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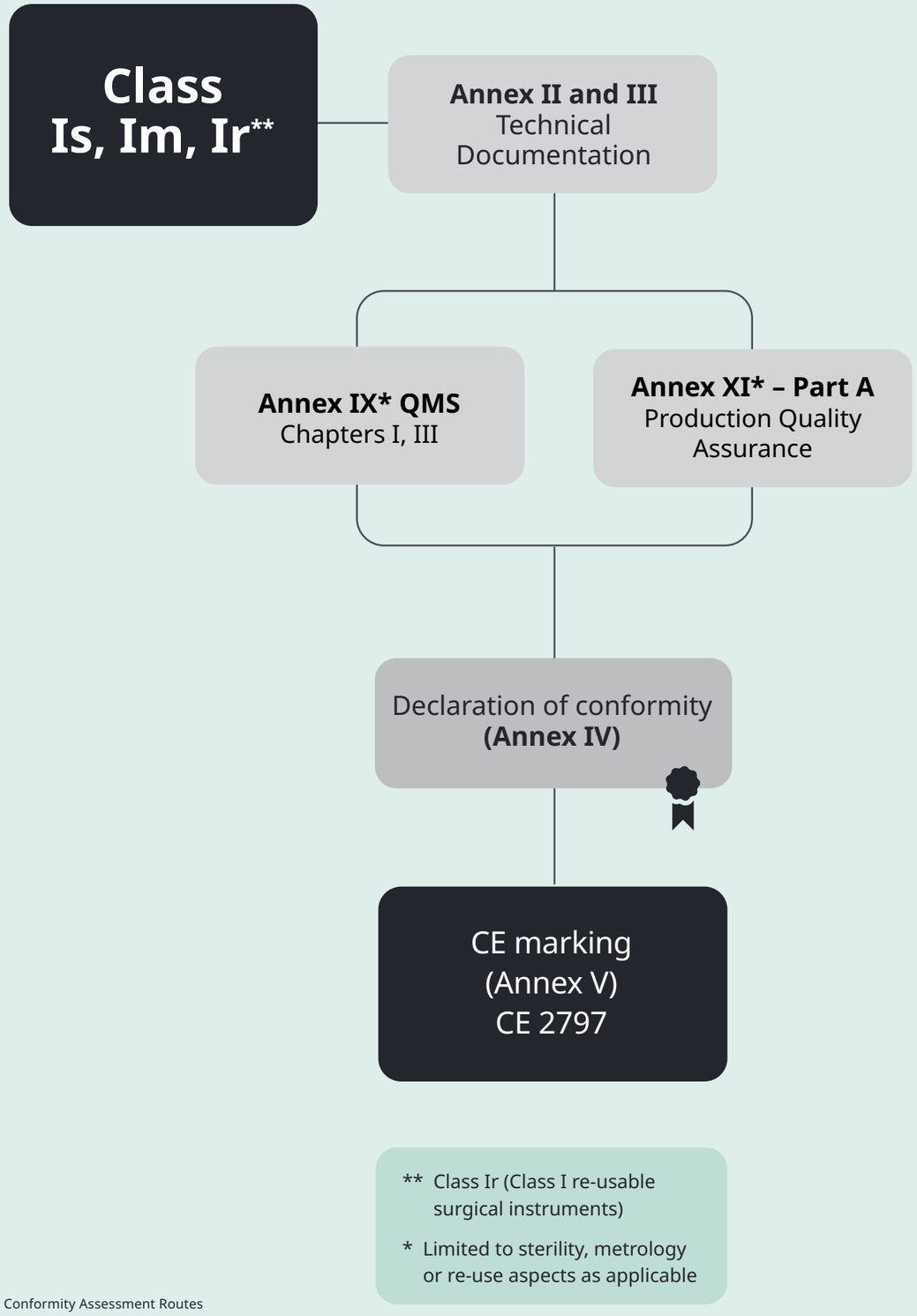
MDR Conformity Assessment Routes

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

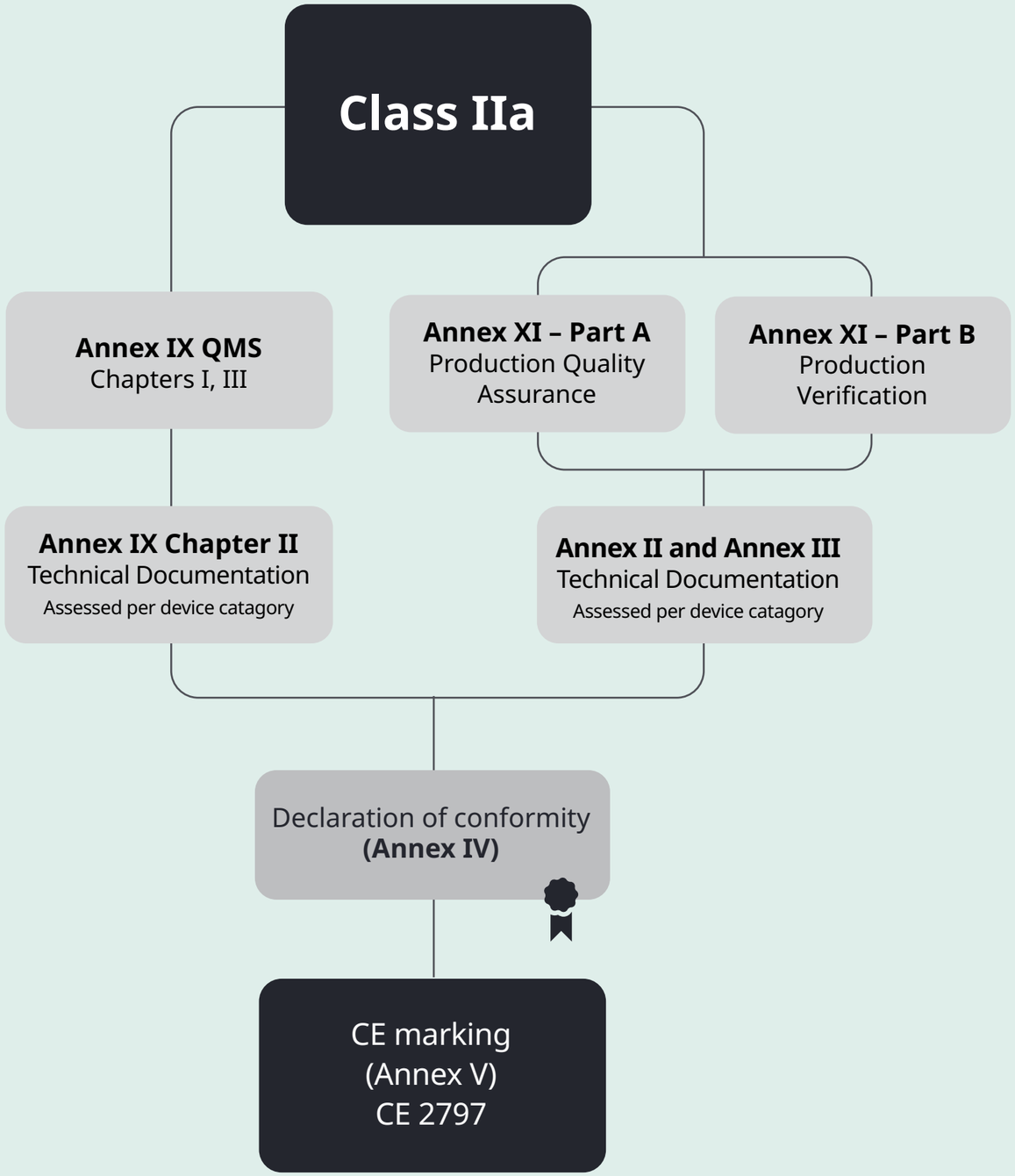
Class Is/Im/Ir devices

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.

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Applicable audits, assessments and requirements

Class IIa implantable devices

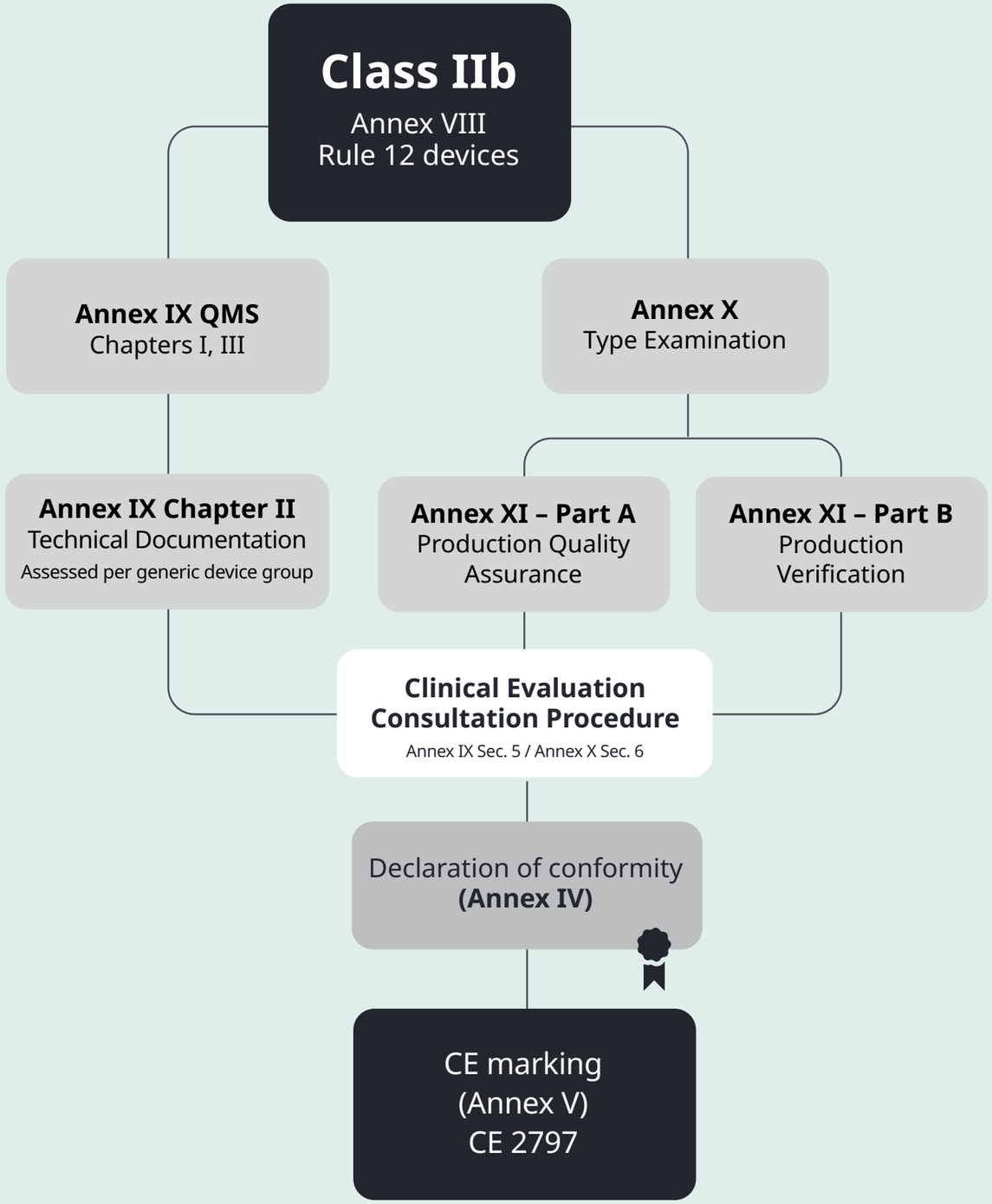
Class IIa implantable devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per category of devices	At least one Technical Documentation surveillance assessment 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.

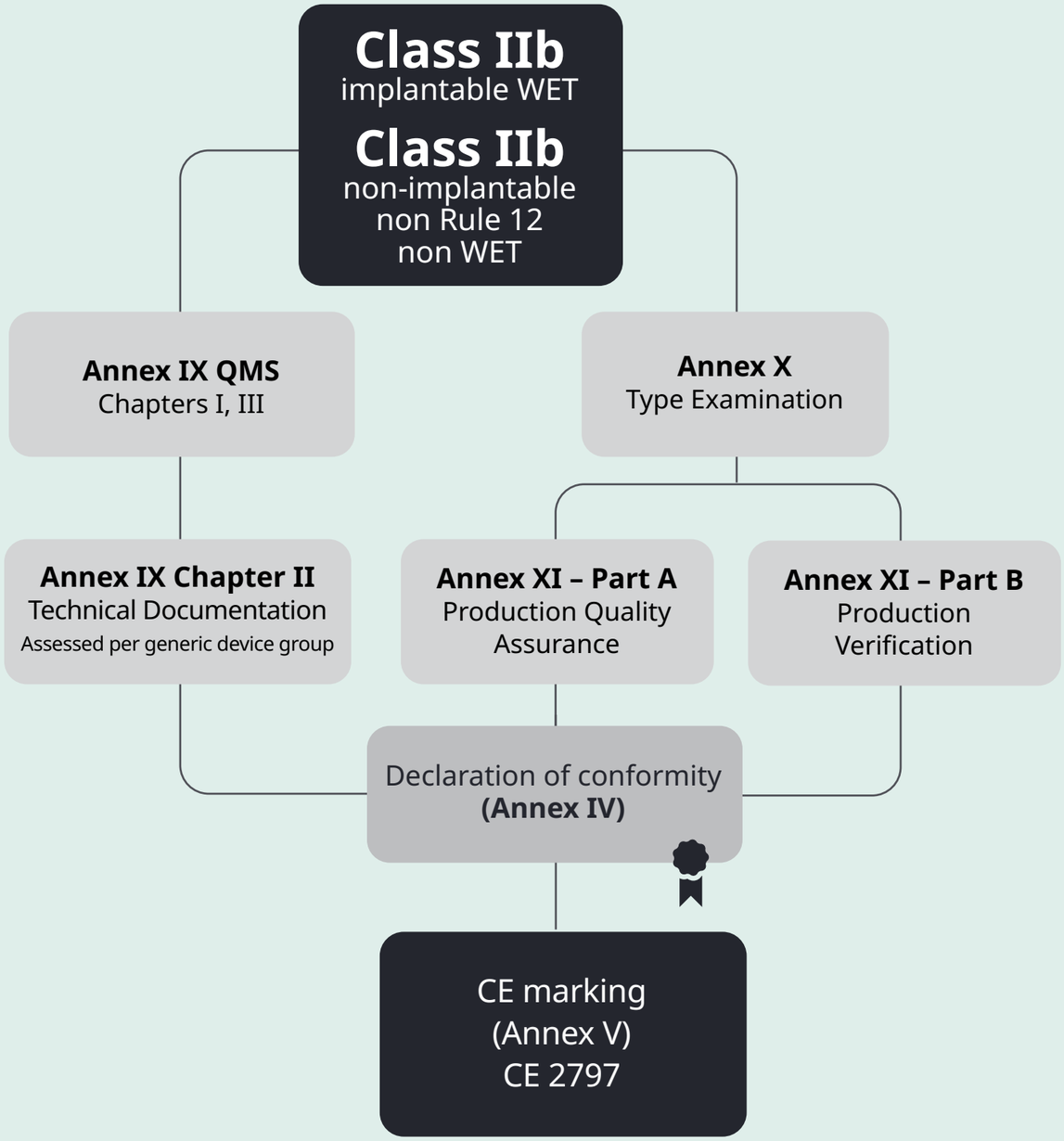
Class IIb Annex VIII Rule 12 devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per generic device group	At least one Technical Documentation surveillance 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.

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Applicable audits, assessments and requirements

Class IIb non-implantable non WET non Rule 12 devices

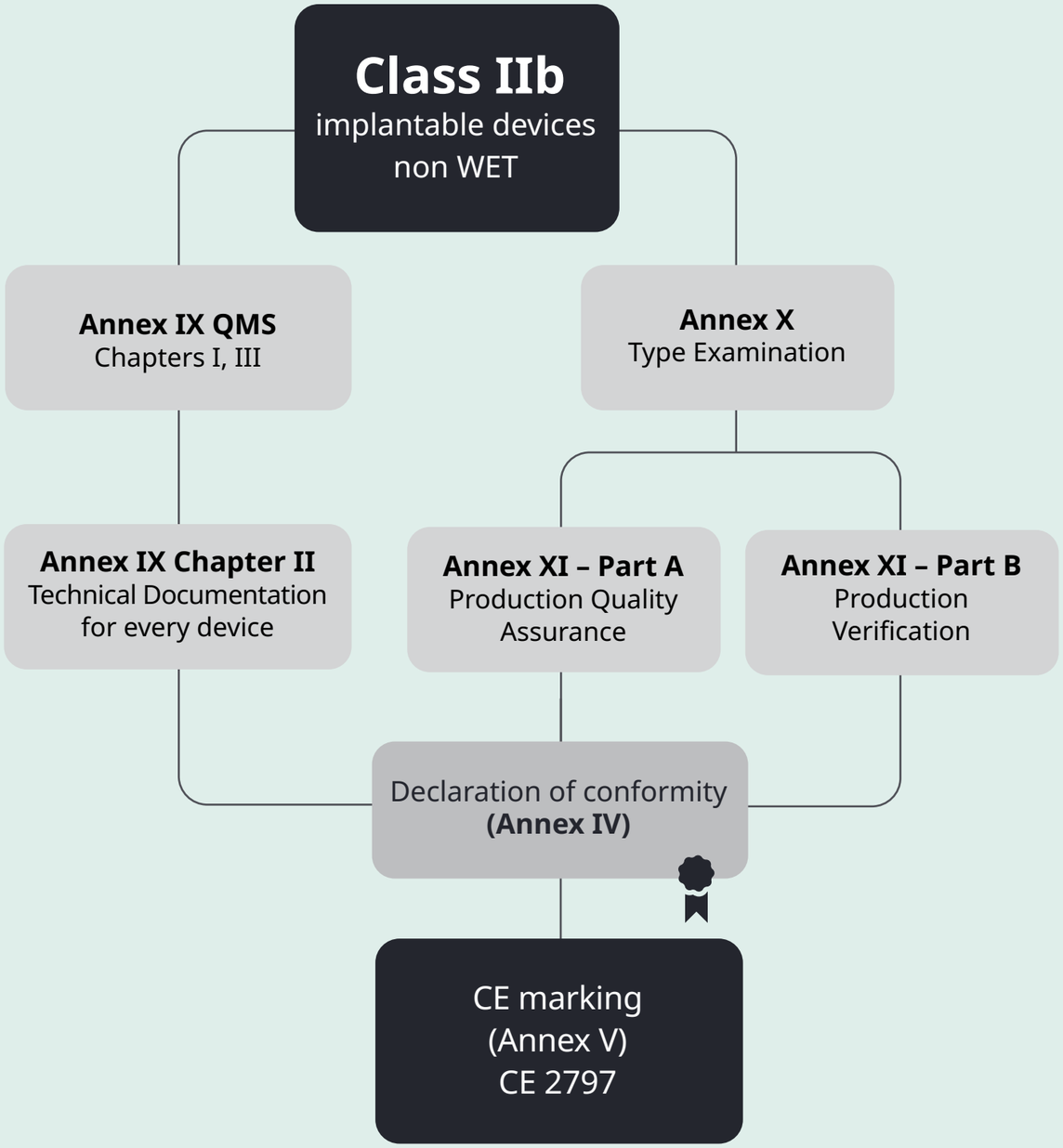
Class IIb non-implantable non-WET non-Rule 12 devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per generic device group	At least one Technical Documentation 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

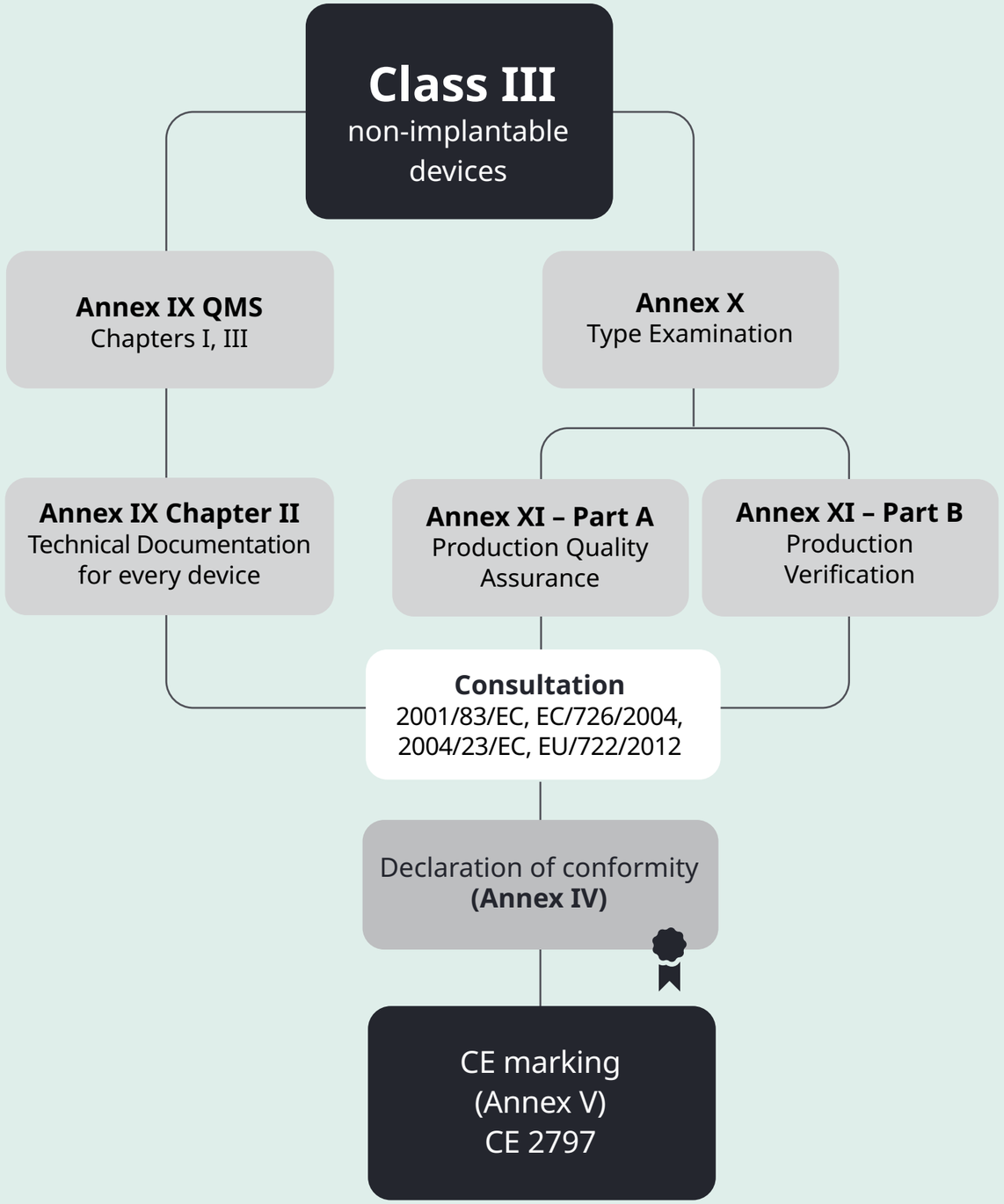
Class IIb implantable non-WET devices

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

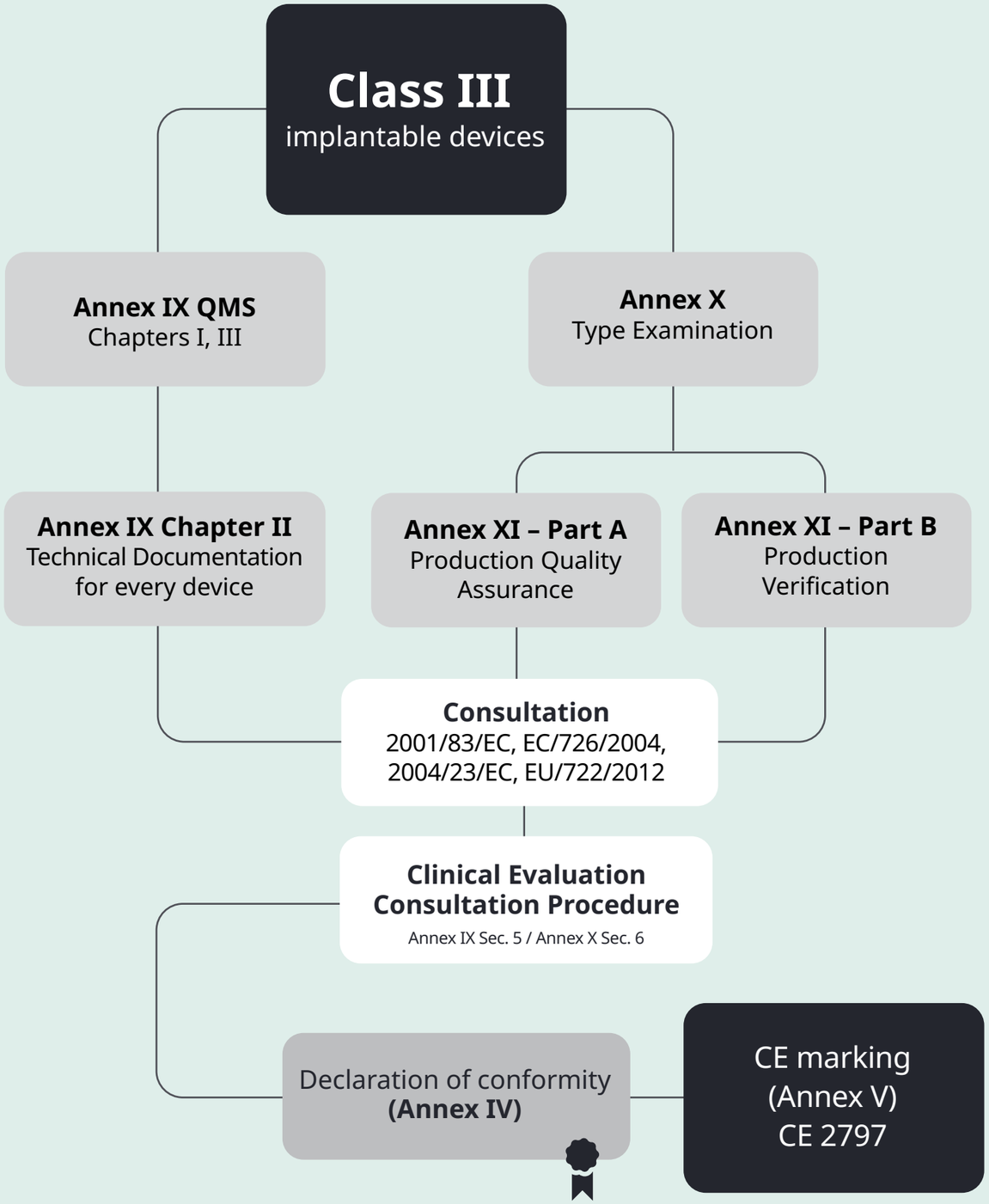
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

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

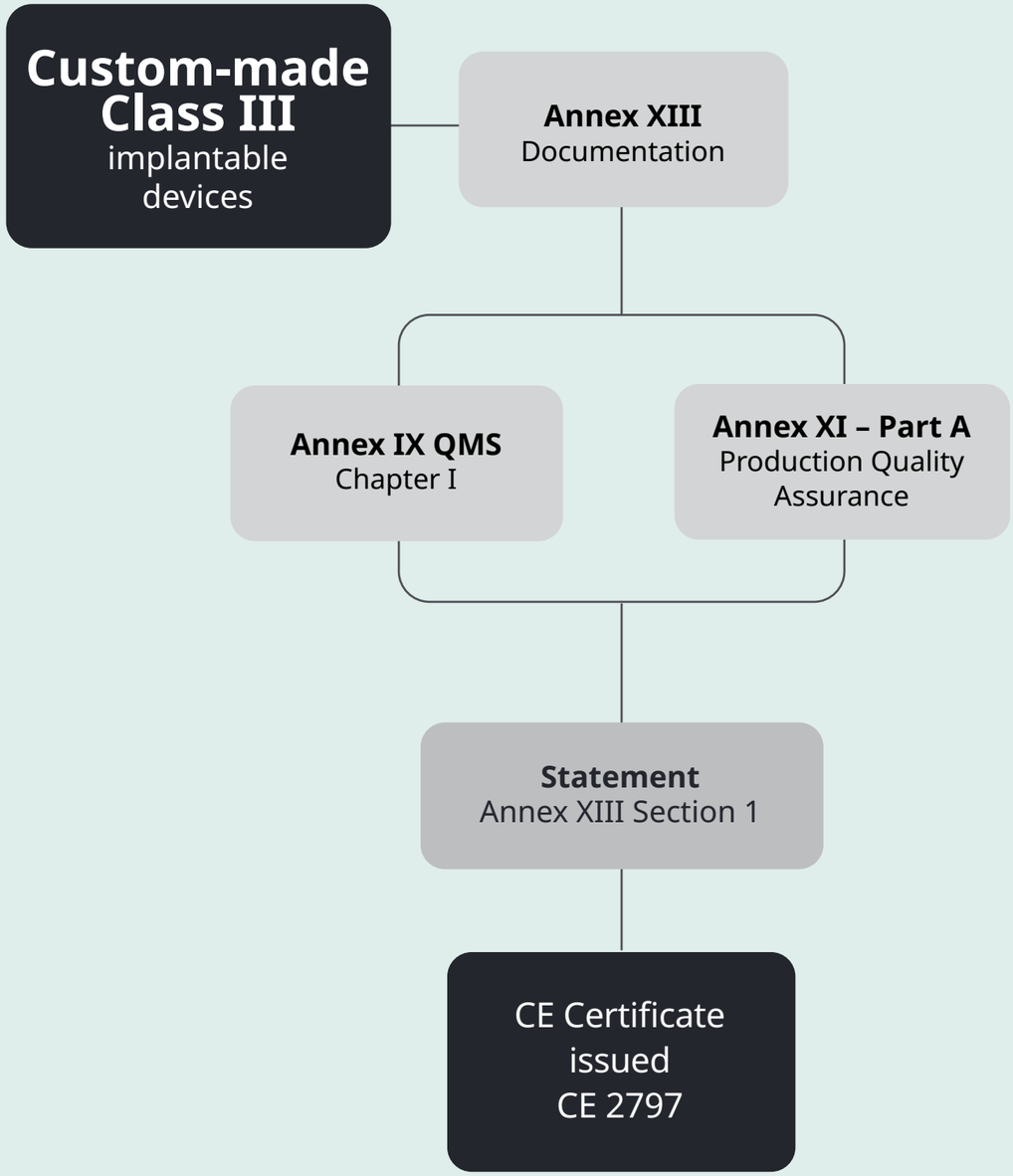
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

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

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

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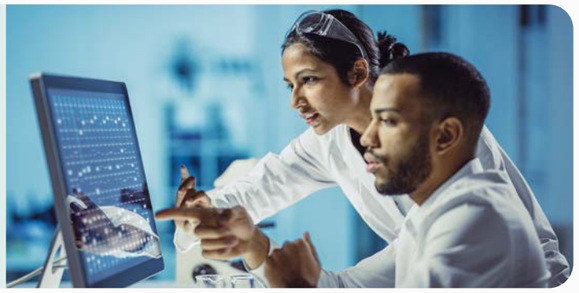
Call BSI on +44 345 080 9000, visit our **CE marking webpage** and read our **Excellence Pathways brochure**



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

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