MDR Conformity Assessment Routes

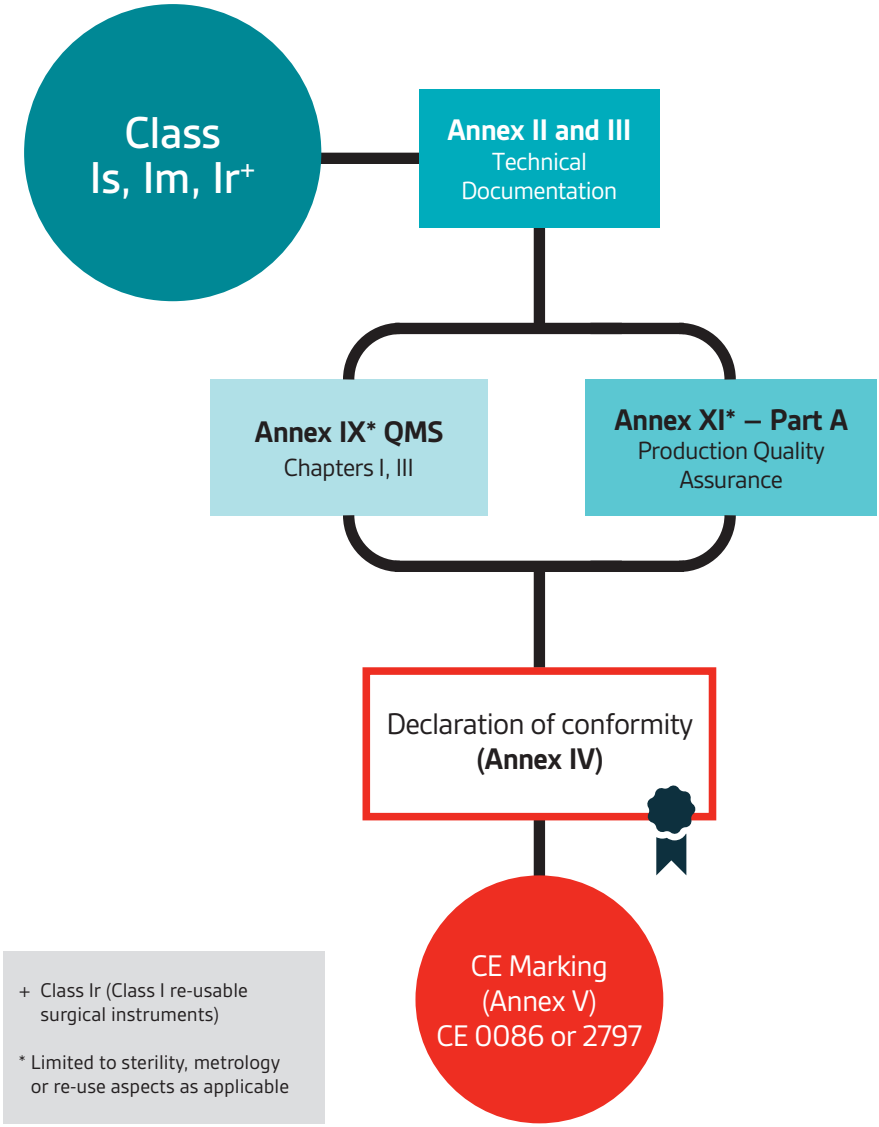
Notified Body Assessments

Contents

DISCLAIMERS:
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

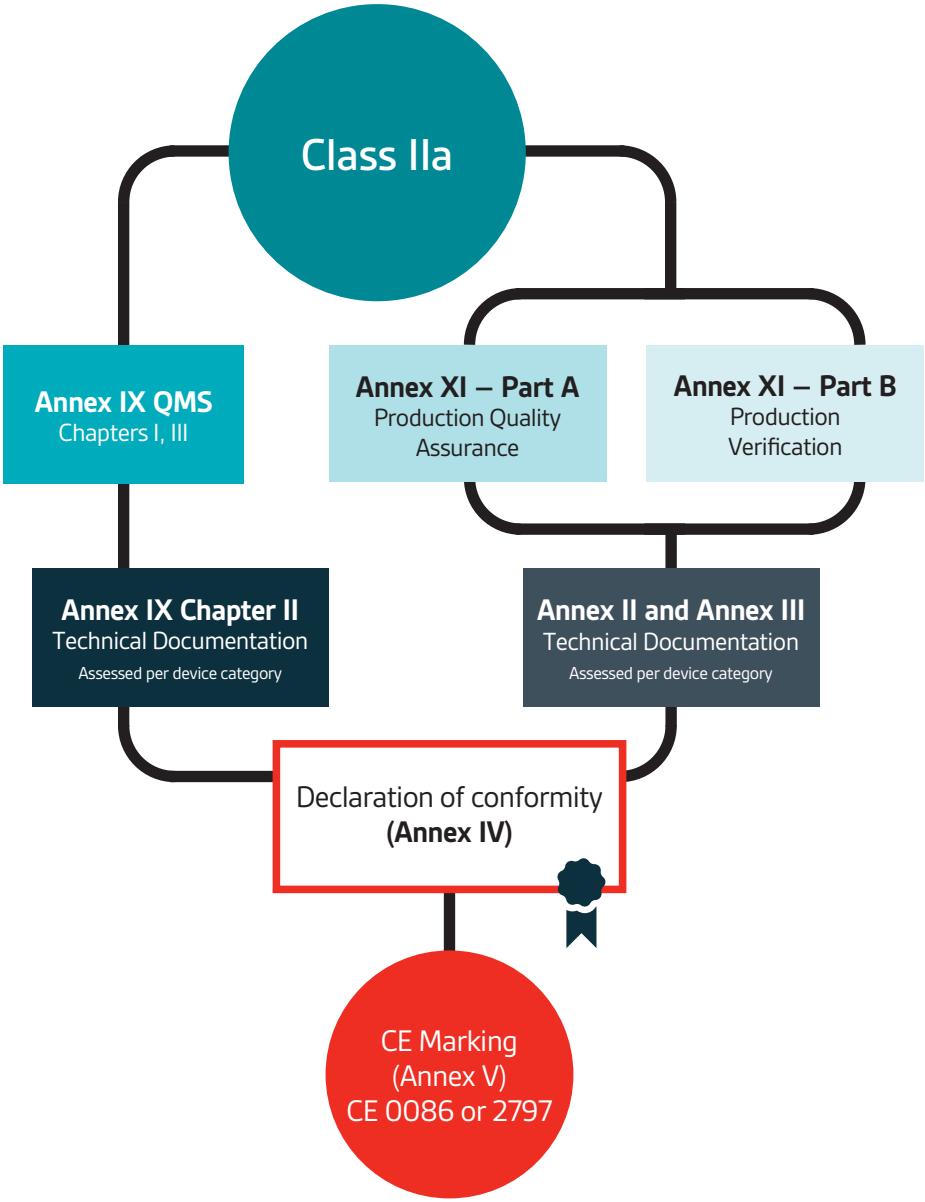
CLASS Is/Im/Ir DEVICES

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	Yes*	N/A	Yes*	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

*if sterile or re-usable surgical instruments

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; NB QMS audits to verify implementation of the plan by sampling complaints, vigilance information etc.				
Periodic Safety Update Report (Article 86)	N/A	N/A	N/A	N/A	N/A
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 5 years				

Class IIa devices



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 (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	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; NB 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; NB to review as per Technical Documentation Sampling Plan
Periodic Safety Update Report (Article 86)	PSUR update required at least once every 2 years; NB to review as per Technical Documentation Sampling Plan
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 5 years

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Class IIa devices continued

CLASS IIa IMPLANTABLE DEVICES

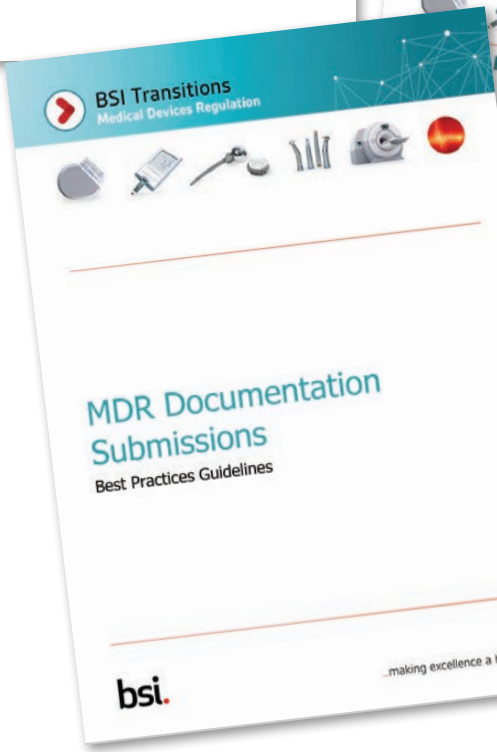
Class IIa implantable devices	Initial Conformity Assessment	SURVEILLANCE				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert	Yes	Yes
Microbiology Audits	Yes (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	N/A
Technical Documentation Assessment	Sample per category of devices	As per the Technical 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"; NB 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; NB 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; NB 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 NB via EUDAMED for NB review
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 3 years

General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation

Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive

Laurel Macomber, Senior Manager, Medical Operations Shared Services, DePuy Synthes, and Alexandra Schroeder, Product Expert, Vascular Devices Certification, BSI

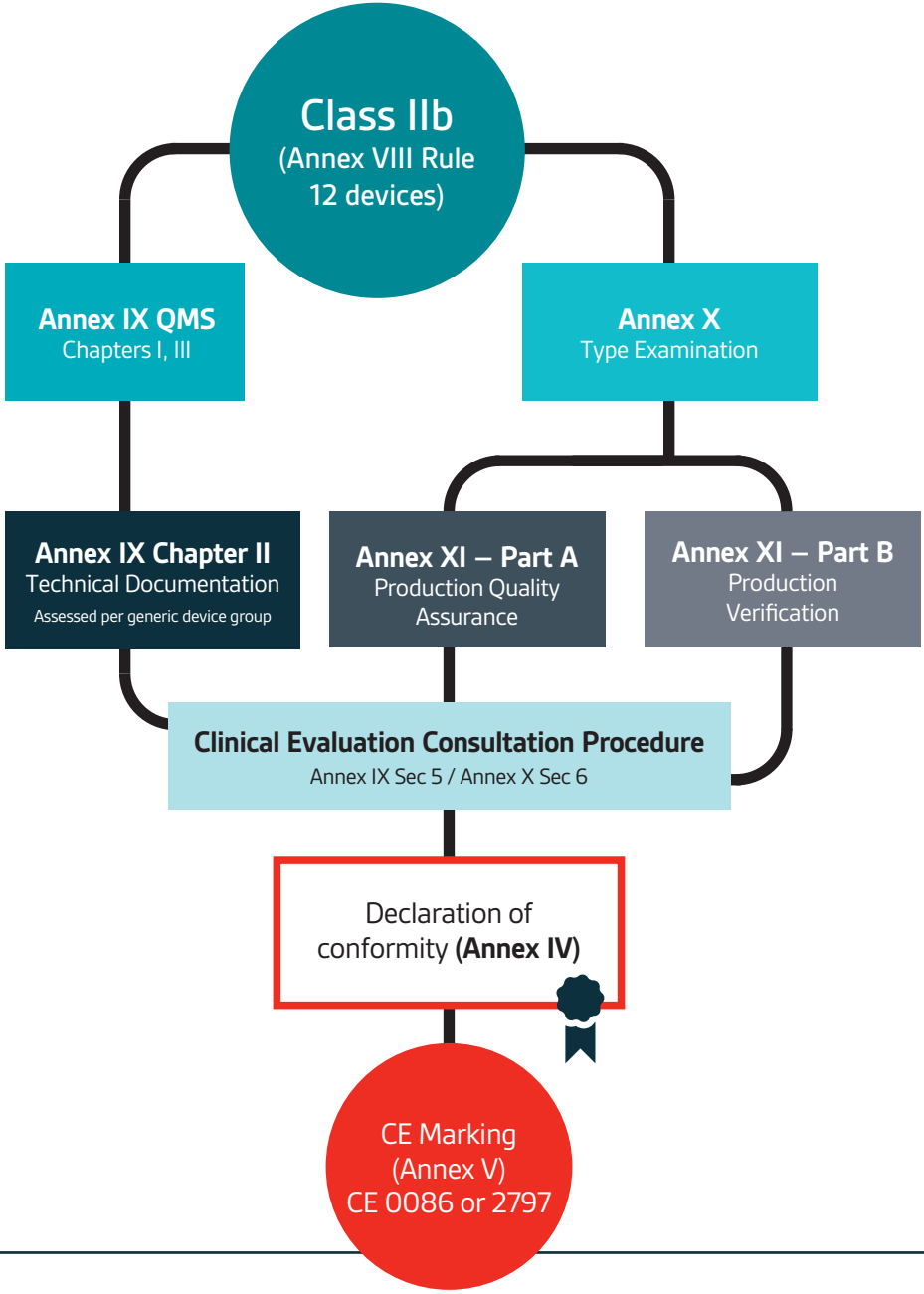


Our website offers a wealth of useful resources including white papers, guidance documents and webinars.

To find out more, visit

bsigroup.com/medicaldevices

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.

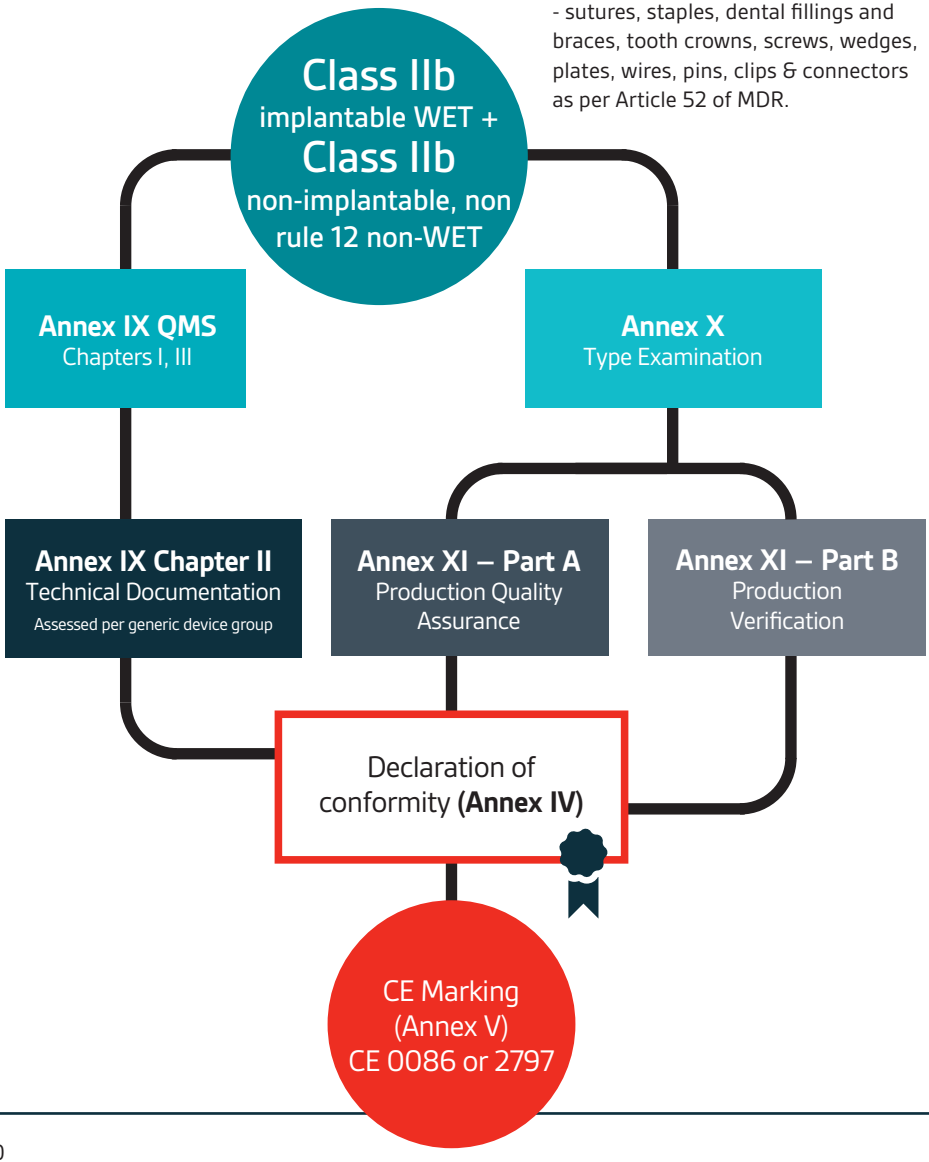
CLASS IIb ANNEX VIII RULE 12 DEVICES

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 (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				
Clinical Evaluation Consultation Procedure (Article 54)	Yes, but exemptions may apply as per Article 54.2	Maybe 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; NB 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; NB to review updates as per Technical Documentation Sampling Plan
Periodic Safety Update Report (Article 86)	Updated at least annually; NB to review updates as per Technical Documentation Sampling Plan
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 5 years

Class IIb implantable WET
Class IIb 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

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 (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				
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"; NB 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; NB to review as per Technical Documentation Sampling Plan
Post Market Clinical Follow-Up Update Report (Article 61)	Updated at least annually; NB 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 NB via EUDAMED for NB review (assuming WET devices are implantable devices)
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 3 years

Continued on page 12

CLASS IIb NON-IMPLANTABLE, NON WET, NON RULE 12

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 (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				
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; NB 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; NB to review updates as per Technical Documentation Sampling Plan
Periodic Safety Update Report (Article 86)	Updated at least annually; NB to review updates as per Technical Documentation Sampling Plan
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 5 years

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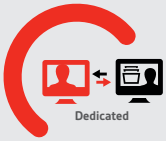
The CE-Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert via phone and email, as required.



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 technical documentation. This allows you to interact with your BSI expert, providing them information during the review. The CE-Dedicated service improves the efficiency of the process, and provides predictability in your planning of the review.

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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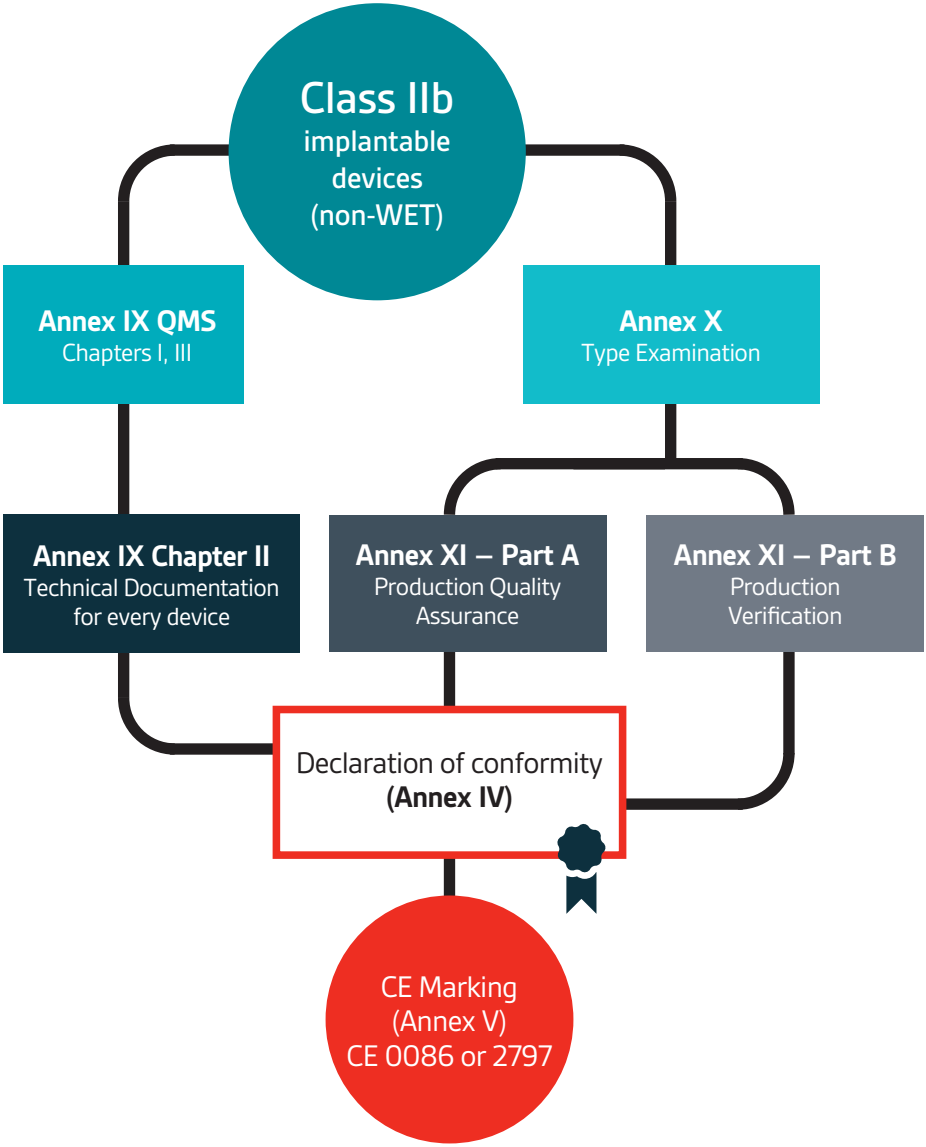
Class IIb implantable devices
(excluding WET)



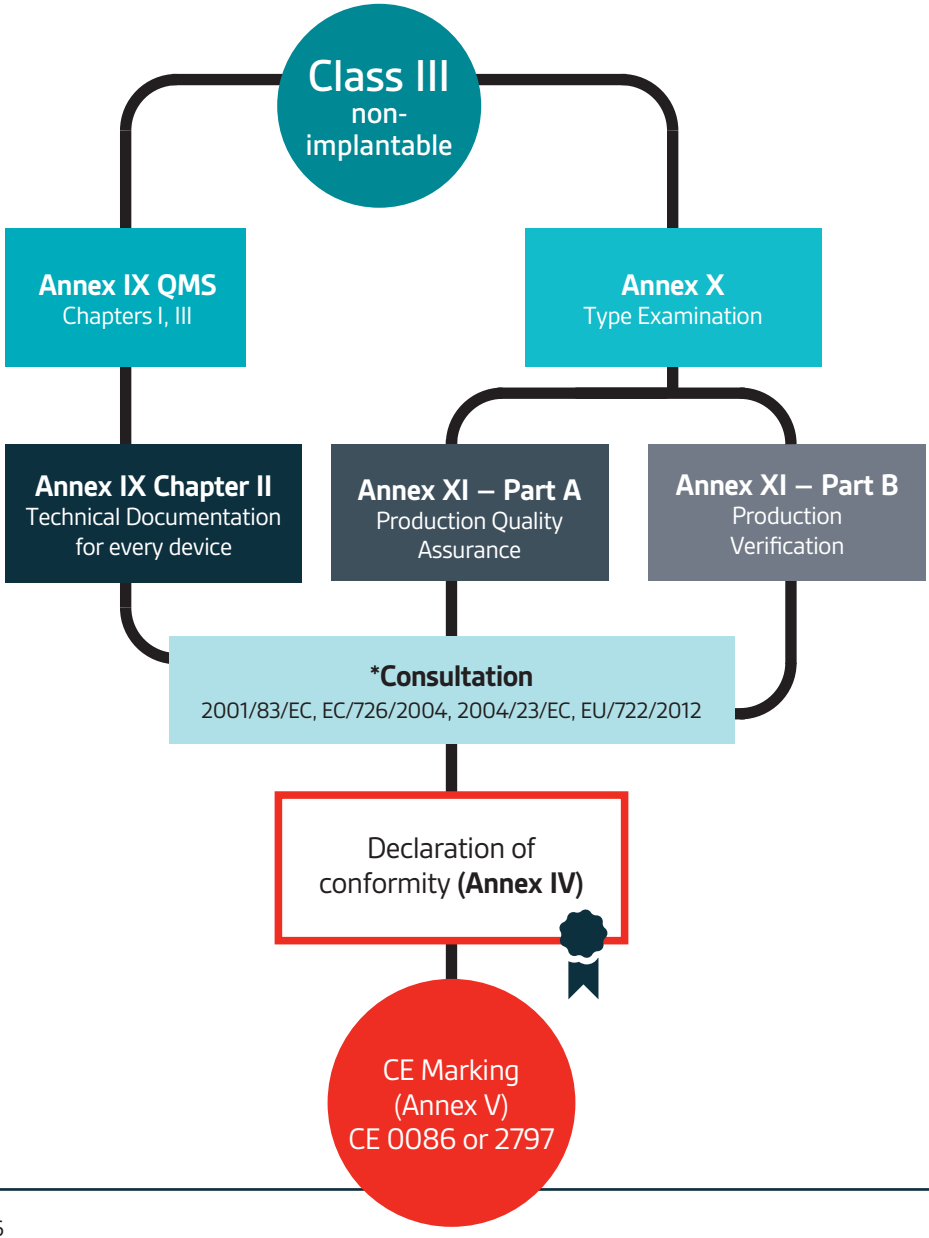
CLASS IIb IMPLANTABLE NON-WET DEVICES

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 (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	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"; NB to review at the time of PSUR reviews or substantial change reviews				

Clinical Evaluation Report updates	Updated as per Manufacturer's clinical evaluation plan; NB 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; NB to review at the time of PSUR reviews or substantial change reviews
Periodic Safety Update Report (Article 86)	Updated at least annually; submitted to NB via EUDAMED for NB review
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 3 years

Class III non-implantable devices

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



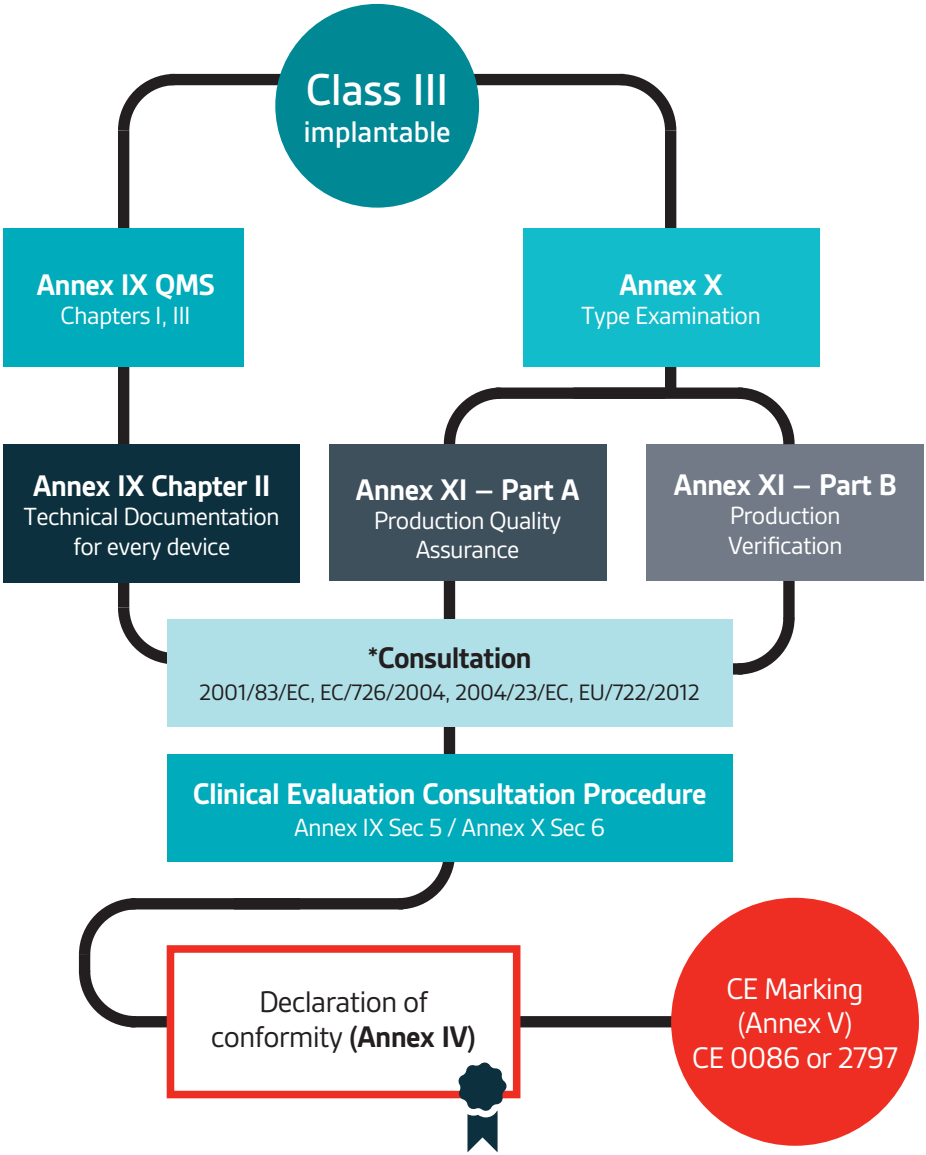
CLASS III NON-IMPLANTABLE DEVICES

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 (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	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"; NB to review at the time of PSUR reviews or substantial change reviews				

Clinical Evaluation Report Updates	Updated as per Manufacturer's clinical evaluation plan; NB 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; NB to review at the time of PSUR reviews or substantial change reviews
Periodic Safety Update Report (Article 86)	Updated at least annually; submitted to NB via EUDAMED for NB review
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 3 years

Class III Implantable devices

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

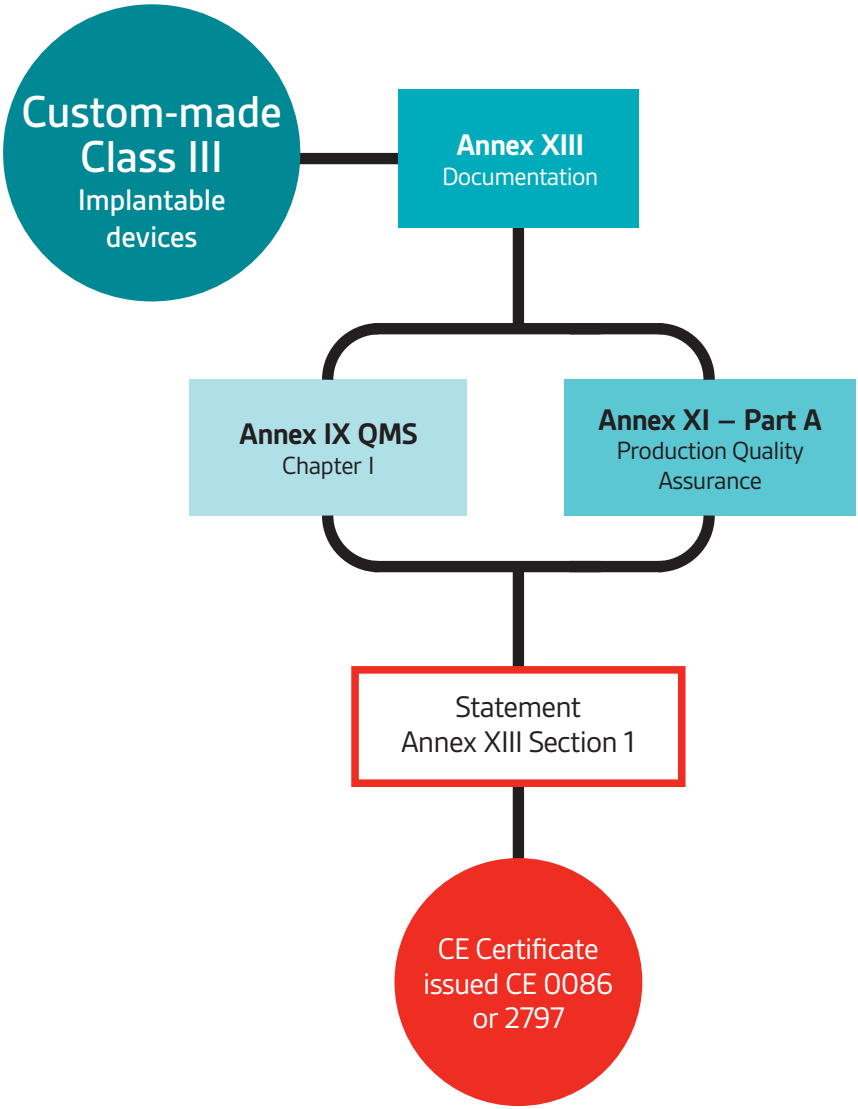


CLASS III IMPLANTABLE DEVICES

Class III implantable devices	Initial Conformity Assessment	SURVEILLANCE				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert	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	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"; NB to review at the time of PSUR assessments or substantial change reviews				

Clinical Evaluation Report Updates	Updated as per Manufacturer's clinical evaluation plan; NB 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; NB review at the time of PSUR reviews or substantial change reviews
Periodic Safety Update Report (Article 86)	Updated at least annually; submitted to NB via EUDAMED for NB review
Unannounced Audits (BSI policy as of Feb 2019)	At least once every 3 years

Custom-made Class III implantable devices



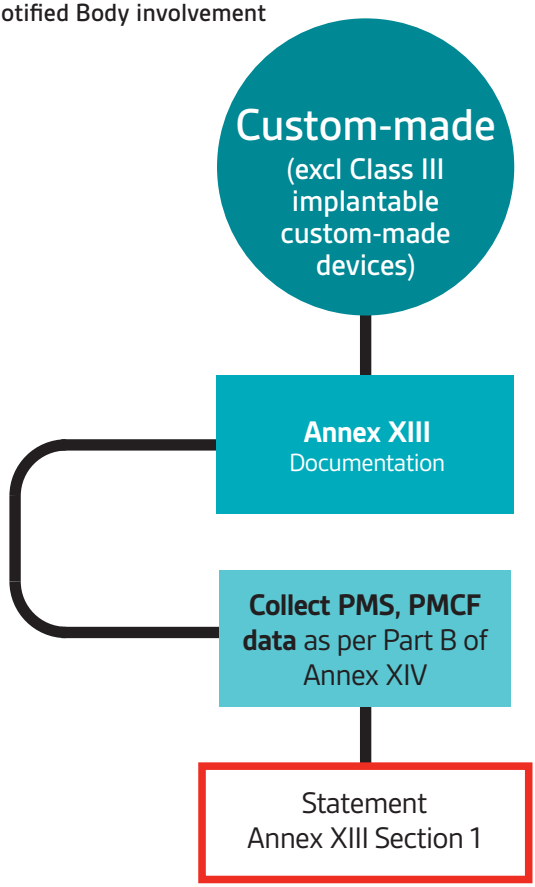
CUSTOM-MADE CLASS III IMPLANTABLE DEVICES

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 (if sterile)	N/A	Yes (if sterile)	N/A	Yes (if sterile)	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
Post Market Clinical Follow-Up Update Report (Article 61)		As per Manufacturer's PMS, PMCF plans; NB QMS audits to verify implementation of the plan				
Periodic Safety Update Report (Article 86)		Updated at least annually; unclear whether to be submitted to EUDAMED for NB review or not; NB to verify updates at the time of surveillance QMS audits				
Unannounced Audits (BSI policy as of Feb 2019)		At least once every 3 years				

Custom-made devices

(excluding custom-made Class III implantable devices)

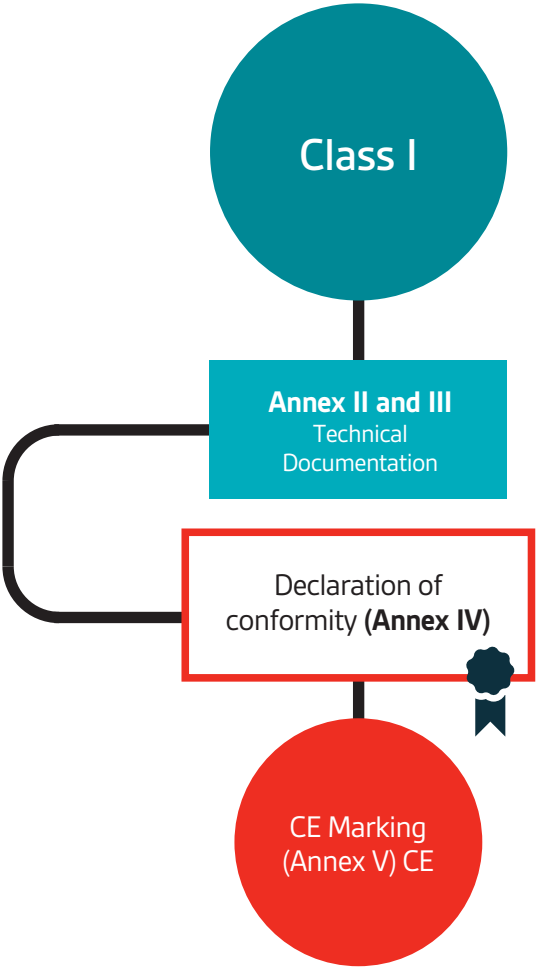
Note: No Notified Body involvement



Class I devices

(excluding Class Is/Im/Ir devices)

Note: No Notified Body involvement



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