MDR Conformity Assessment Routes

bsi.

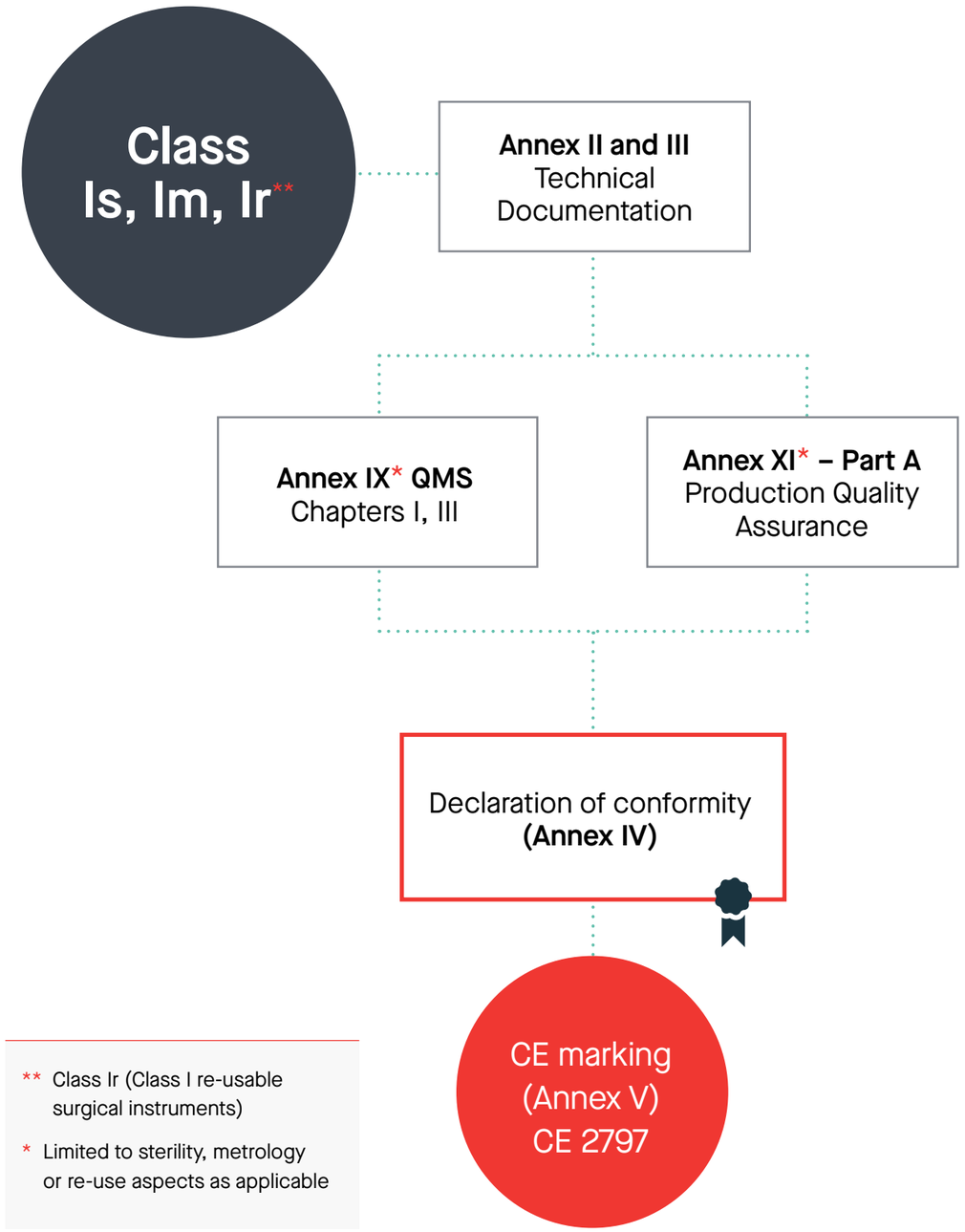
By Royal Charter

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

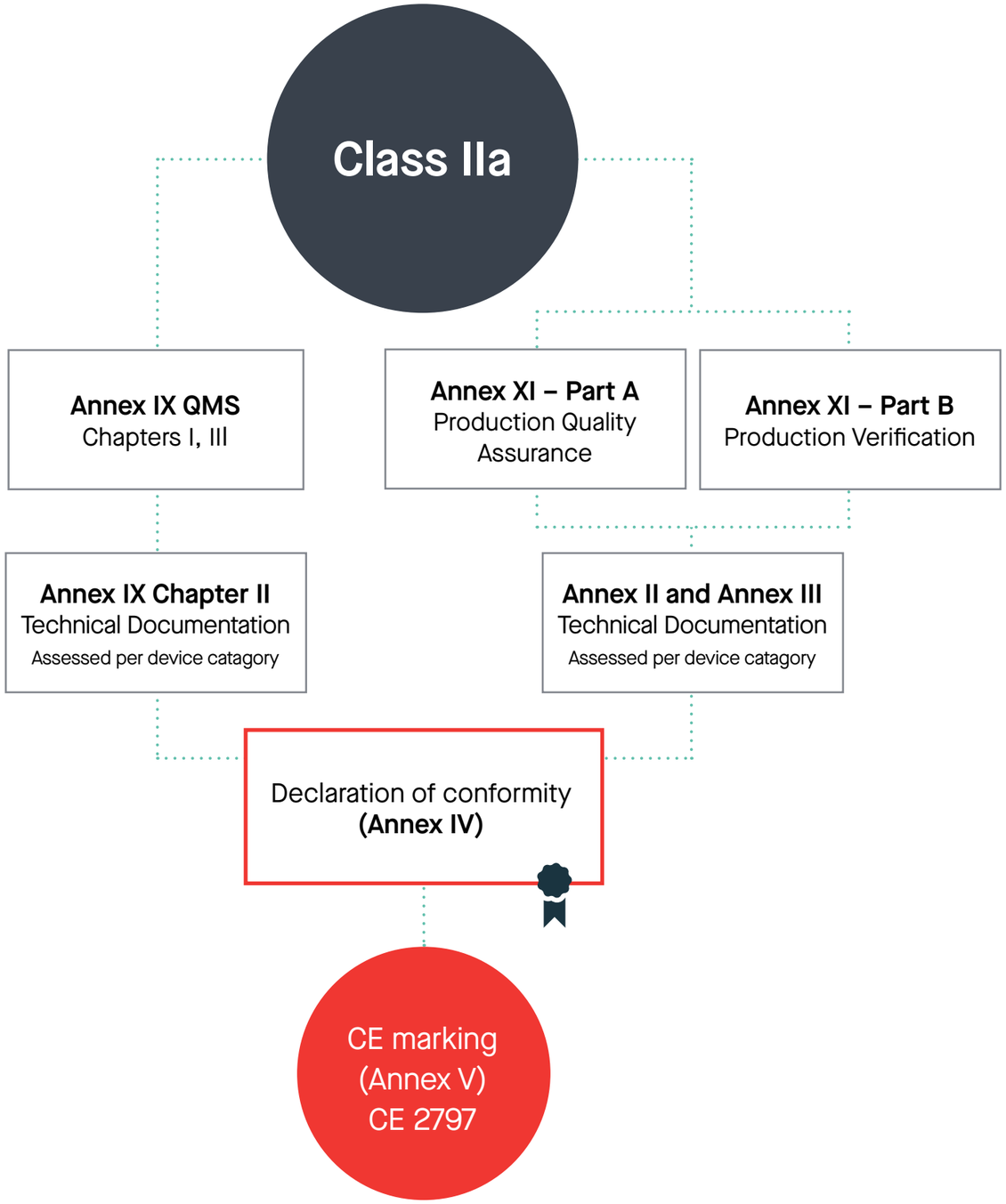
Class Is/Im/Ir devices

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	N/A	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)	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

** 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 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	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					

Continues on page 7

* 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

Applicable audits, assessments and requirements

Class IIa implantable devices

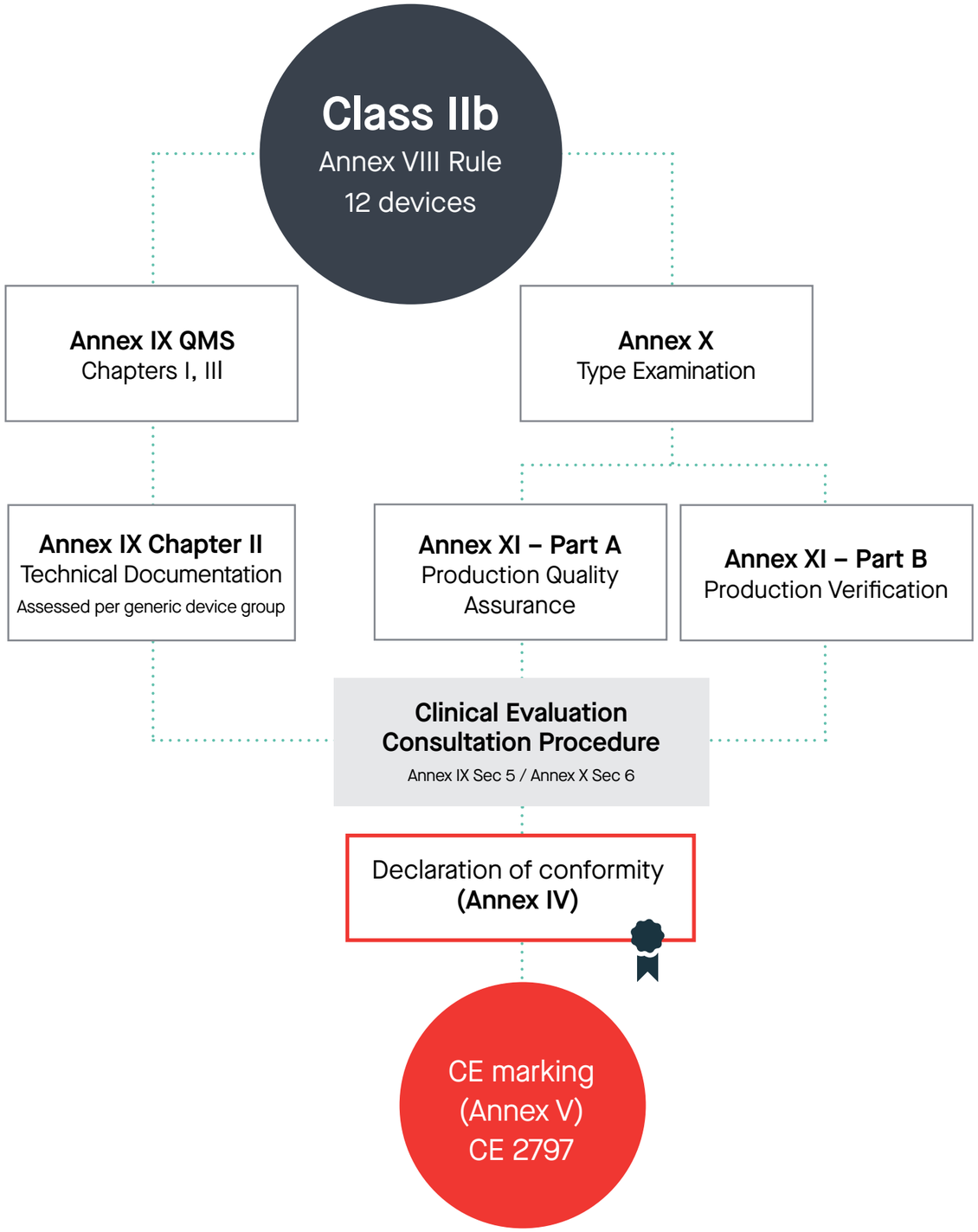
Class IIa implantable devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per category of devices	As per the Technical Documentation Sampling Plan				
Clinical 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

** 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 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.

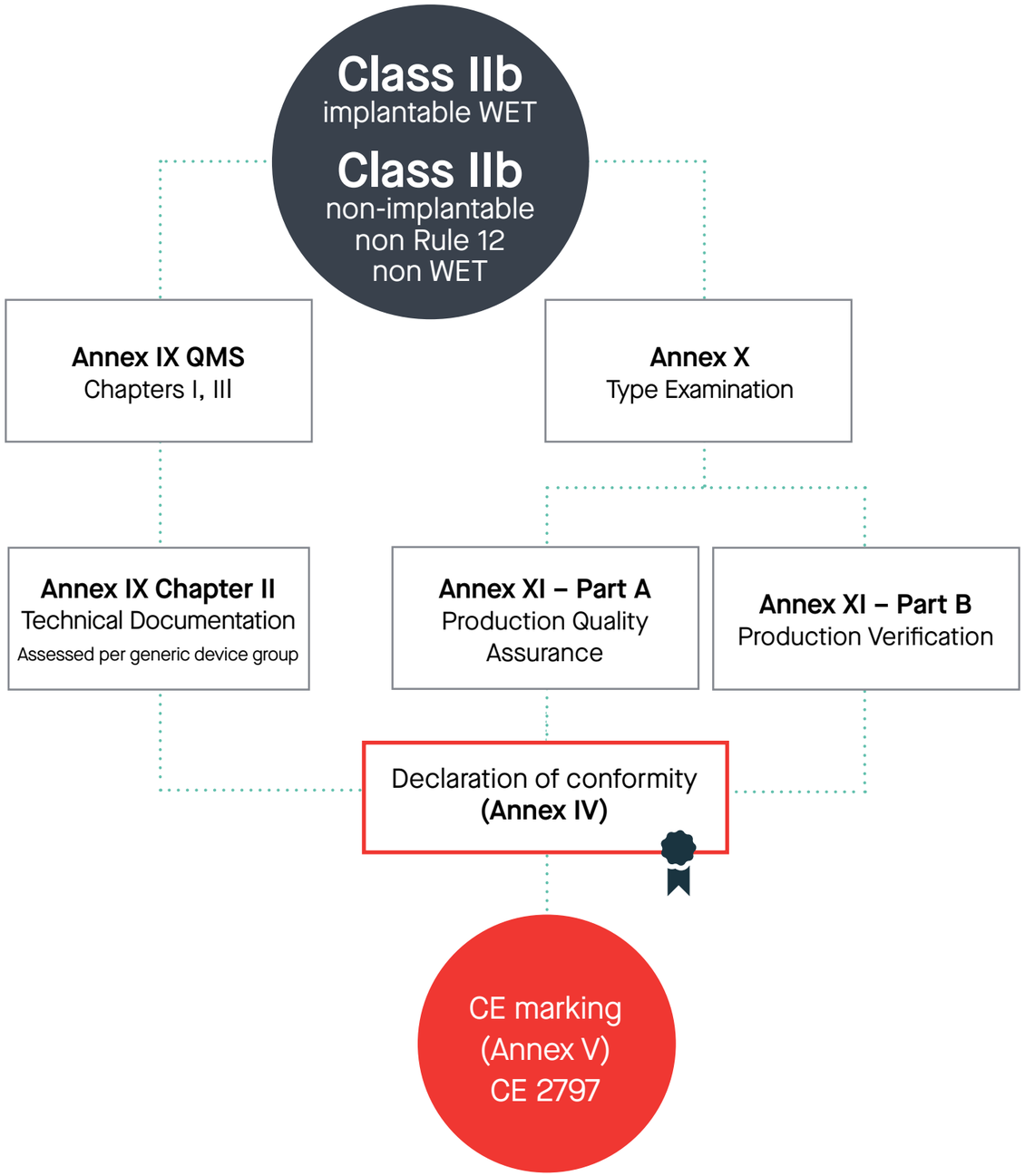
Class IIb Annex VIII Rule 12 devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per generic device group	As per the Technical Documentation Sampling Plan				
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

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



Applicable audits, assessments and requirements
Class IIb implantable 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	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				

Continues on page 12

* 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

Applicable audits, assessments and requirements
Class IIb non-implantable non WET non Rule 12 devices

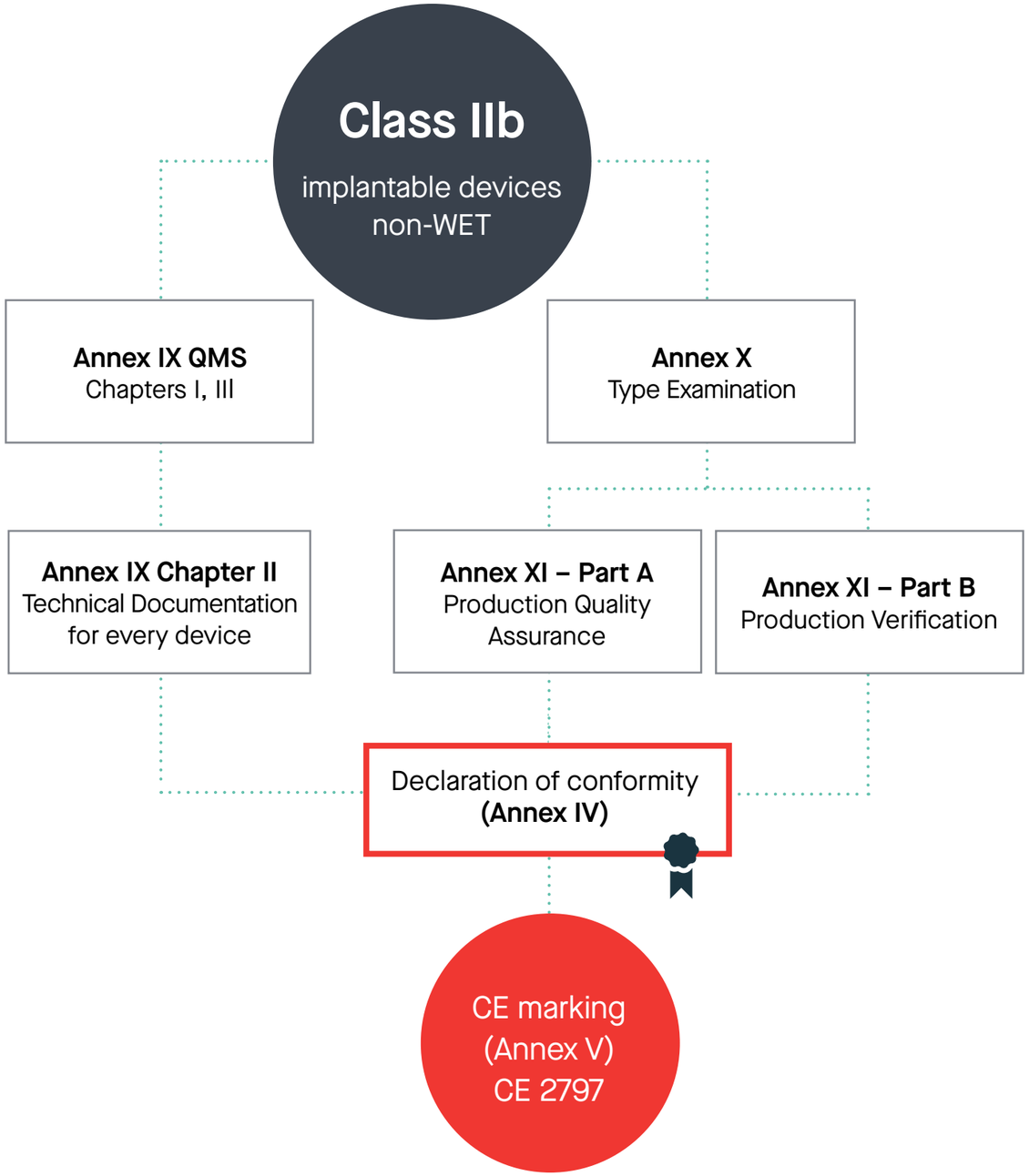
Class IIb non-implantable non-WET non-Rule 12 devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Sample per generic device group	As per the Technical Documentation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

** 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 IIb implantable devices
Excluding WET



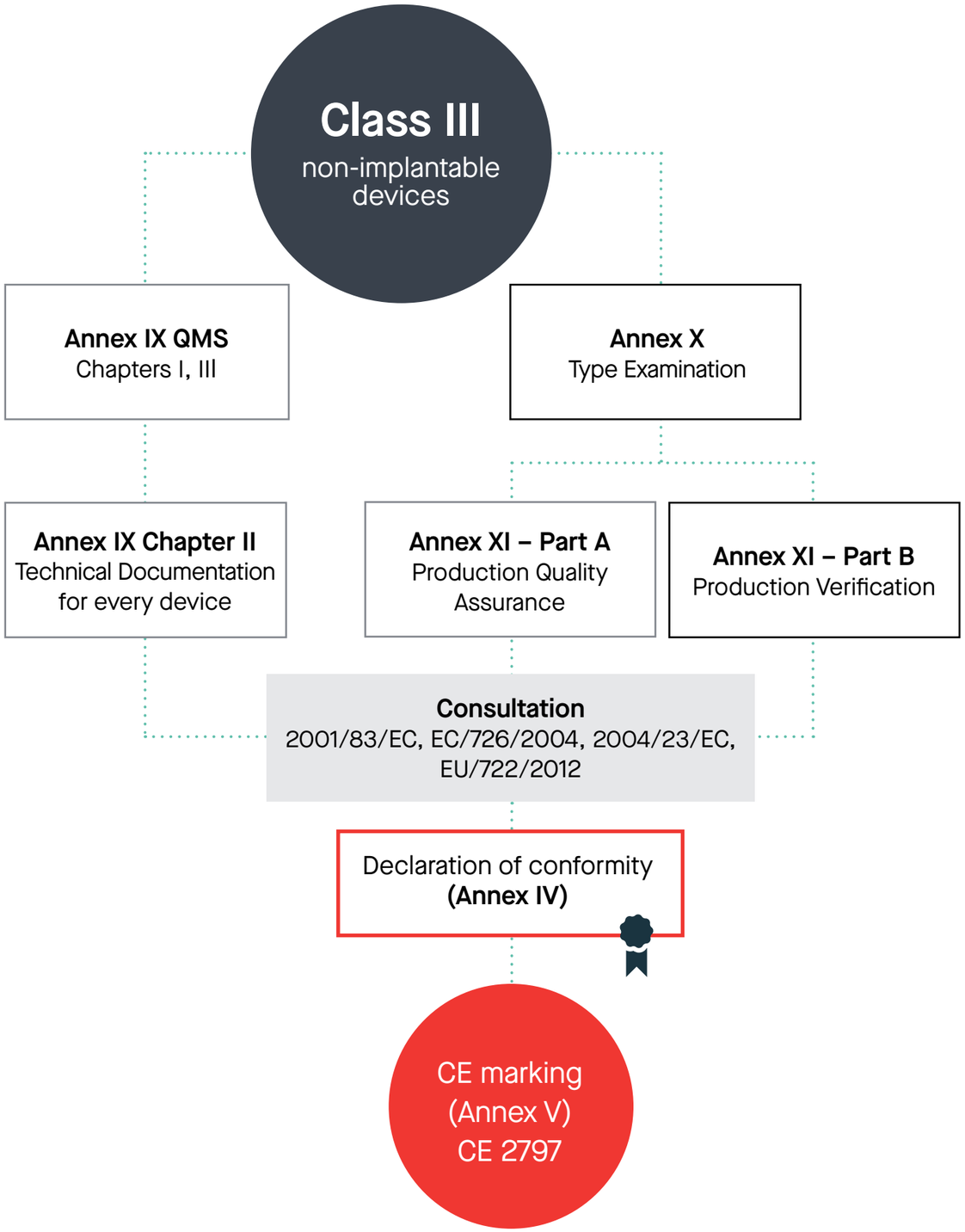
Applicable audits, assessments and requirements
Class IIb implantable non-WET devices

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

** 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 III non-implantable devices



Applicable audits, assessments and requirements
Class III non-implantable devices

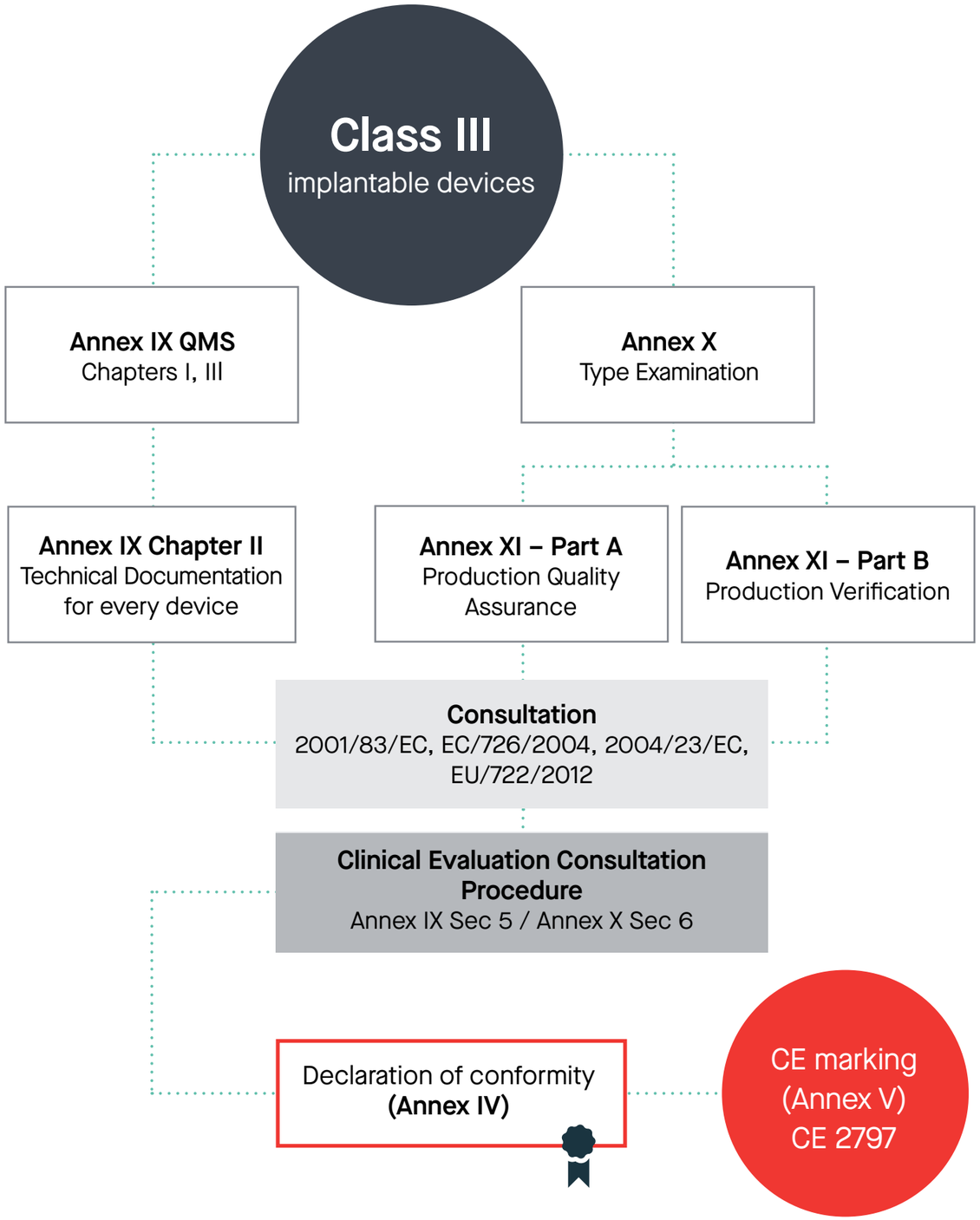
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

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

** 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 III implantable devices



Applicable audits, assessments and requirements
Class III implantable devices

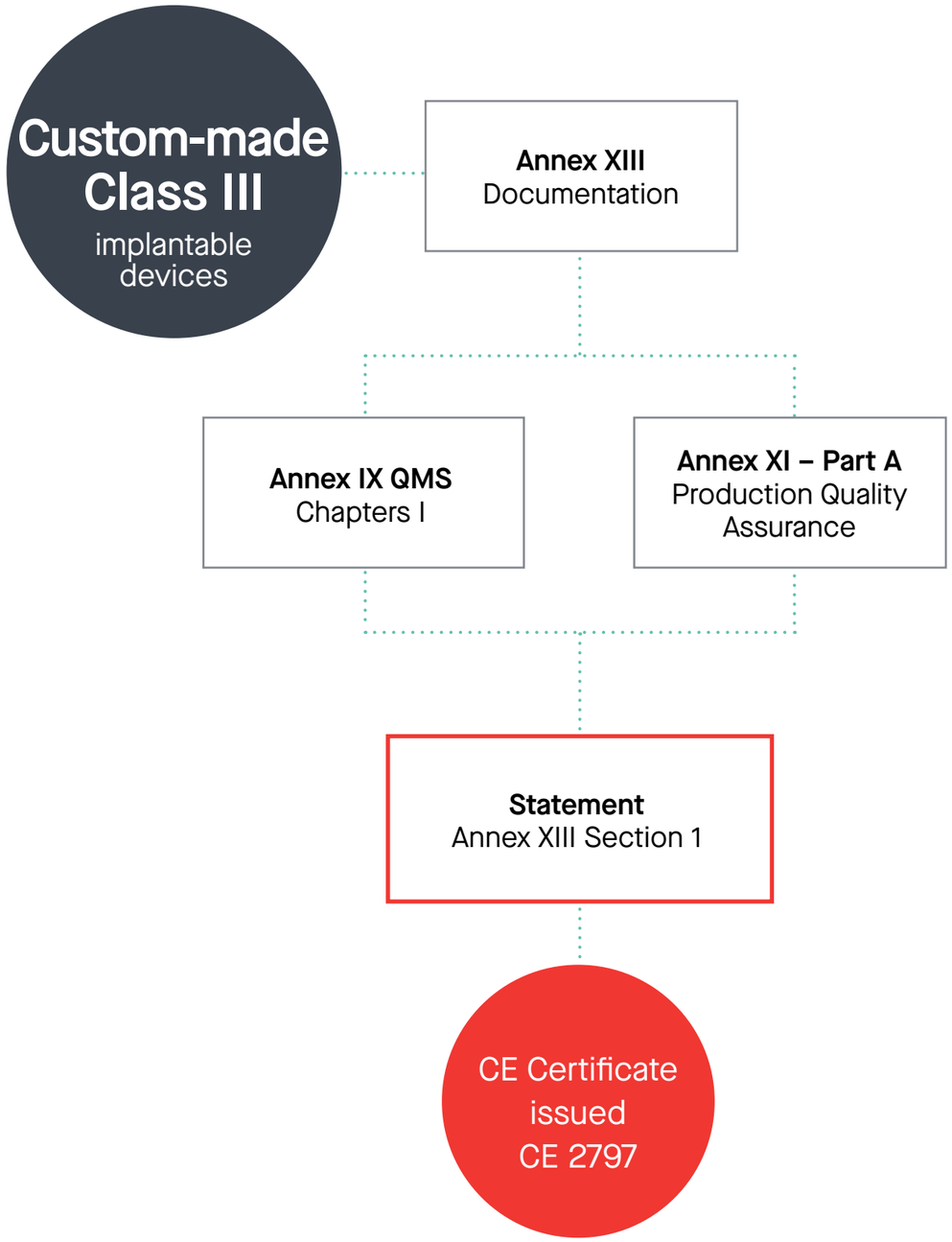
Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

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

** 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

Custom-made Class III implantable devices



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

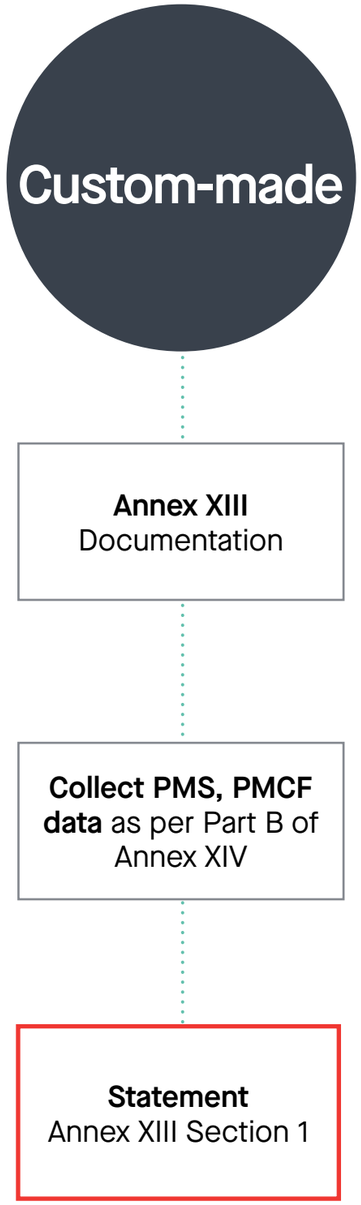
Custom-made Class III implantable devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Consultation Procedure (Article 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)	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	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

** 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

Custom-made devices

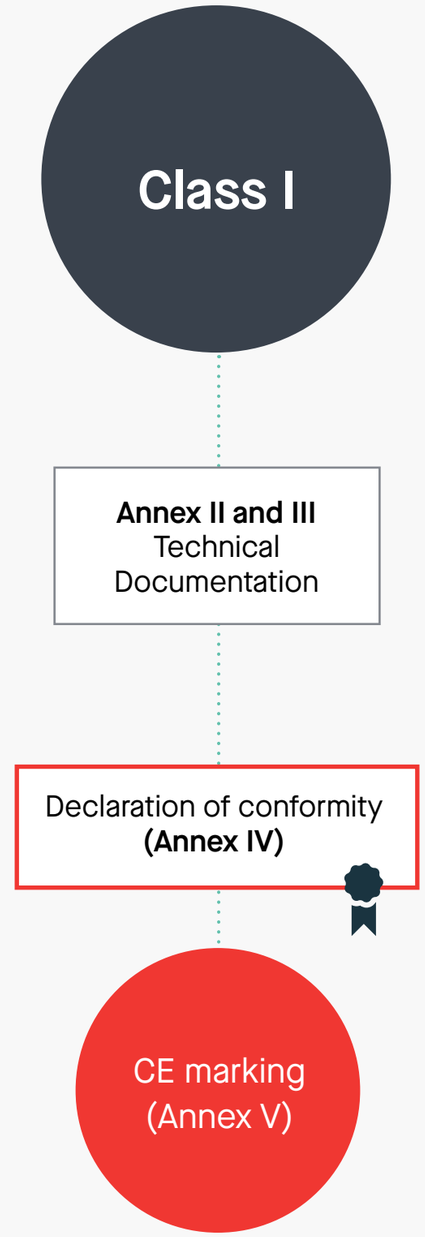
Excluding custom-made Class III implantable devices



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

Class I devices

Excluding Class Is, Ir, Im devices



Note: No Notified Body involvement

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

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- 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

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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.

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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 +44 345 080 9000 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.

BSI UK Approved Body (0086)

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