IVDR Conformity Assessment Routes Guide

IVDR Conformity Assessment Routes

Notified Body Assessments

bsi.

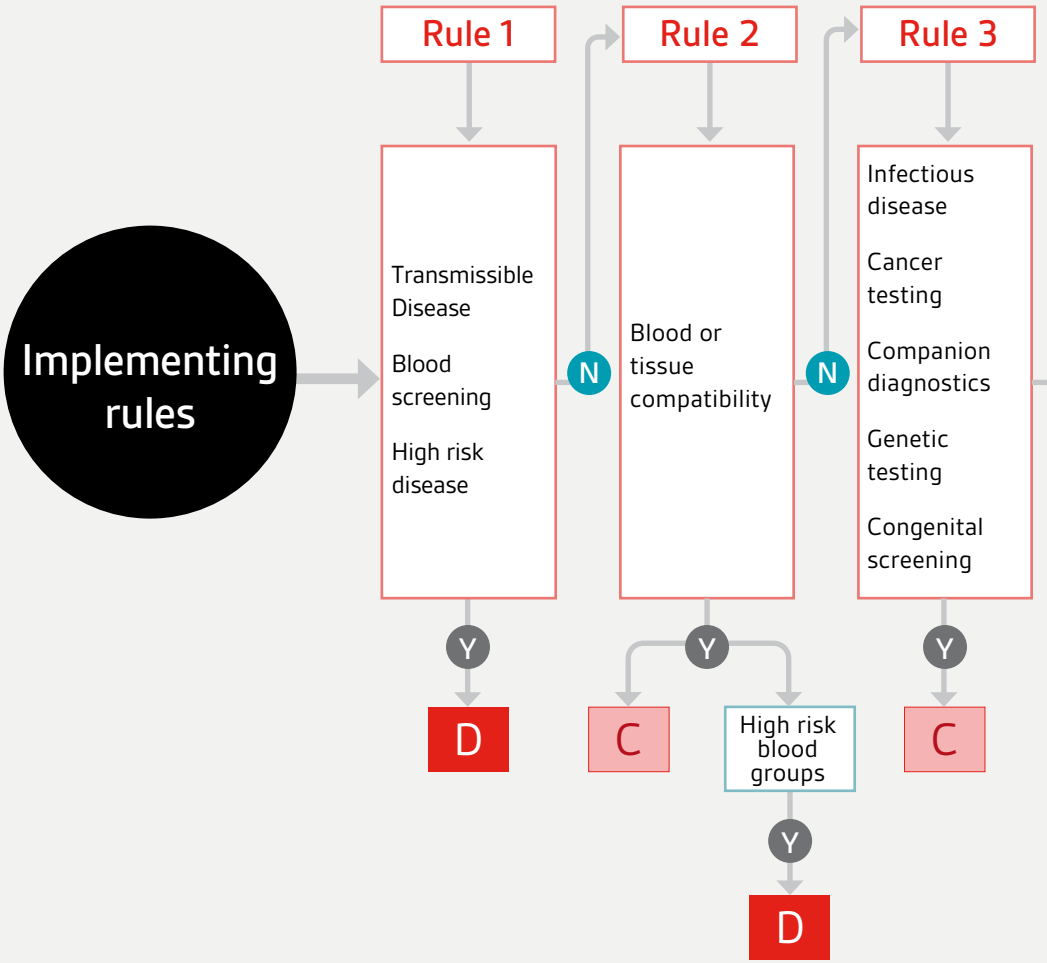
Inspiring trust for a more resilient world.

Contents

Disclaimers:

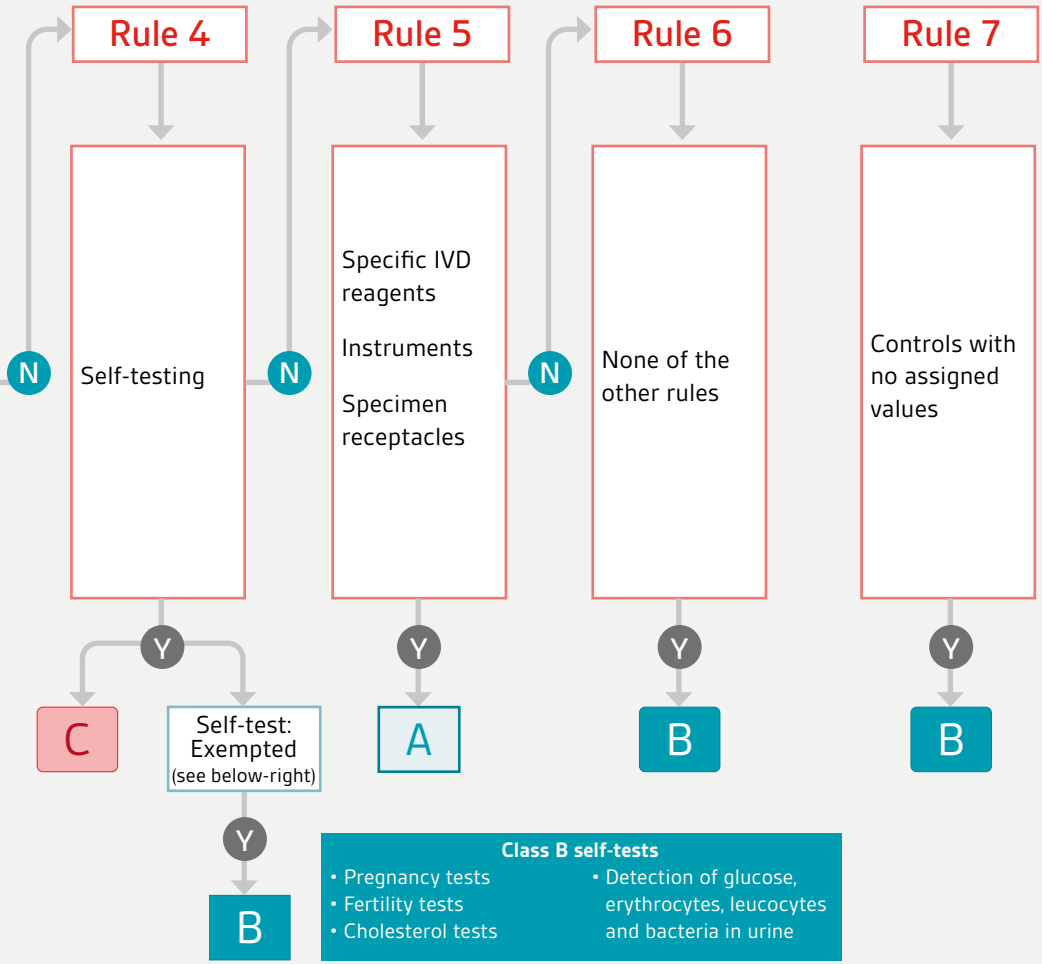
- The information presented in this brochure is based on our current understanding of the IVDR requirements at the time of publishing and is subject to change
- The tables do not cover assessments under the conformity route of Annex XI (Production Quality Assurance). BSI is not designated to Annex X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

Illustration of the Classification rules as per



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

Annex VIII of the IVDR



All near patient tests are classified in their own right, they can be D, C, or B, depending on intended purpose.

Useful definitions

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.

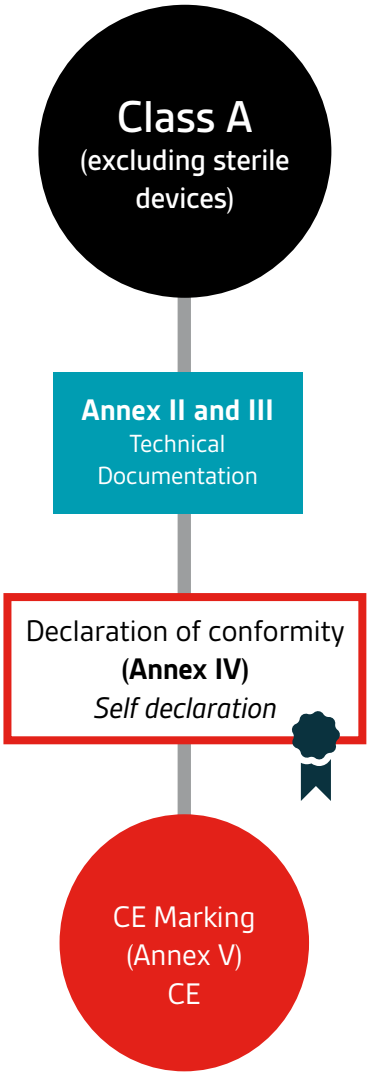
The Competent Authority may ask for verification testing by the EU Reference Laboratory for devices other than Class D.

Notified Body (NB)

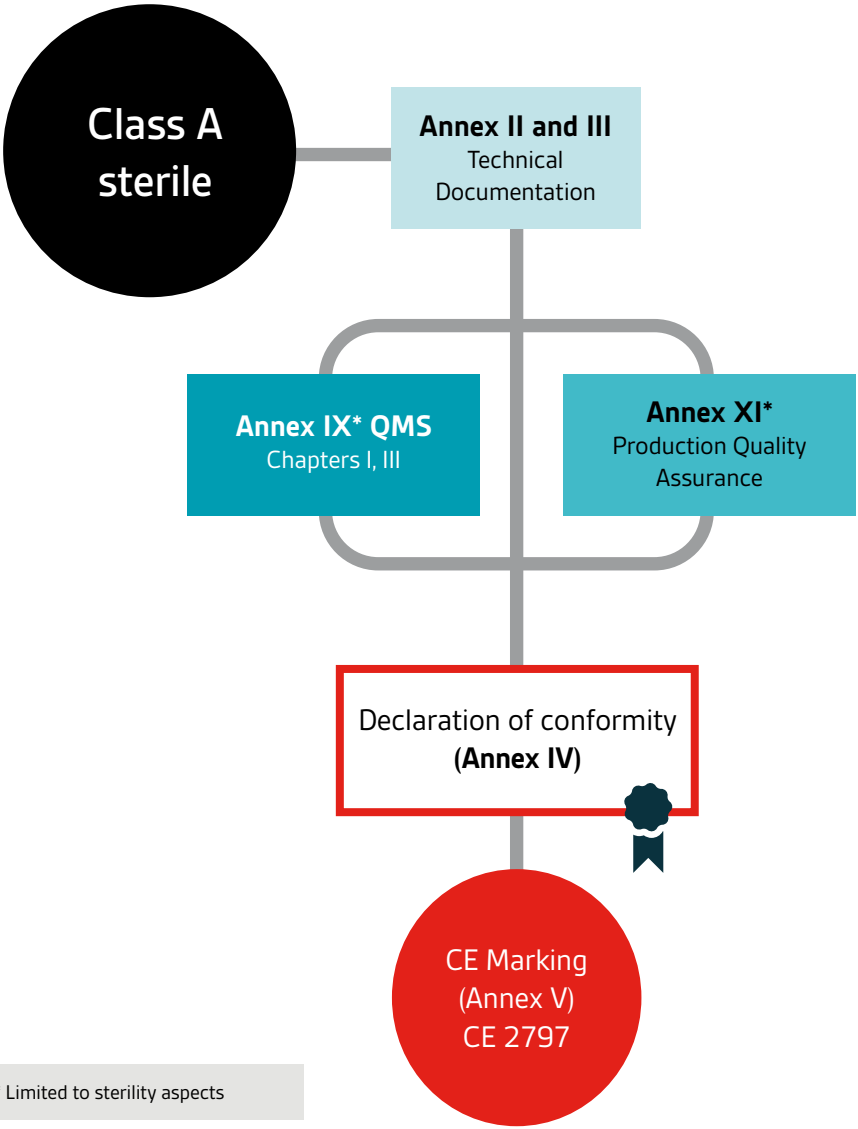
The role of BSI as a Notified Body is to conduct a conformity assessment under the IVDR. This usually requires an audit of the manufacturer's quality management system and, depending on the particular classification of the device, a review of the relevant Technical Documentation in support of the safety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

Class A devices

Note: No Notified Body involvement



Class A sterile devices



* Limited to sterility aspects

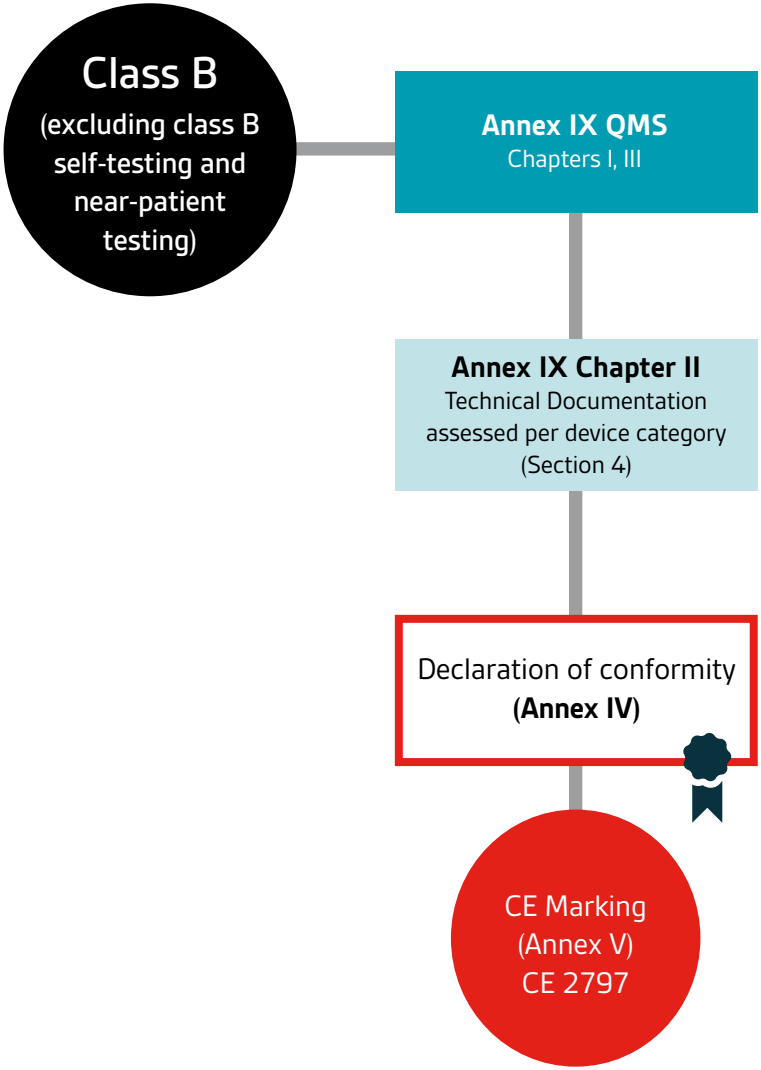
Class A sterile devices

Class A sterile devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes	N/A	Yes	N/A	Yes	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 NB upon request.				
Periodic Safety Update Report (PSUR) (Article 81)		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 devices

(excluding self-testing and near-patient testing (NPT) devices)

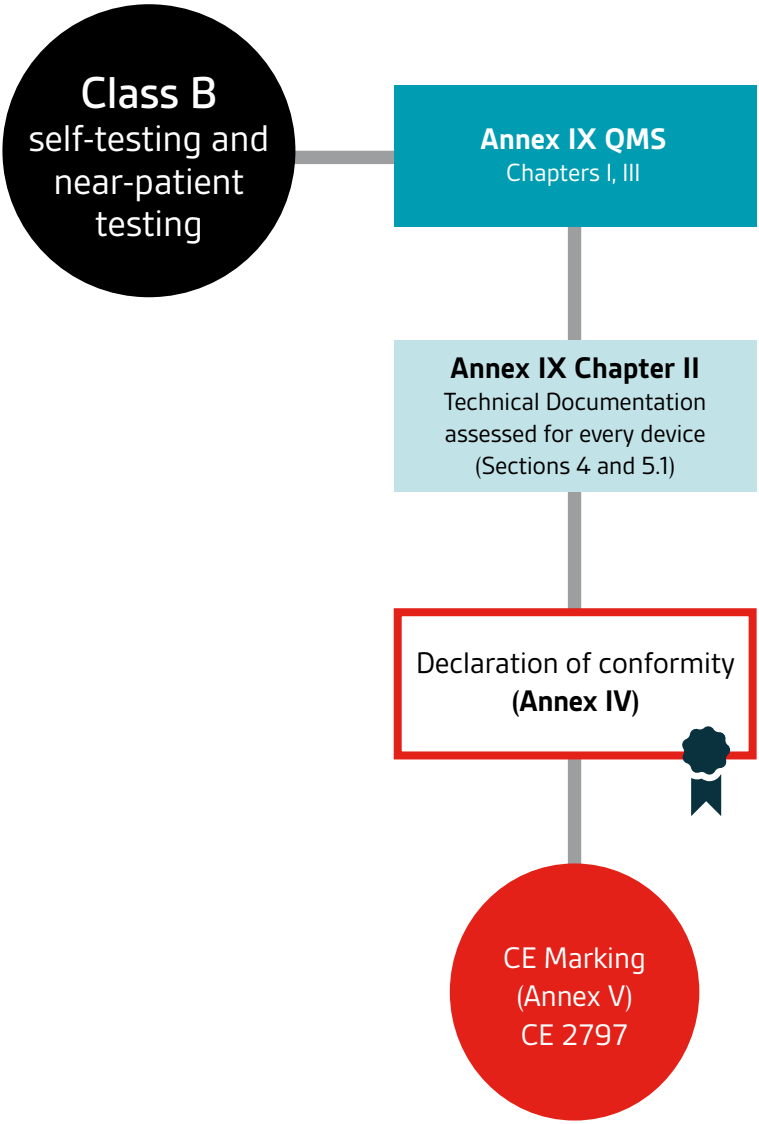


Class B devices (excluding self-testing and NPT devices)

Class B devices (excluding self-testing and NPT devices)	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	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; NB 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; NB 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 NB upon request				
Periodic Safety Update Report (PSUR) (Article 81)		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 self-testing and NPT devices



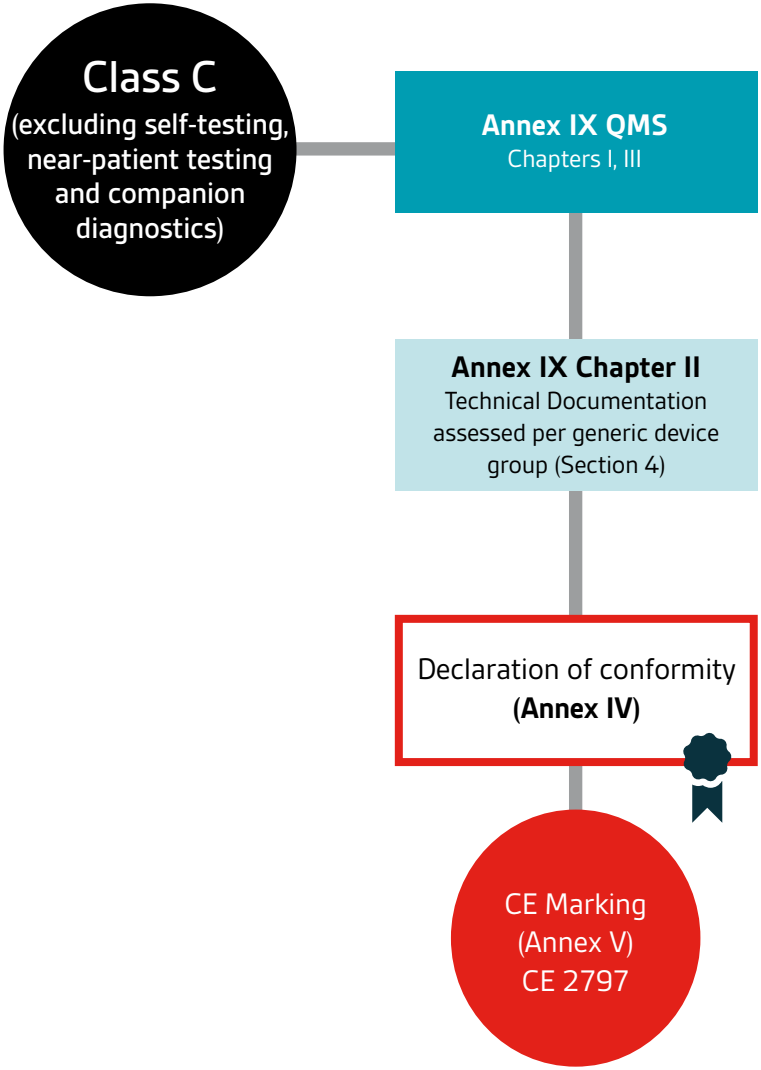
Class B devices self-testing and NPT devices

Class B devices self-testing and NPT devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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; NB 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; NB 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. NB 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
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 C devices

(excluding self-testing, NPT and companion diagnostics (CDx))

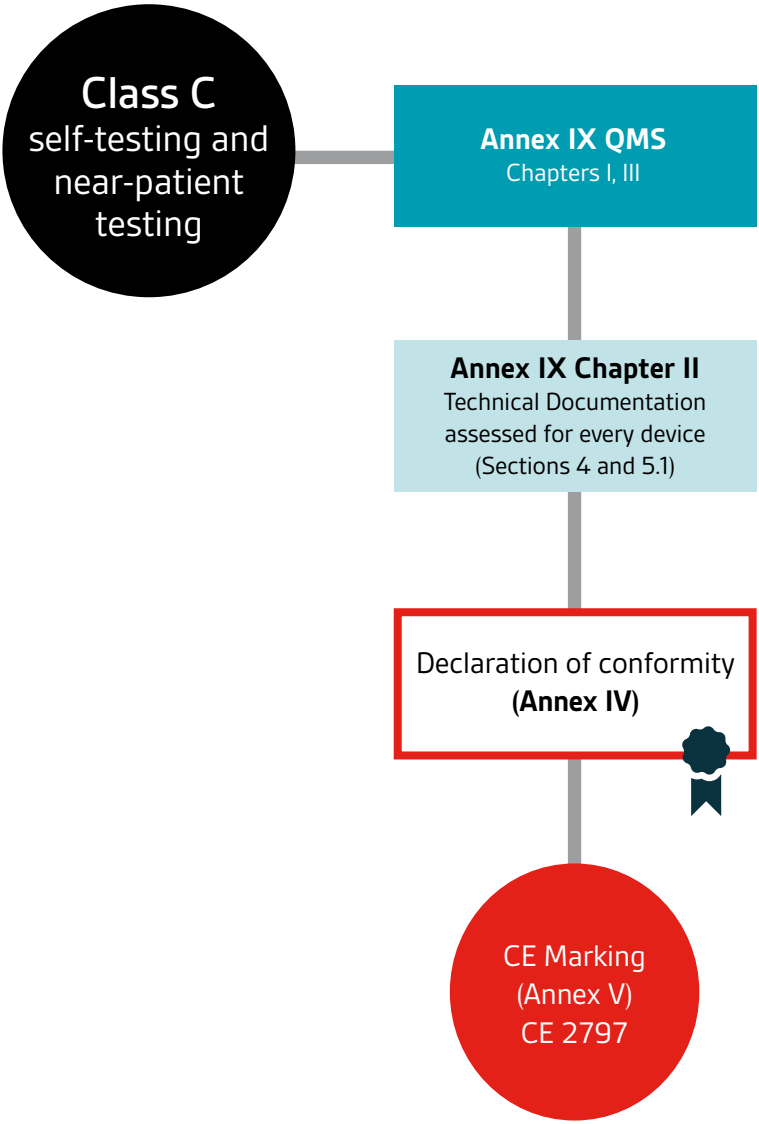


Class C devices (excluding self-testing, NPT and companion diagnostics (CDx))

Class C devices (excluding self-testing, NPT and CDx devices)	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	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; NB 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; NB to review as per Technical Documentation Sampling Plan. NB 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 NB upon request				
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 C self-testing and NPT devices

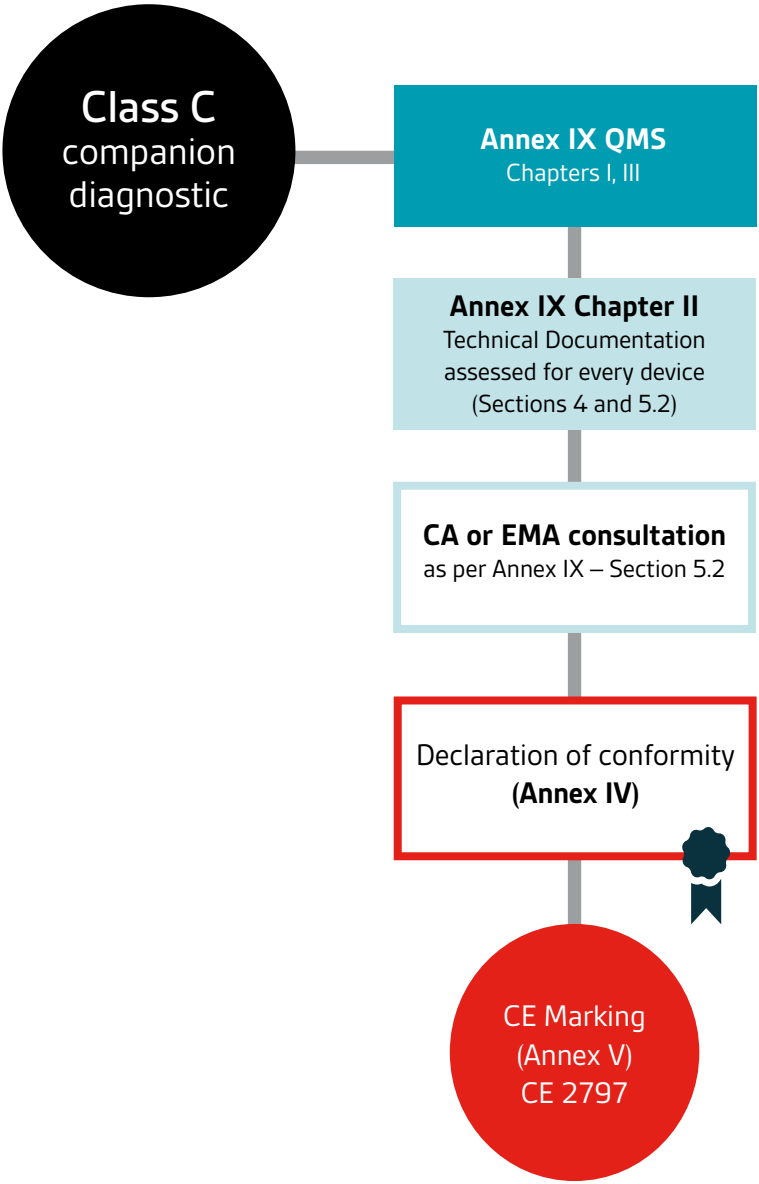


Class C devices self-testing and NPT devices

Class C self-testing and NPT devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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; NB 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; NB 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 NB upon request				
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 C companion diagnostic (CDx) devices



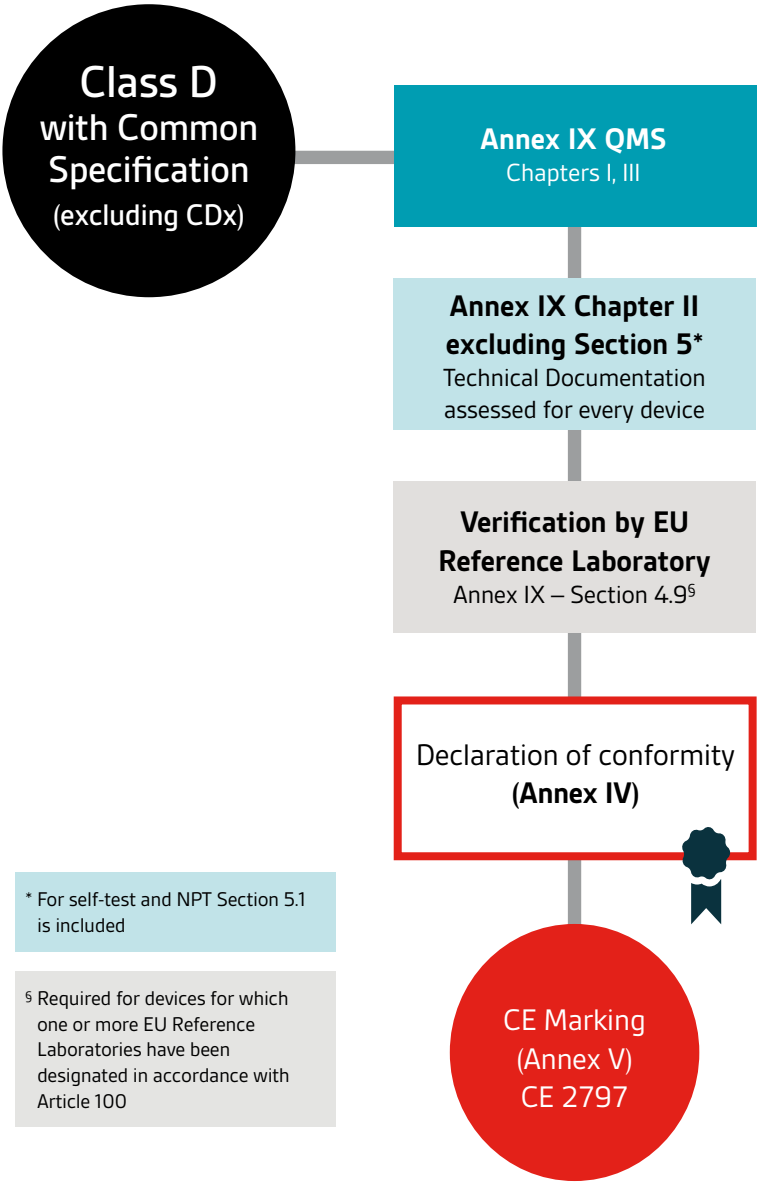
Class C companion diagnostic (CDx) devices

Class C companion diagnostic (CDx) devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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; NB 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; NB 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 NB upon request				
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 D with Common Specification

(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

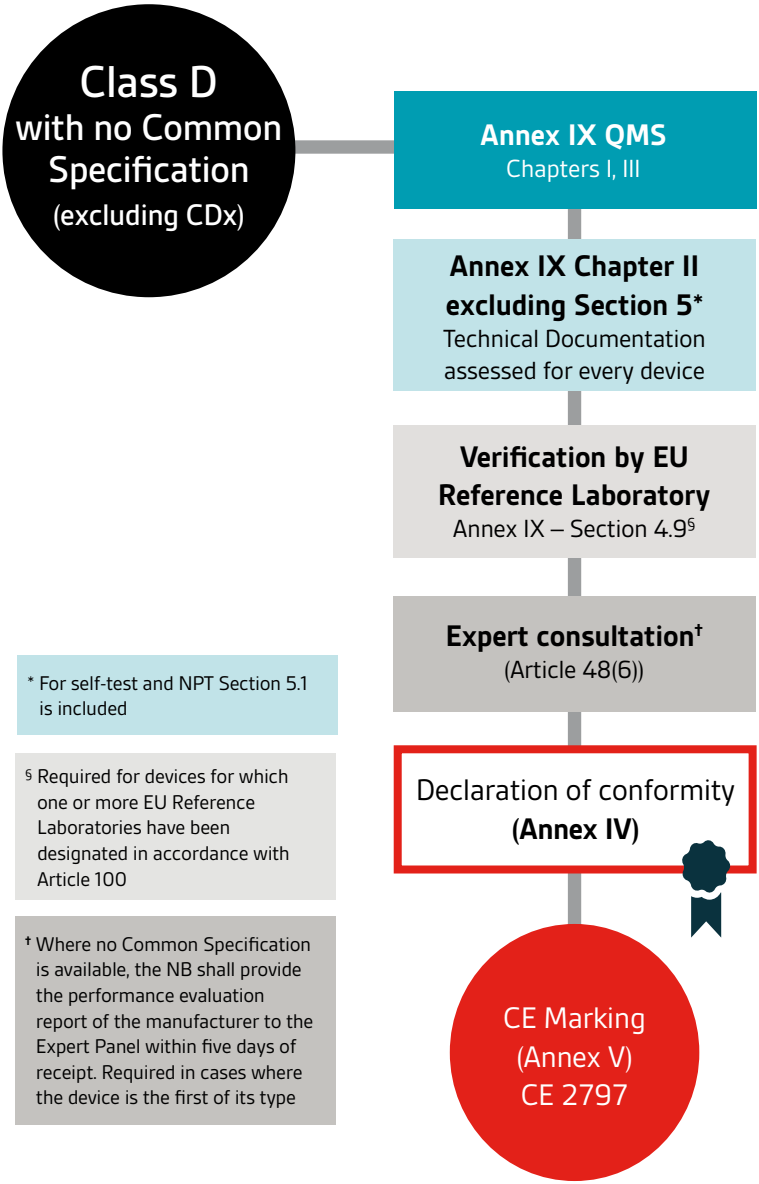
Class D with Common Specification (excluding CDx)

Class D with Common Specification (excluding CDx)	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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. NB 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; NB 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 NB via EUDAMED for NB review				
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 D with no Common Specification

(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

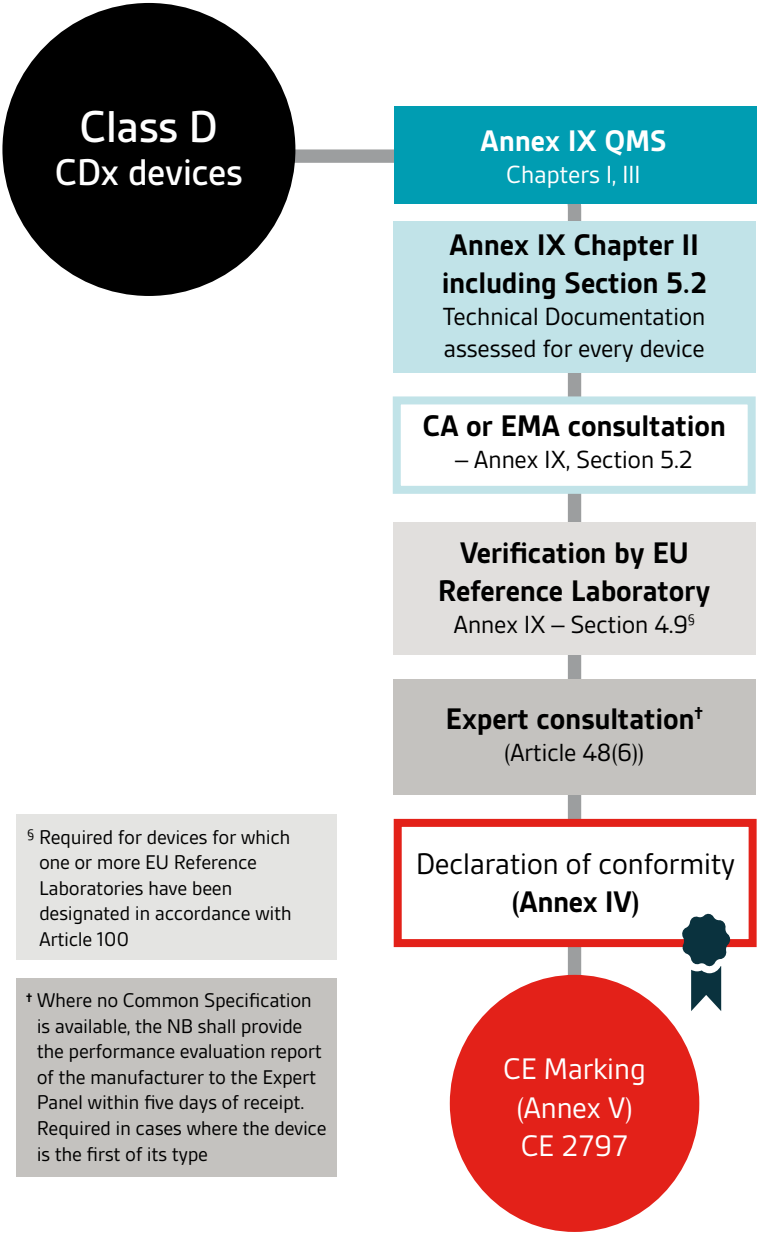
† Where no Common Specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type

Class D with no Common Specification (excluding CDx)

Class D with no Common Specification (excluding CDx)	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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. NB 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; NB 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 NB via EUDAMED for NB review				
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 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

Class D CDx devices

Class D CDx devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recertification*	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	Recertification
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 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; the NB will provide it to the expert panel as needed. NB 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; NB 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 NB via EUDAMED for NB review				
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.

Our website provides a wealth of resources including guidance documents, training courses, webinars and whitepapers.

To find out more, visit

bsigroup.com/IVD

Notes

Your resource for excellence

Talk to BSI

- We have 4,600 colleagues globally
- Offices in 31 countries around the world
- Over 84,000 clients operating in 193 countries
- Together our clients account for 75% of the FTSE 100 49% of the Fortune 500 and 77% of the Nikkei 225 listed companies
- More than 750 colleagues in BSI Medical Devices

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Our technical specialists collaborate with external experts to bring you the latest views and understanding on complex regulatory issues. Download your complimentary copies now.

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