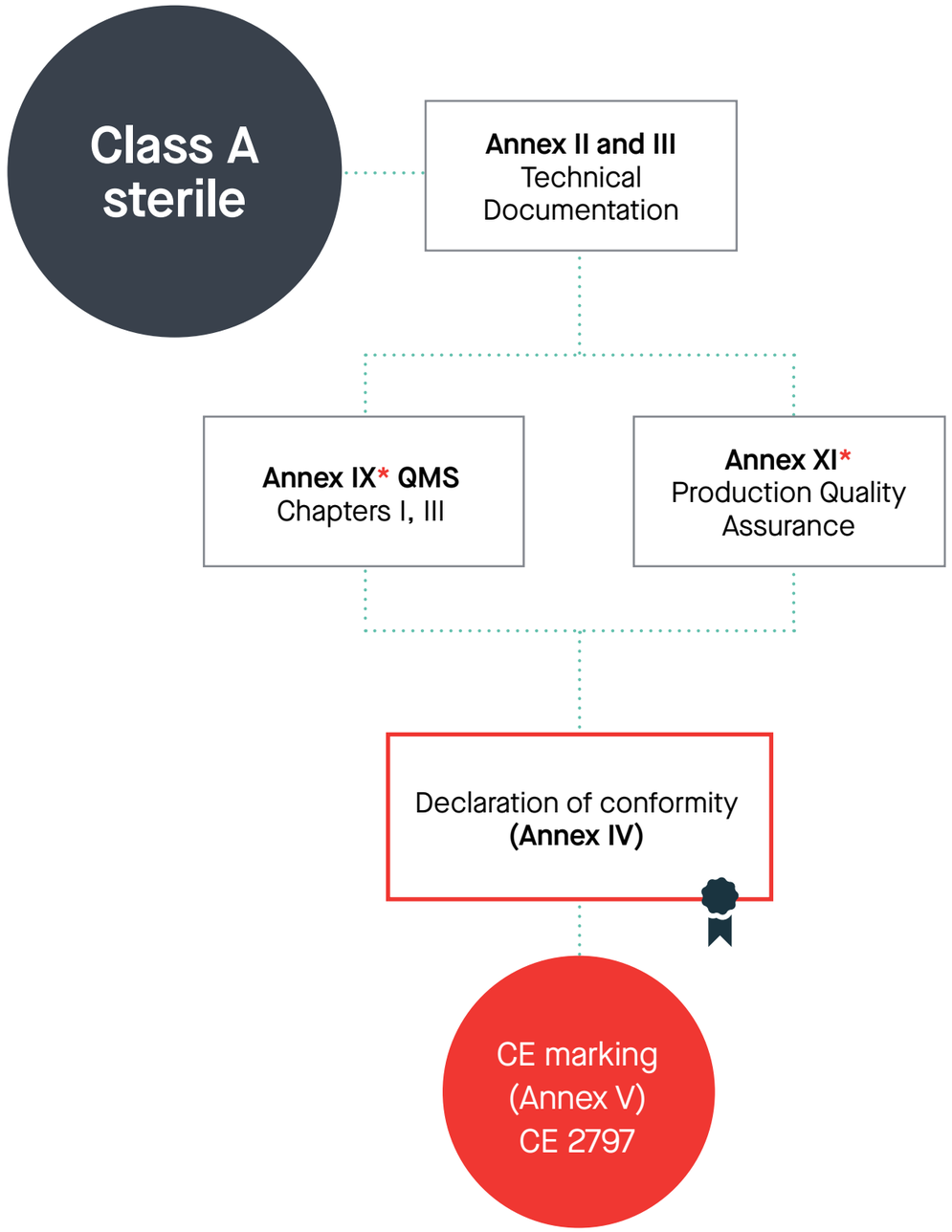


# Class A devices




**Note:** No Notified Body involvement

# Class A sterile devices




* Limited to sterility aspacts



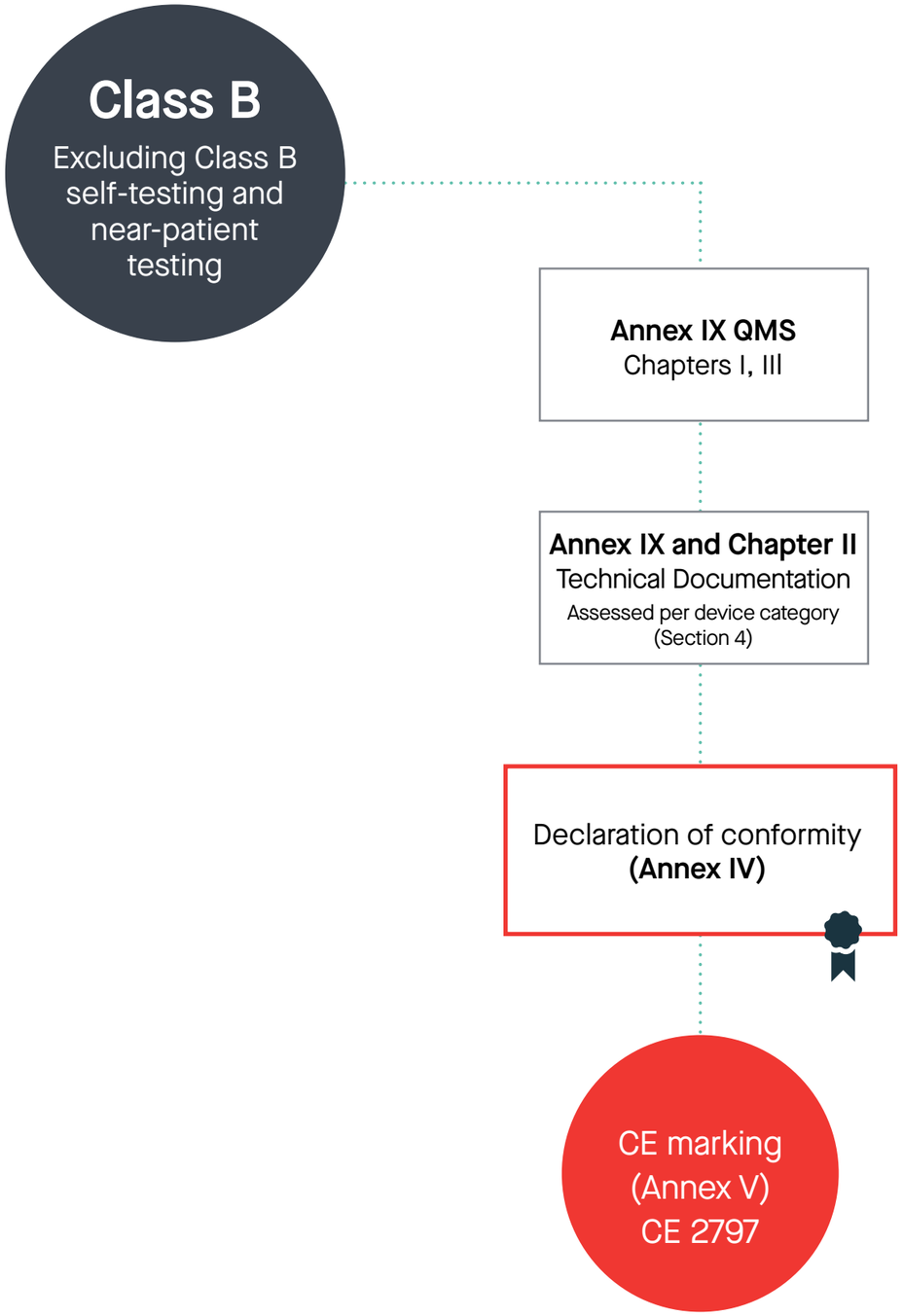
## Applicable audits, assessments and requirements

Class A sterile devices

| **Class A** Sterile 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** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (Article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Not required for NB assessment | | | | | |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Not required for NB assessment | | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | Updated when necessary and made available to the Notified Body upon request | | | | | |
| **Periodic Safety Update Report (PSUR) (Article 81)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Unannounced Audits** | At least once every 5 years | | | | | |

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class B
## Excluding self-testing and NPT devices





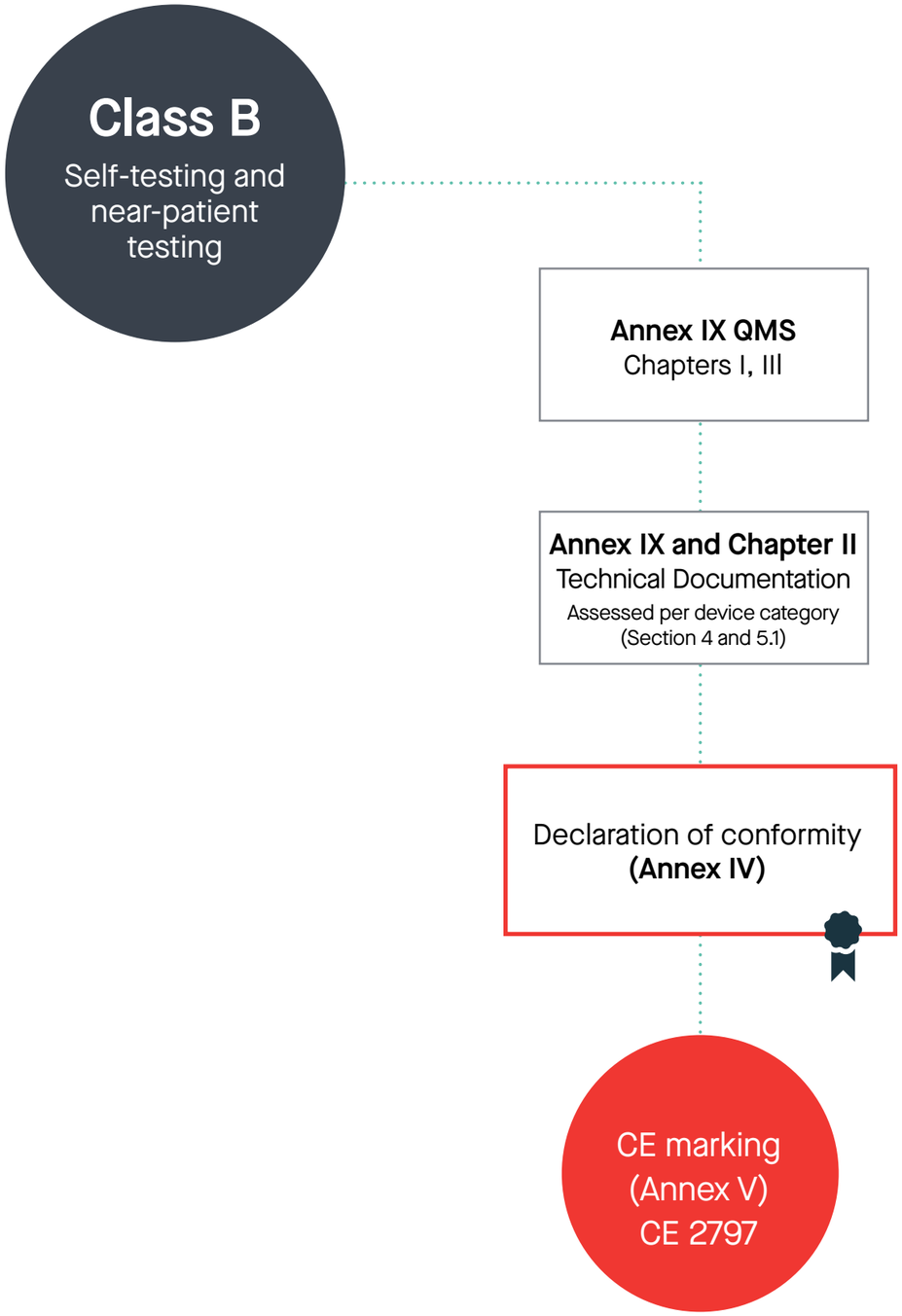

## Applicable audits, assessments and requirements
Class B excluding self-testing and NPT devices

| **Class B** Excluding self-testing and NPT 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 device category | As per the Technical Documentation Sampling Plan. A Technical Documentation surveillance audit is required every year whilst there are still devices left to be reviewed under the certificate scope. | | | | |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated as per manufacturer's Performance Evaluation Plan. Notified Body to review as per Technical Documentation Sampling Plan | | | | | |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review as per Technical Documentation Sampling Plan. Implementation of the PMPF plan will be verified during annual surveillance visits | | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | Updated when necessary and provided to the CA and/or Notified Body upon request | | | | | |
| **Periodic Safety Update Report (PSUR)(Article 81)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Unannounced Audits** | At least once every 5 years | | | | | |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class B self-testing and NPT devices






## Applicable audits, assessments and requirements

Class B, self-testing and NPT devices

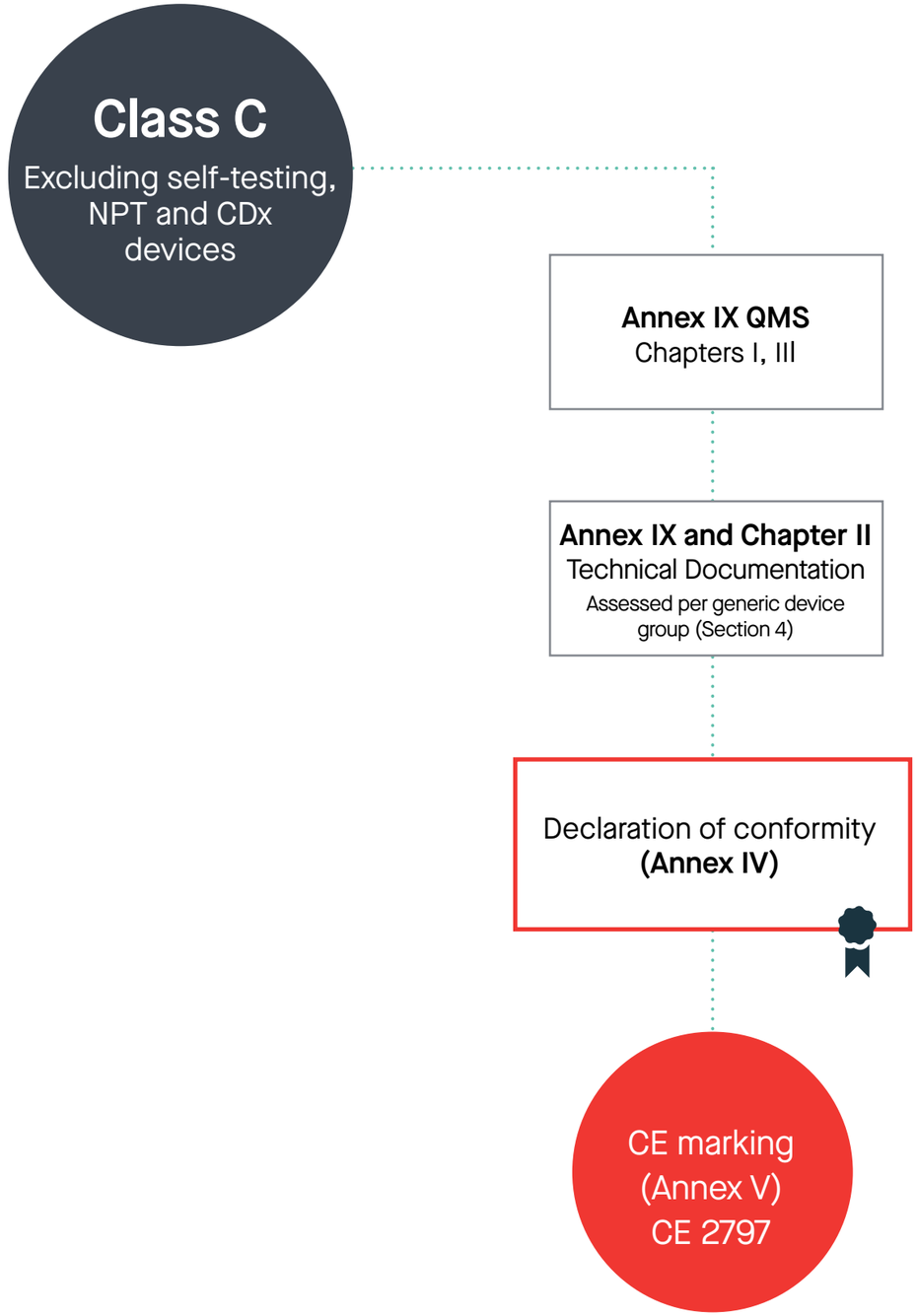
| Class B<br>Self-testing and NPT devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated as per Manufacturer's Performance Evaluation Plan; Notified Body to review at the time of substantial change reviews | | | | | |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of substantial change reviews | | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | Updated when necessary and provided to the CA upon request. Notified Body to review at time of substantial change reviews | | | | | |
| **Periodic Safety Update Report (PSUR) (Article 81)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Unannounced Audits** | At least once every 5 years | | | | | |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class C devices

## Excluding self-testing, NPT and CDx devices






## Applicable audits, assessments and requirements

Class C excluding self-testing, NPT and CDx devices

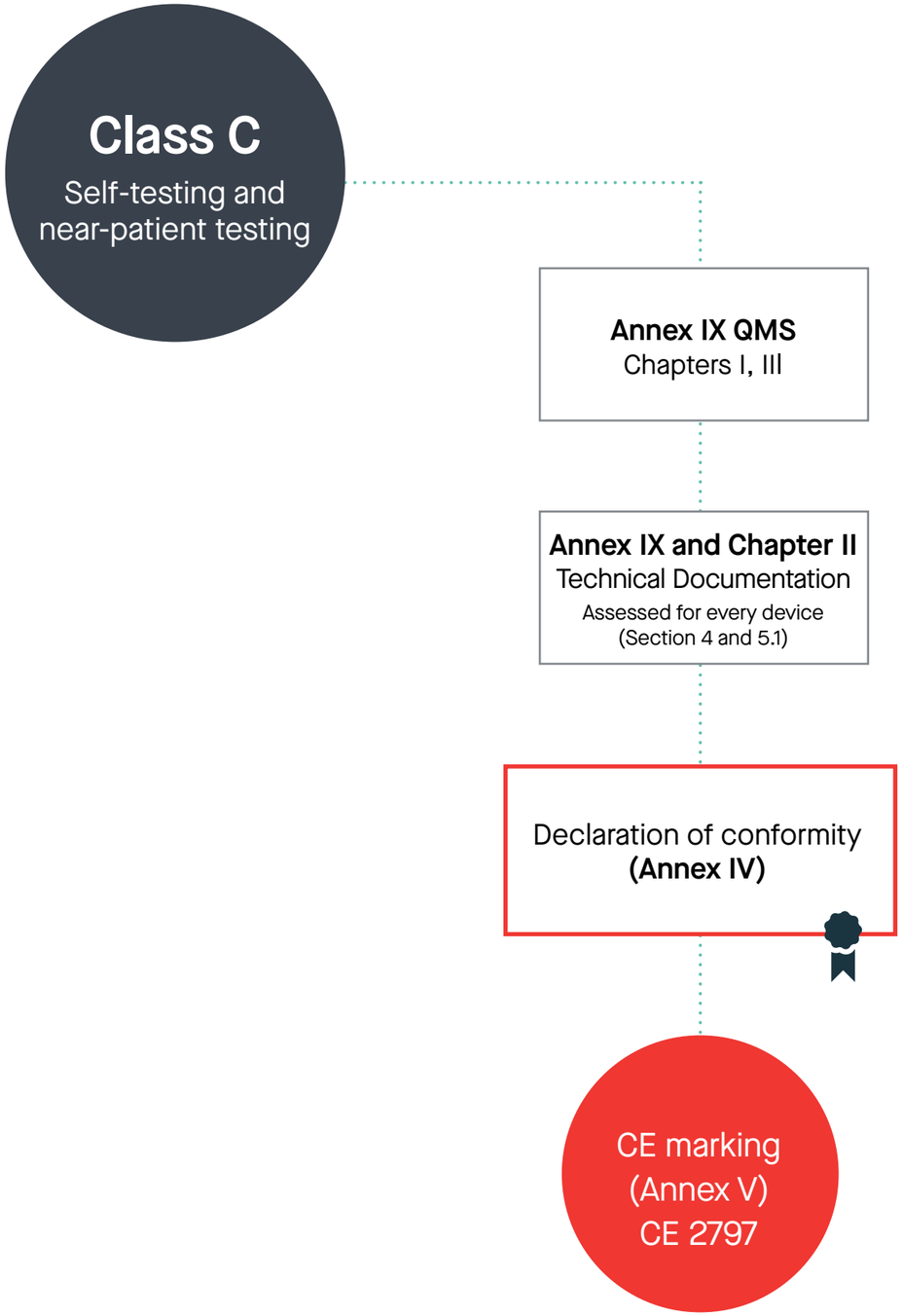
| **Class C** Excluding self-testing, NPT and CDx devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Sample per generic device group | As per the Technical Documentation Sampling Plan. A Technical Documentation surveillance audit is required every year whilst there are still devices left to be reviewed under the certificate scope | | | | |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |

| | |
|---|---|
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated at least annually. Notified Body to review as per Technical Documentation Sampling Plan |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review as per Technical Documentation Sampling Plan. Notified Body QMS audits to verify implementation of the plan by sampling complaints, vigilance information etc. |
| **Post Market Surveillance (PMS) Report (Article 80)** | Post-market surveillance will be captured in the Periodic Safety Update Report |
| **Periodic Safety Update Report (PSUR) (Article 81)** | PSUR update required at least annually. The PSUR should be available to the Notified Body upon request |
| **Unannounced Audits** | At least once every 5 years |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class C self-testing and NPT devices






## Applicable audits, assessments and requirements

Class C Self-testing and NPT devices

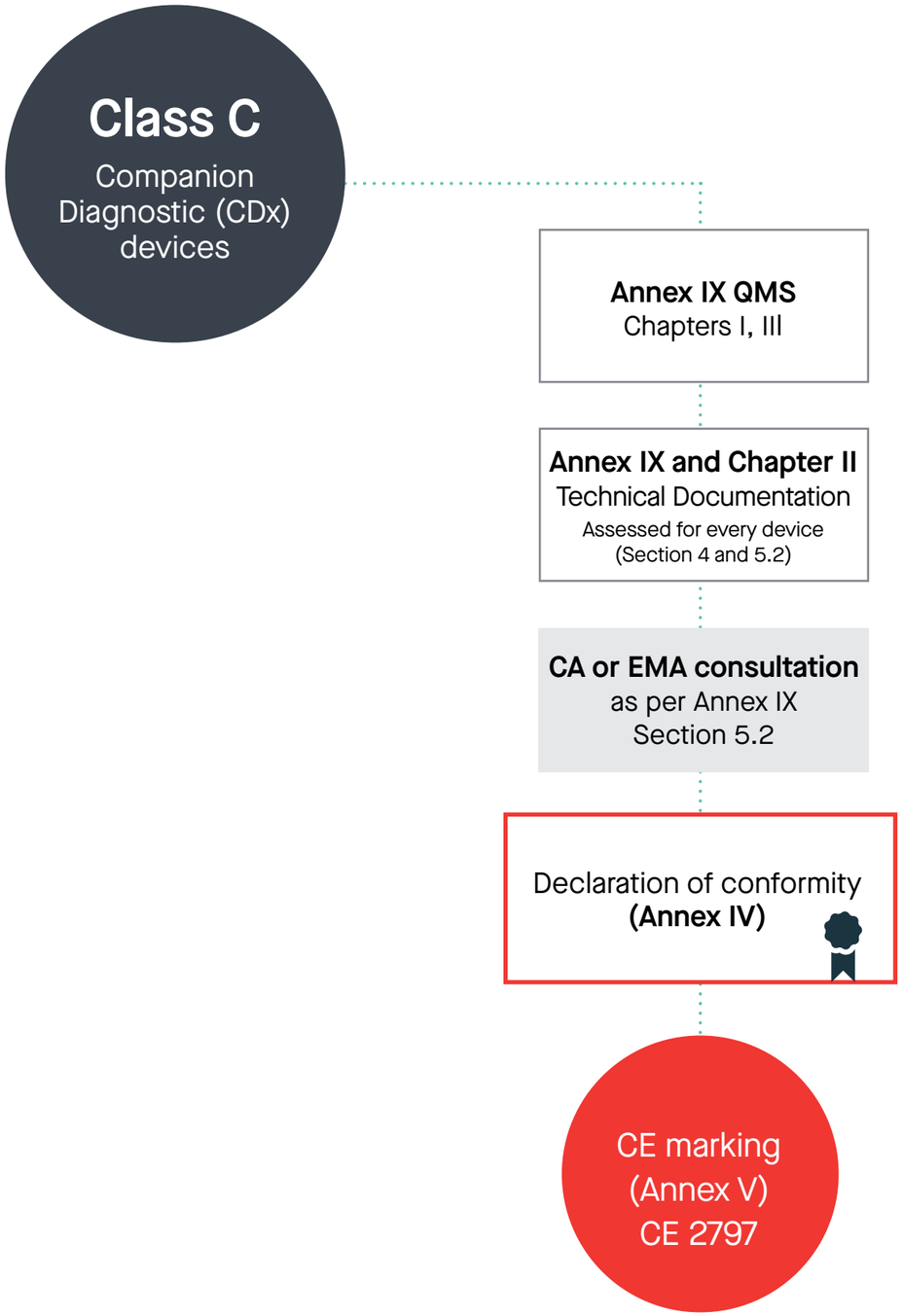
| **Class C** Self-testing, and NPT devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |

| | |
|---|---|
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| U**Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| **Post Market Surveillance (PMS) Report (Article 80)** | Post-market surveillance will be captured in the Periodic Safety Update Report |
| **Periodic Safety Update Report (PSUR) (Article 81)** | PSUR update required at least annually. The PSUR should be available to the Notified Body upon request |
| **Unannounced Audits** | At least once every 5 years |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class C Companion Diagnostic (CDx) devices






## Applicable audits, assessments and requirements

Class C Companion Diagnostic (CDx) devices

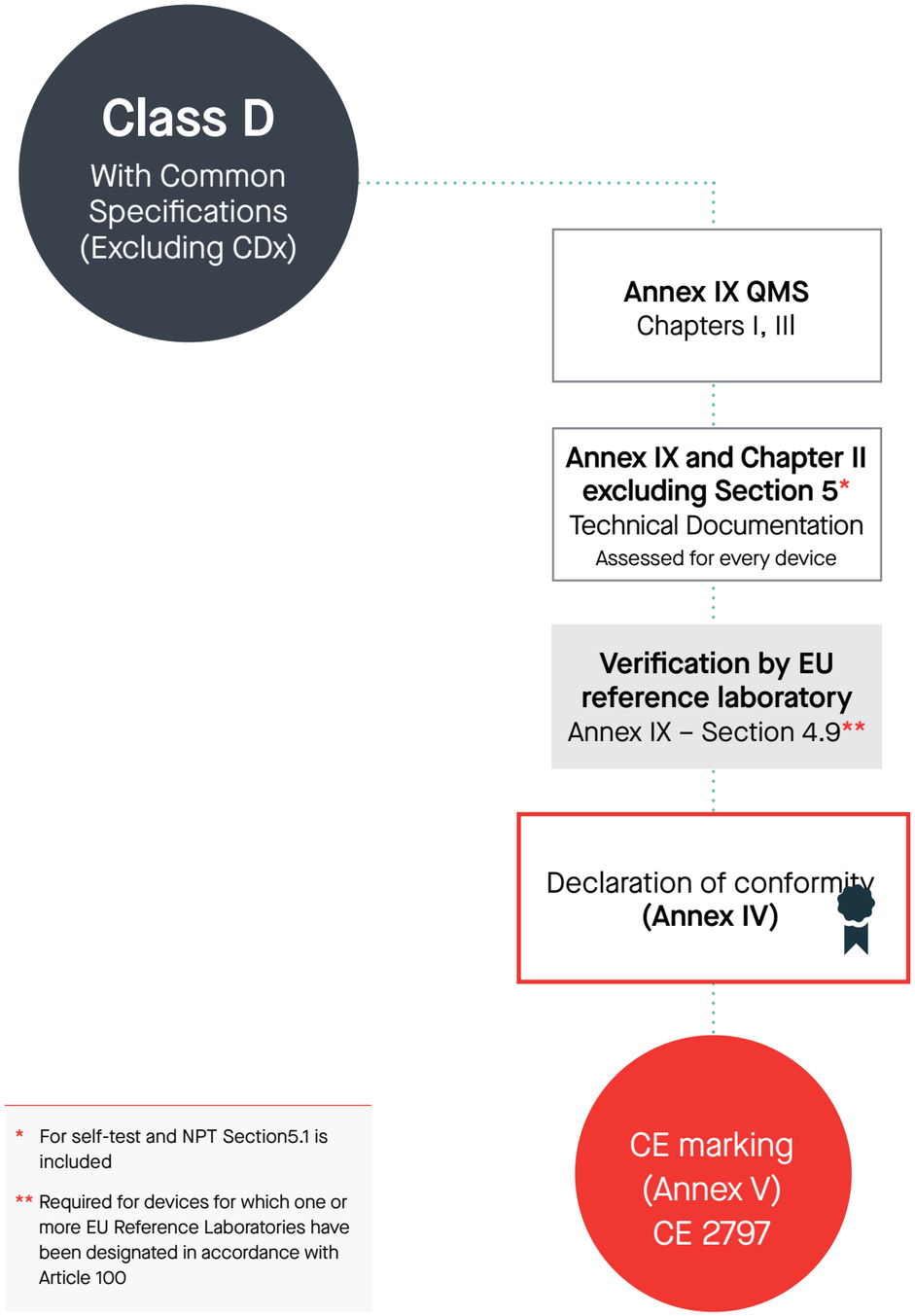
| **Class C** Companion Diagnostic (CDx) devices | Initial Conformity Assessment | Surveillance | | | | |
|---|---|---|---|---|---|---|
| | | Y1 | Y2 | Y3 | Y4 | Y5 |
| **QMS Audits** | Yes | Yes | Yes | Recert** | Yes | Yes |
| **Microbiology Audits** | Yes* | N/A | N/A | Yes* | N/A | N/A |
| **Technical Documentation Assessment** | Review for every device | N/A | N/A | N/A | N/A | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | Yes | Modifications to the devices may need supplementary consultations (determined on a case-by-case basis taking into account the nature of the changes proposed) | | | | |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews | | | | |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of PSUR reviews or substantial change reviews | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | | Post-market surveillance will be captured in the Periodic Safety Update Report | | | | |
| **Periodic Safety Update Report (PSUR) (Article 81)** | | PSUR update required at least annually. The PSUR should be available to the Notified Body upon request | | | | |
| **Unannounced Audits** | | At least once every 5 years | | | | |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class D with Common Specifications

(Excluding CDx)




* For self-test and NPT Section5.1 is included

** Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100



## Applicable audits, assessments and requirements

Class D with Common Specifications (Excluding CDx)

| **Class D** with Common Specification (Excluding CDx) | 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 | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | Yes | Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed) | | | | |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |

| | |
|---|---|
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| **Post Market Surveillance (PMS) Report (Article 80)** | Post-market surveillance will be captured in the Periodic Safety Update Report |
| **Periodic Safety Update Report (PSUR) (Article 81)** | PSUR update required at least annually. Submitted to the Notified Body via EUDAMED for Notified Body review |
| **Unannounced Audits** | At least once every 5 years |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class D with no Common Specifications
(Excluding CDx)


* For self-test and NPT Section 5.1 is included

** Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100

*** Where no common specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type.



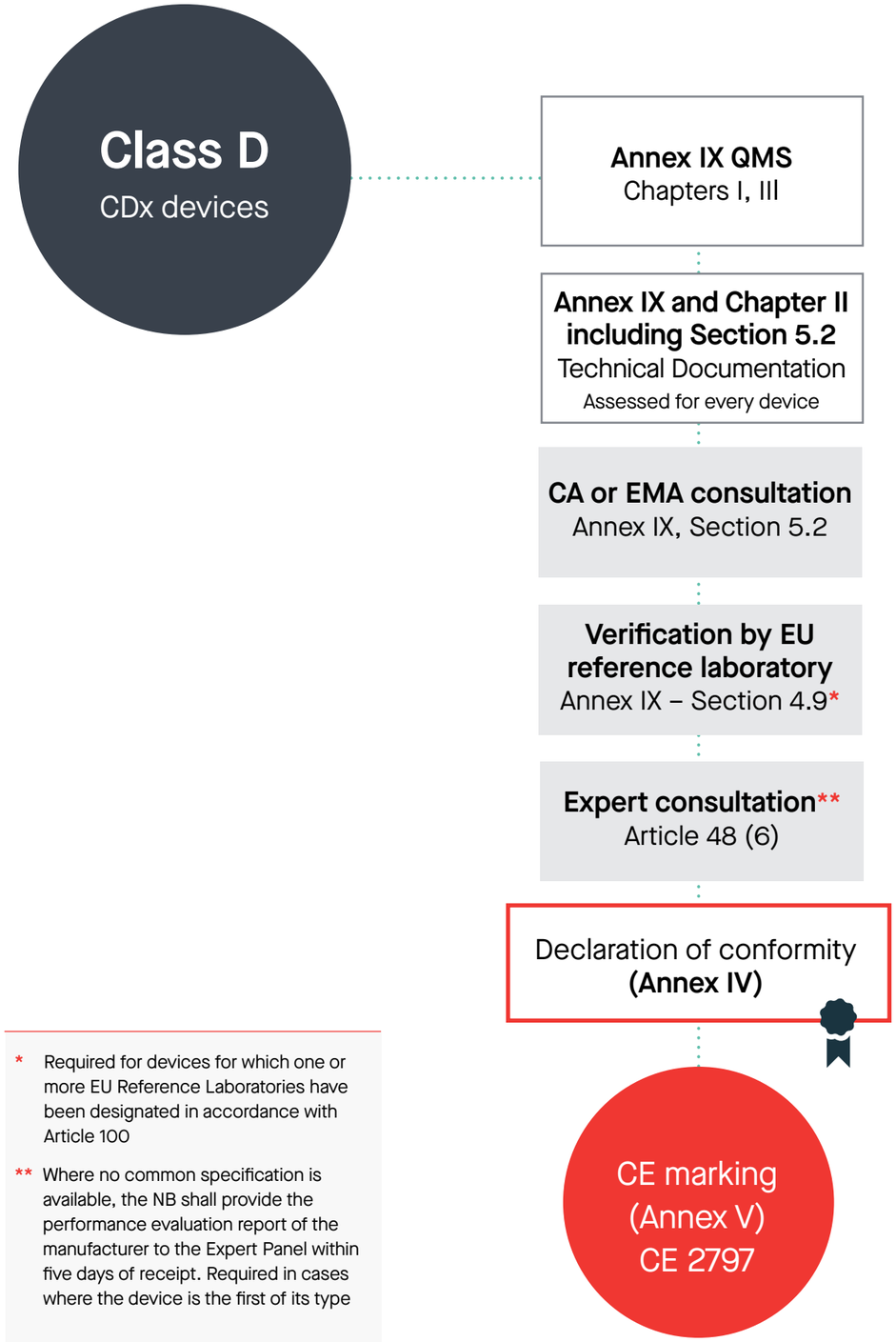
## Applicable audits, assessments and requirements
Class D with no Common Specifications (Excluding CDx)

| **Class D** with no Common Specifications (Excluding CDx) | 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 | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Experts consultations (article 48(6))** | Yes if the device is the first of its type | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | Yes | Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed) | | | | |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | | Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews | | | | |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B)** | | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of PSUR reviews or substantial change reviews | | | | |
| **Post Market Surveillance (PMS) Report (Article 80)** | | Post-market surveillance will be captured in the Periodic Safety Update Report | | | | |
| **Periodic Safety Update Report (PSUR) (Article 81)** | | PSUR update required at least annually. Submitted to the Notified Body via EUDAMED for Notified Body review | | | | |
| **Unannounced Audits** | | At least once every 5 years | | | | |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3

# Class D CDx devices




* Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100

** Where no common specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type



## Applicable audits, assessments and requirements

Class D CDx devices

| Class D CDx 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 | Recert |
| **Competent Authority or EMA consultation (Annex IX, Section 5.2)** | Yes | Modifications to the devices may need supplementary consultations (determined on a case-by-case basis taking into account the nature of the changes proposed) | | | | |
| **Experts consultations (article 48(6))** | Yes, if no CS and the deviceis the first of its type | N/A | N/A | N/A | N/A | N/A |
| **Verification by EU reference laboratory (Annex IX, section 4.9)** | Yes | Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed) | | | | |
| **Summary of Safety and Performance (Article 29)** | Yes | Updated as soon as possible, where necessary | | | | |

| | |
|---|---|
| **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)** | Updated at least annually. Notified Body will provide it to the expert panel as needed. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| **Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B** | Updated as per manufacturer's PMS, PMPF plans. Notified Body to review at the time of PSUR reviews or substantial change reviews |
| **Post Market Surveillance (PMS) Report (Article 80)** | Post-market surveillance will be captured in the Periodic Safety Update Report |
| **Periodic Safety Update Report (PSUR) (Article 81)** | PSUR update required at least annually. Submitted to the Notified Body via EUDAMED for Notified Body review |
| **Unannounced Audits** | At least once every 5 years |

* If sterile

** QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.

# How BSI supports your Medical Devices 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.

### Worldwide Access

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.

We are a recognized certification body in Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP auditing organization for all participating regulatory authorities.

### BSI Transfer

We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

### 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
- Comprehensive white papers providing the latest insights on key industry topics

Our website offers useful resources. You can find white papers, guidance documents and webinars.

**To find out more, visit bsigroup.com/medical**



# 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 CE-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 CE-Dedicated review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Product Expert, who uses the time allocated to your company to conduct a focused review of your tecnical documentation. This allows you to interact with your BSI product expert, providing them information during the review. The CE-Dedicated service improves the efficiency of the process, and provides predicability in your planning of the review.

For more information on our CE-Excellence services

**call BSI on 1-800-862-4977 or visit our CE marking webpage**

**Note:** Our services do not guarantee a CE Marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation. CE-Dedicated is not available for devices utilizing animal tissue, blood derivatives or medicinal substances.

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