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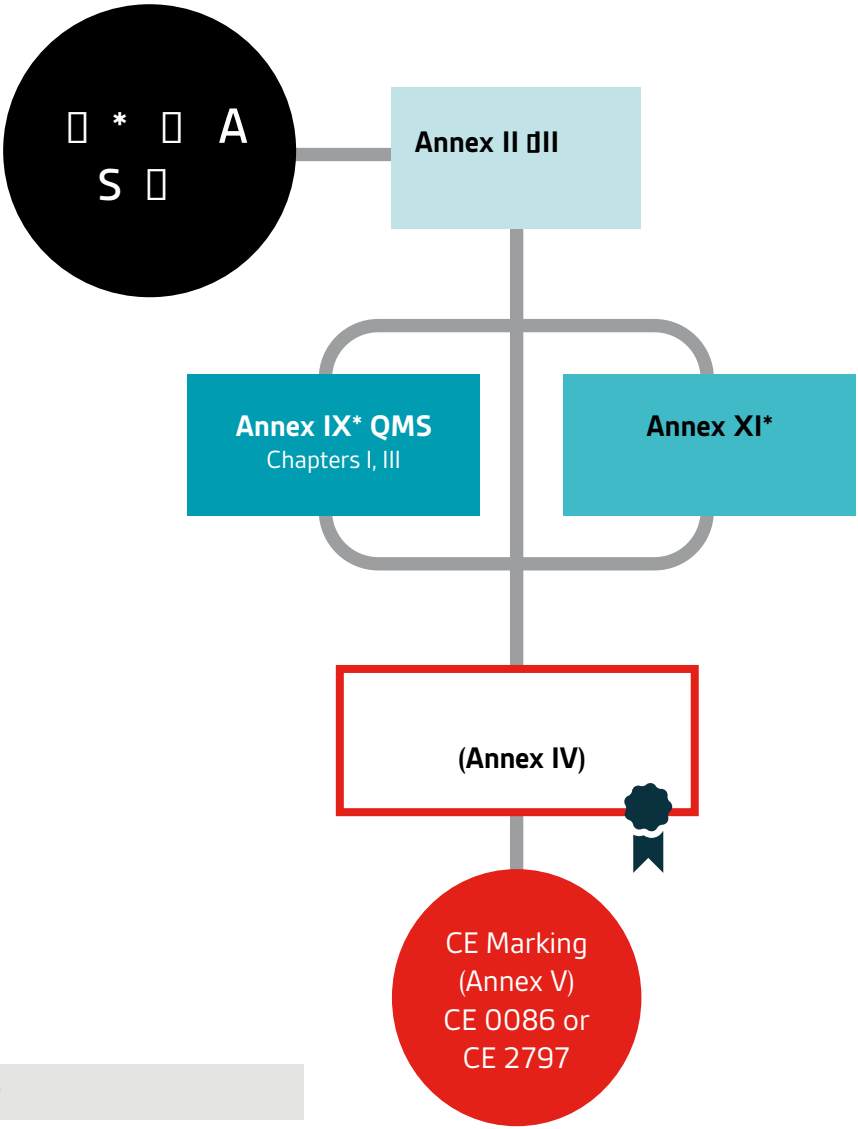

□ * □ A
S □
Annex II □III
Annex IX* QMS
Chapters I, III
Annex XI*
(Annex IV)
CE Marking
(Annex V)
CE 0086 or
CE 2797

*

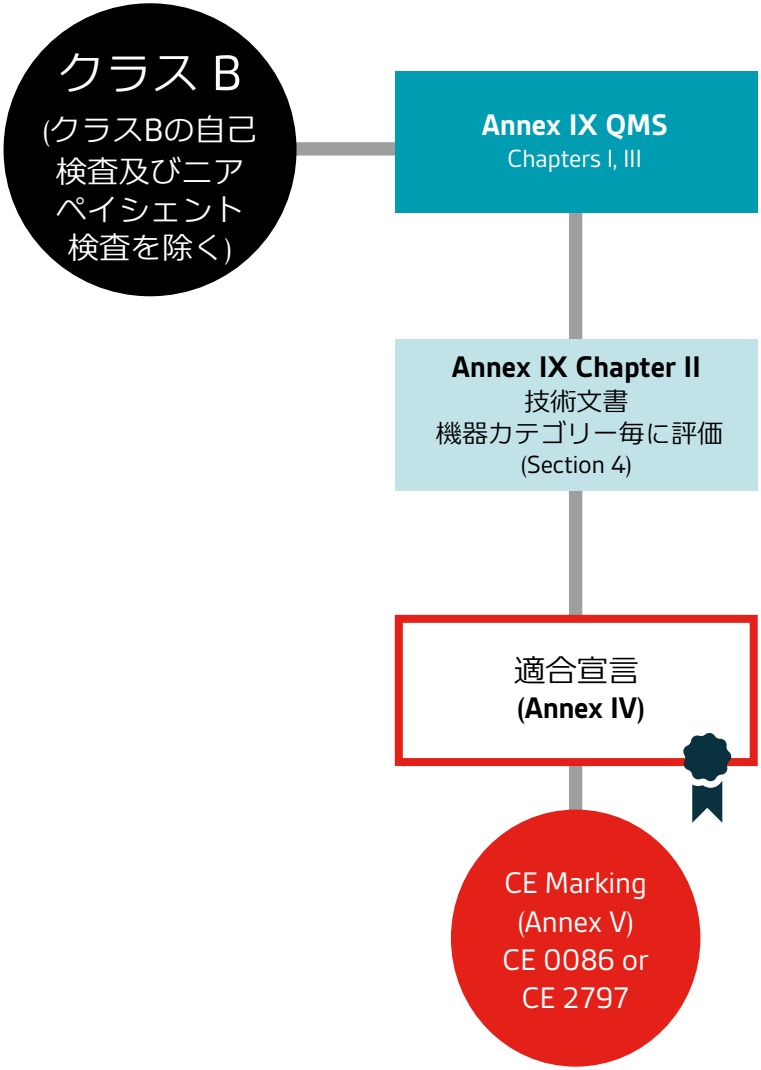
クラスA 滅菌機器

クラス A 滅菌機器	初回 適合性評価	サーベイランス				
		Y1	Y2	Y3	Y4	Y5
QMS 監査	Yes	Yes	Yes	再認証*	Yes	Yes
滅菌監査	Yes	N/A	Yes	N/A	Yes	N/A
技術文書評価	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
専門家による コンサルテーション(article 48(6))	N/A	N/A	N/A	N/A	N/A	N/A
EU reference laboratoryによる 検証 (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
性能評価報告書更新 (Annex XIII - Part A, Section 1.3.2 and Article 56)		NBによる評価不要				
市販後性能フォローアップ (PMPF) 評価報告書 更新 (Article 56 and Annex XIII, Part B)		NBによる評価不要				
市販後調査 (PMS) 報告 (Article 80)		必要なときに更新及び要求に応じNBが利用可能 な状態にする。				
定期的安全性最新報告(PSUR) (Article 81)		N/A	N/A	N/A	N/A	N/A
非通知監査		少なくとも5年に一度実施。				

*QMS認証書は3年間有効ですが、CE証明書は最大5年間有効となります。表に示されている**Y3再認証**はEN ISO 13485:2016の認証サイクルに関連しています。認証サイクルはさまざまで、再認証は常にY3で行われるとは限りません。

クラス B 機器

(自己検査及びニアペイシェント検査（NPT）機器を除く)

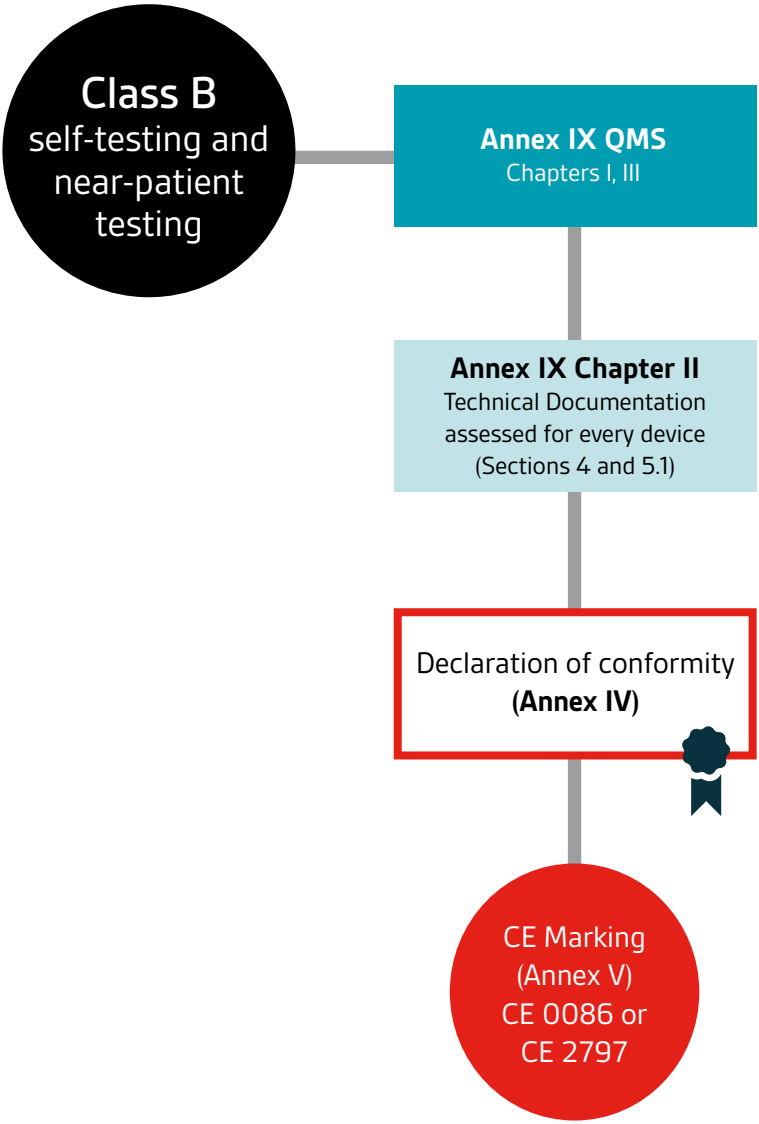


Class B devices (excluding self-testing and NPT devices)

クラス B機器 (自己検査及び NPT 機器を除く)	初回 適合性評価	サーベイランス				
		Y1	Y2	Y3	Y4	Y5
QMS 監査	Yes	Yes	Yes	再認証*	Yes	Yes
滅菌監査	Yes (滅菌品の場合)	N/A	Yes (滅菌品の場合)	N/A	Yes (滅菌品の場合)	N/A
技術文書評価	機器の カテゴリー毎 のサンプル	技術文書のサンプリング計画に従う。 証明書の適用範囲下でまだレビューされていない機器が残っている間、毎年技術文書のサーベイランス監査が必要です。				
Competent Authority or EMA consultation (Annex IX, Section 5.2)	N/A	N/A	N/A	N/A	N/A	N/A
専門家による コンサルテーション(article 48(6))	N/A	N/A	N/A	N/A	N/A	N/A
EU reference laboratoryによる 検証 (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) Evaluation Report updates (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
非通知監査		少なくとも5年に一度実施。				

*QMS認証書は3年間有効ですが、CE証明書は最大5年間有効となります。表に示されている**Y3再認証**はEN ISO 13485:2016の認証サイクルに関連しています。認証サイクルはさまざまで、再認証は常にY3で行われるとは限りません。

Class B self-testing and NPT devices



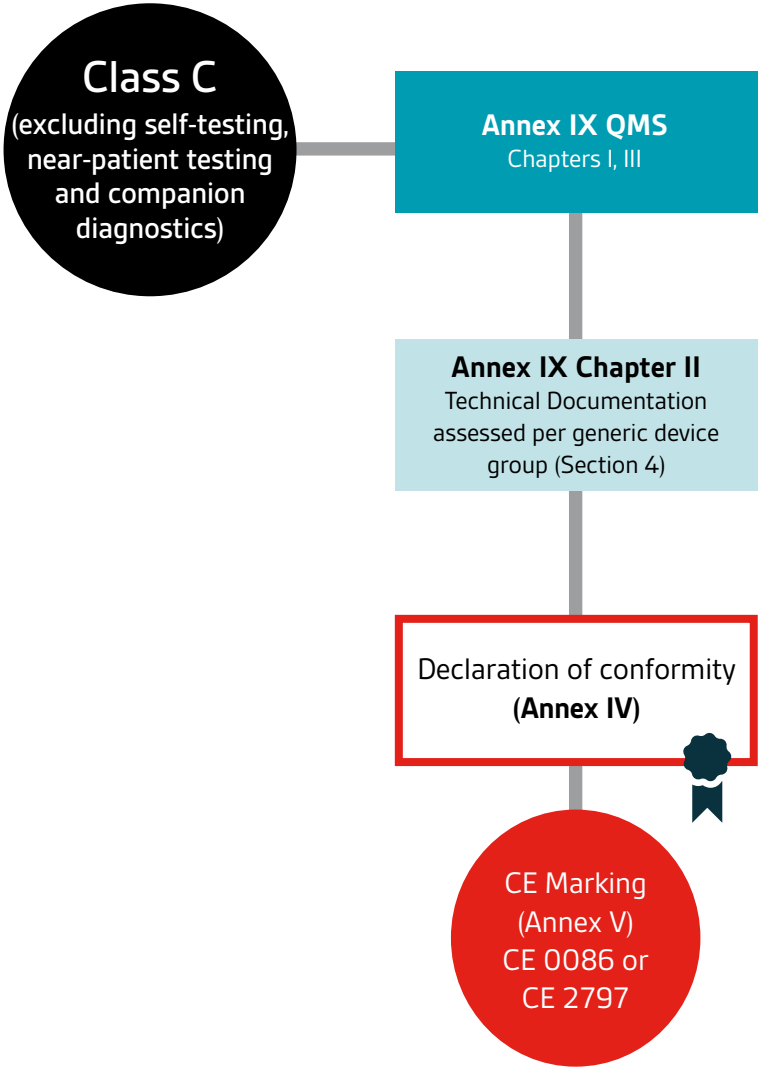
Class B devices self-testing and NPT devices

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) Evaluation Report updates (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))

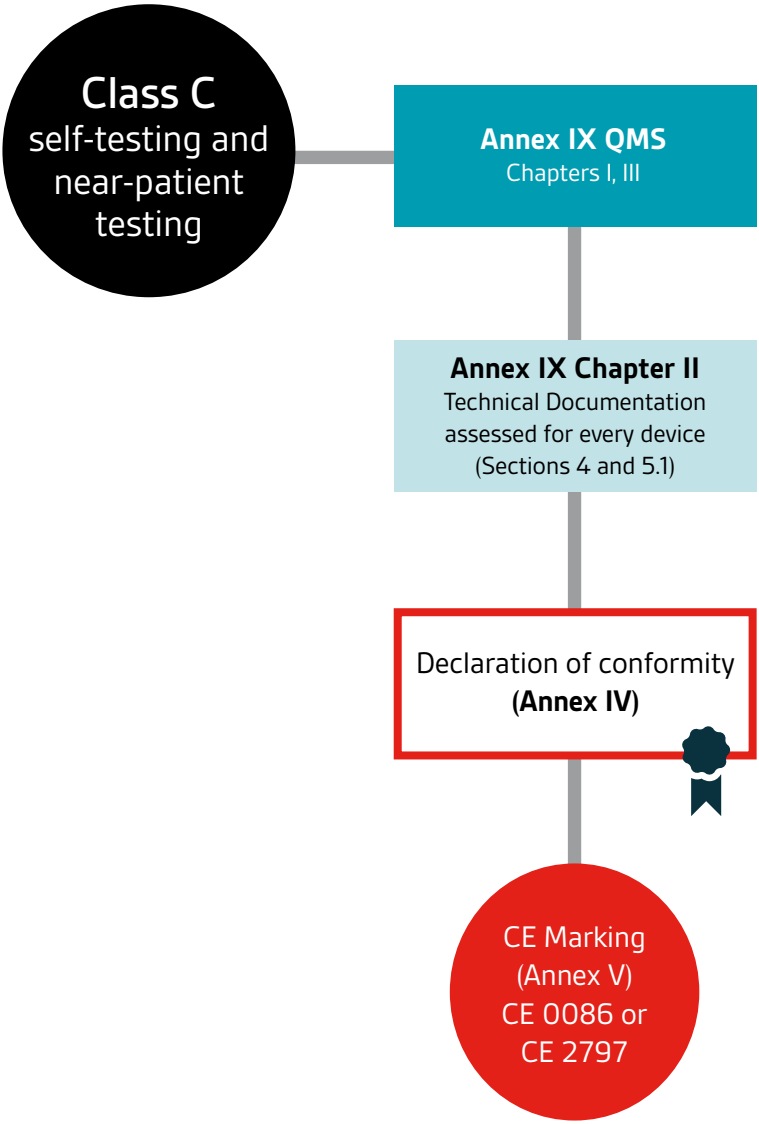


Class C devices (excluding self-testing, NPT and companion diagnostics (CDx))

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) Evaluation Report updates (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

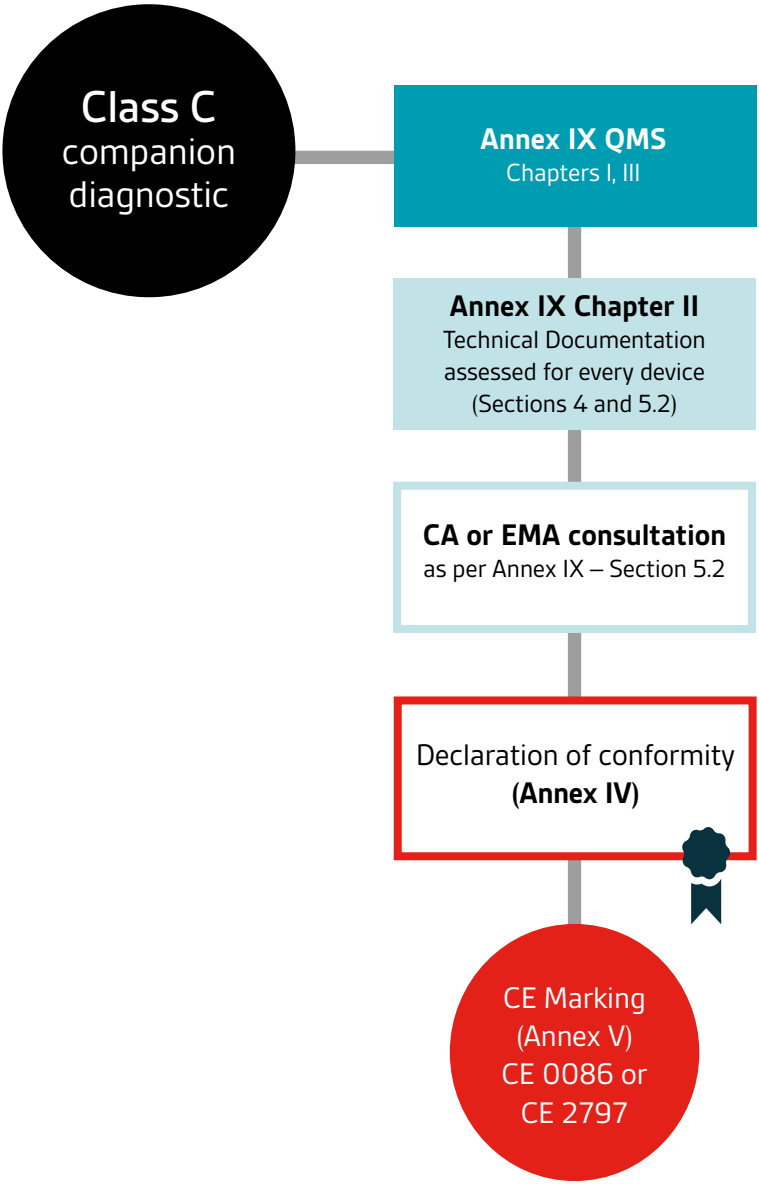


Class C devices self-testing and NPT devices

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) Evaluation Report updates (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



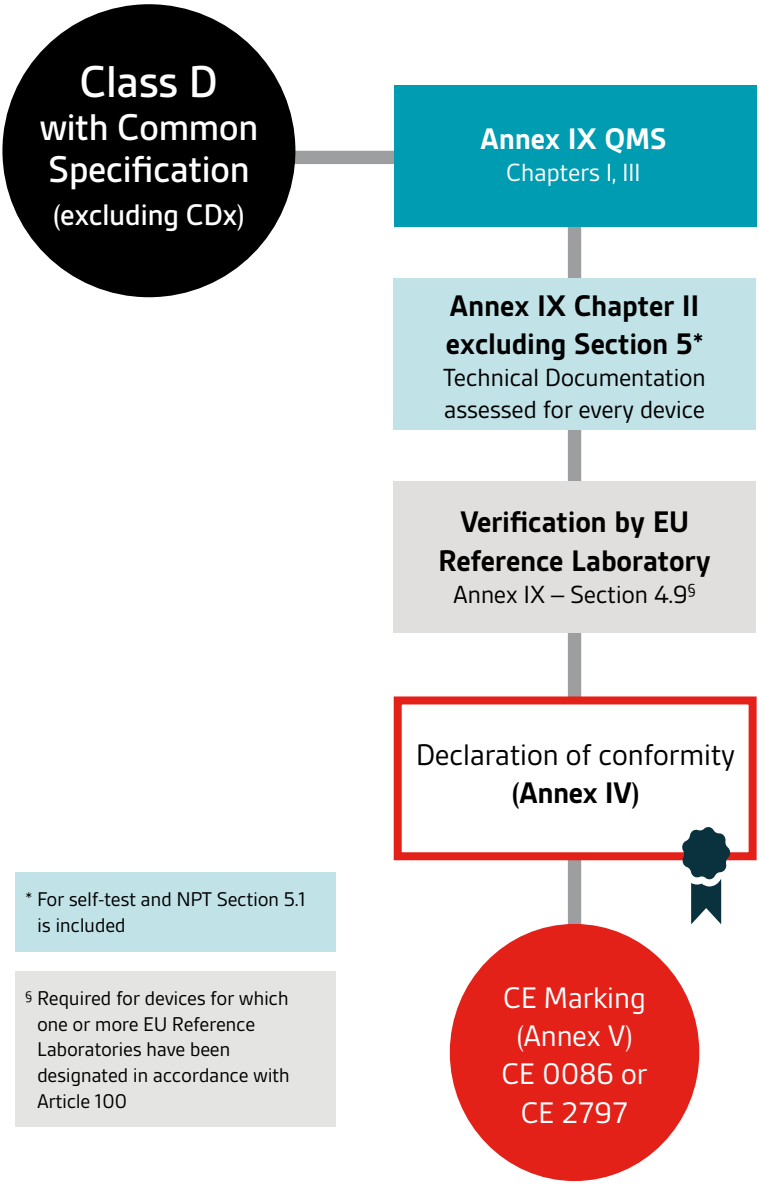
Class C companion diagnostic (CDx) devices

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) Evaluation Report updates (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

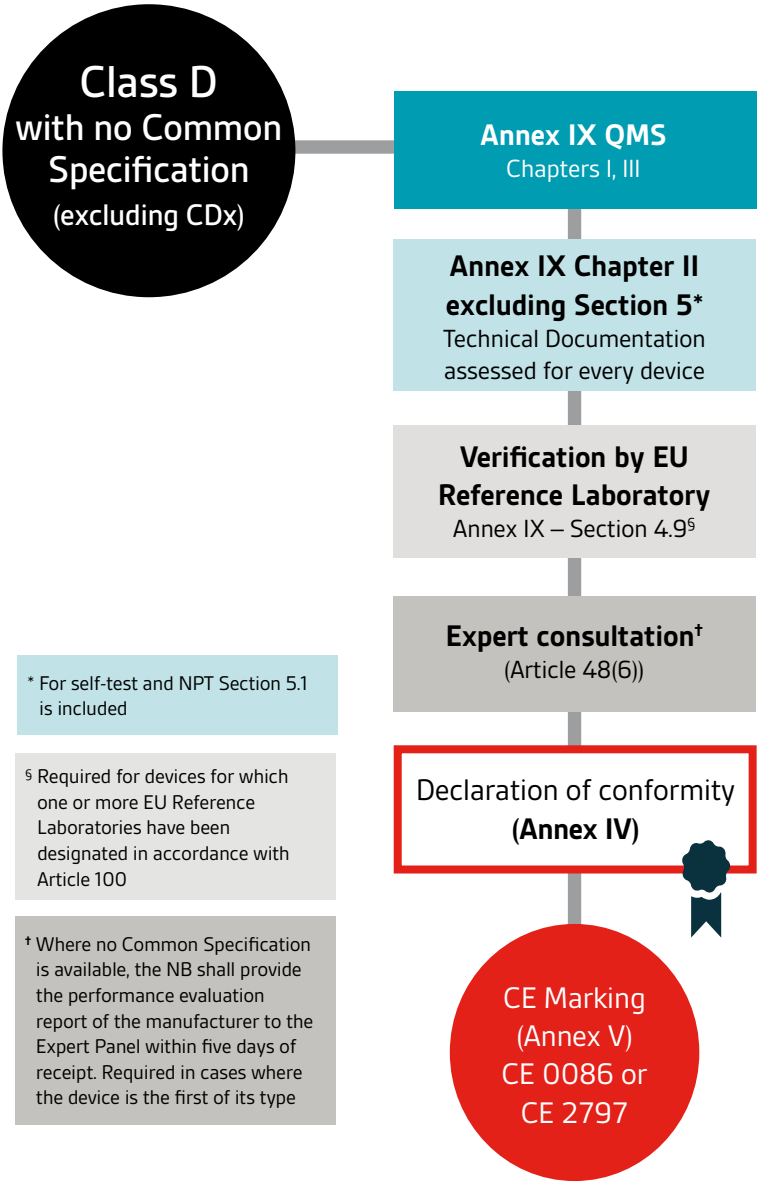
Class D with Common Specification (excluding CDx)

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) Evaluation Report updates (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

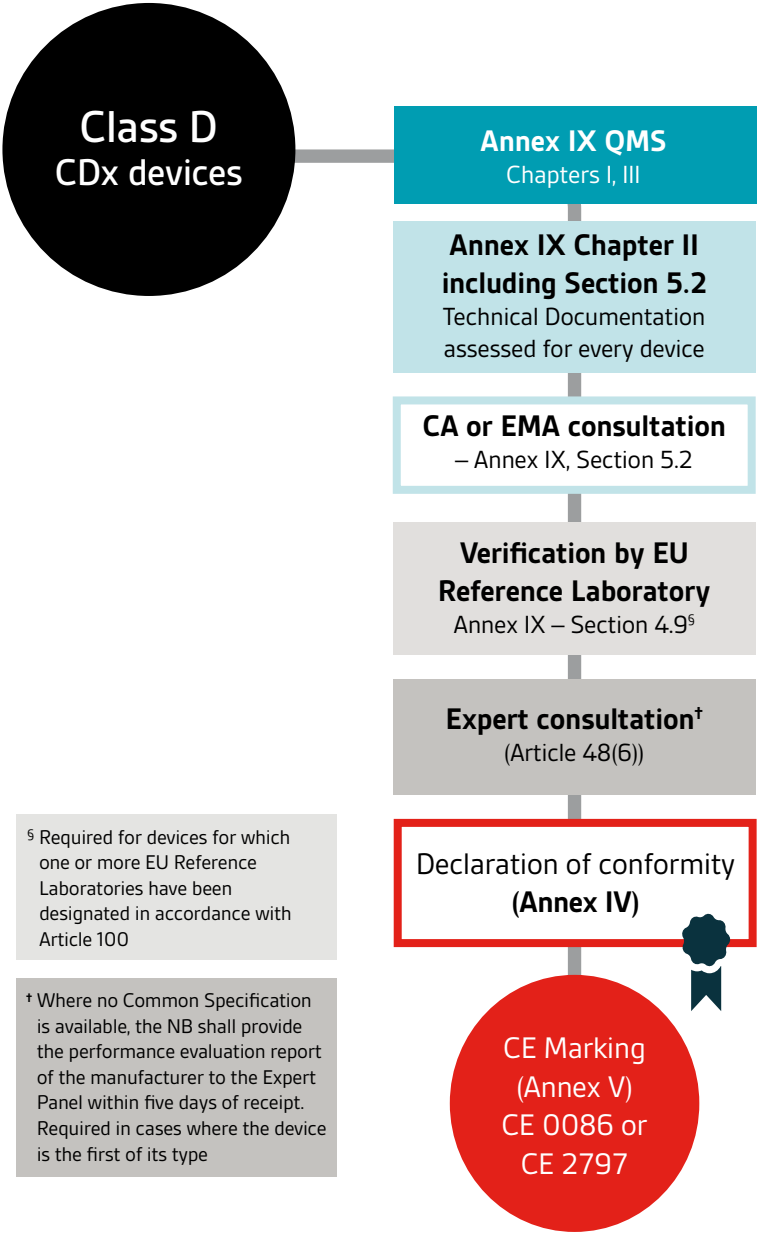
† Where no Common Specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type

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) Evaluation Report updates (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) Evaluation Report updates (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.

弊社のウェブサイトで、ガイダンス文書、研修コース、オンラインセミナー、ホワイトペーパーなどの役立つリソースを豊富に提供しています。ぜひご参照ください。

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