Medical Device Regulation (EU 2017/745) – Conformity Assessment Routes

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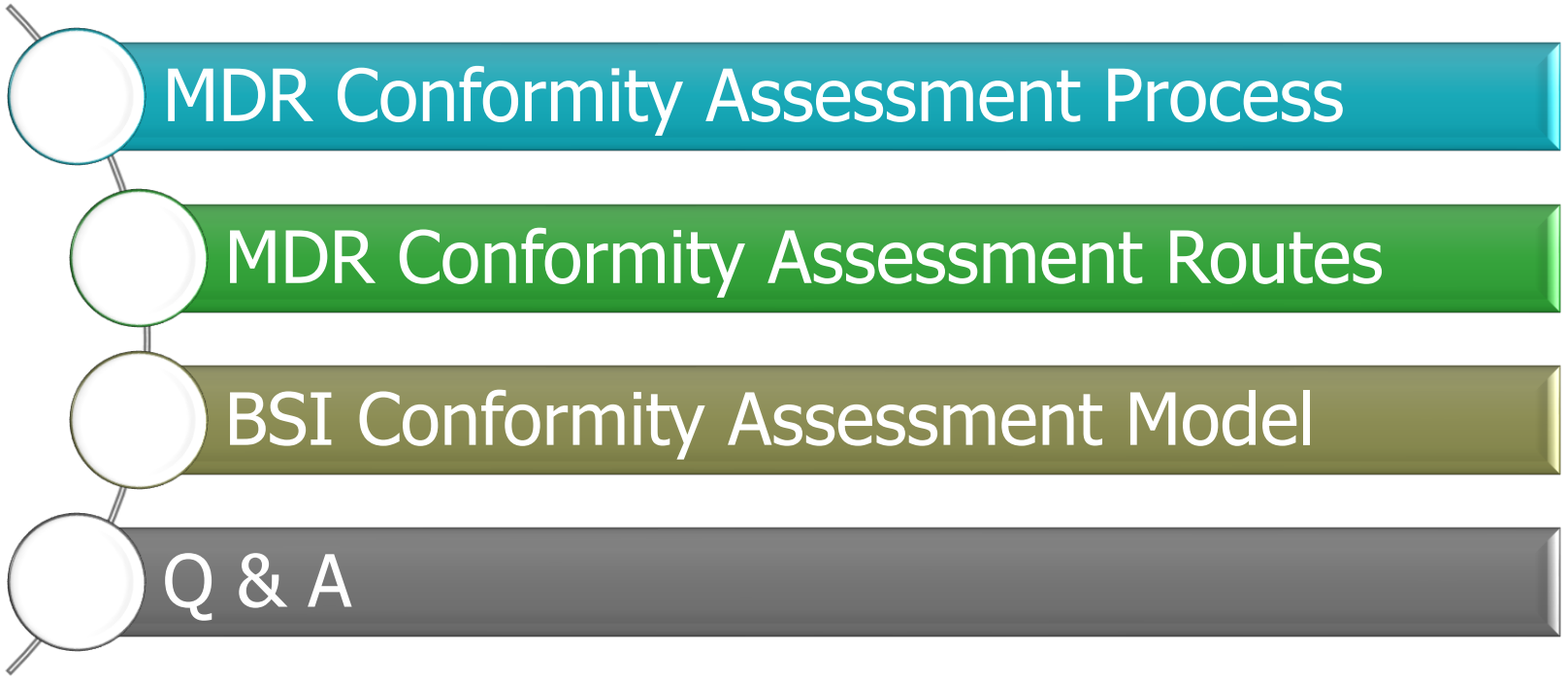
By Royal Charter

Agenda



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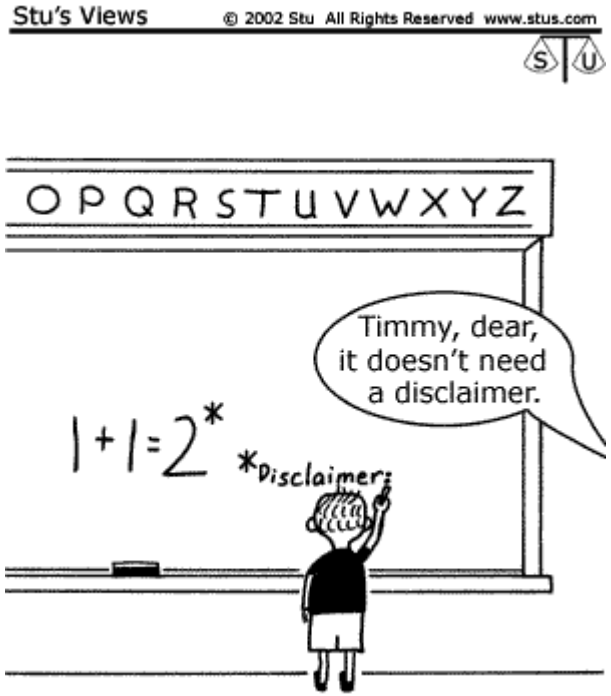

- Information presented within this webinar is based on our current understanding of the MDR
- Subject to change

Conformity Assessment Process

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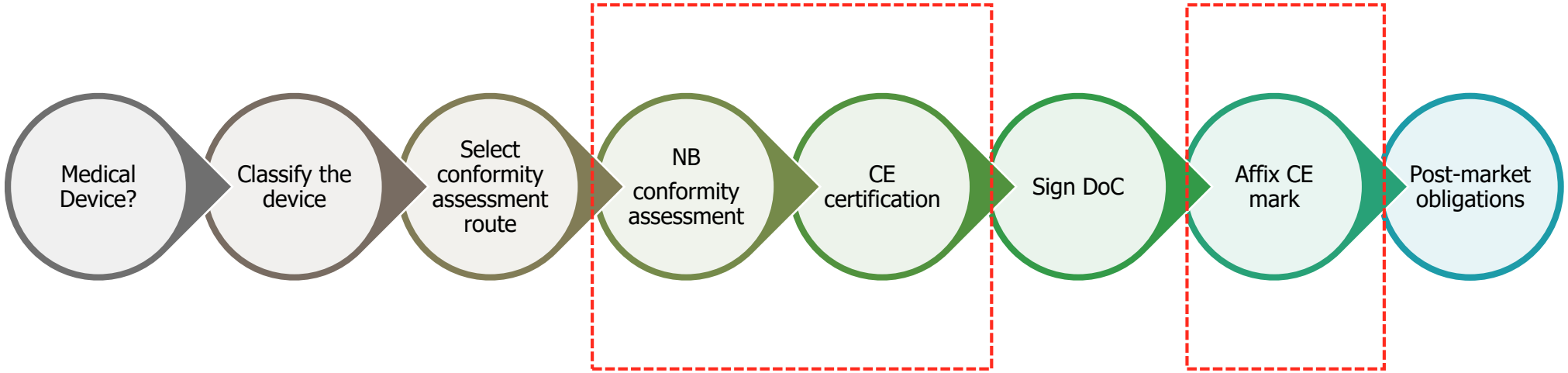
MDR – Conformity Assessment Process



If required as per the legislation

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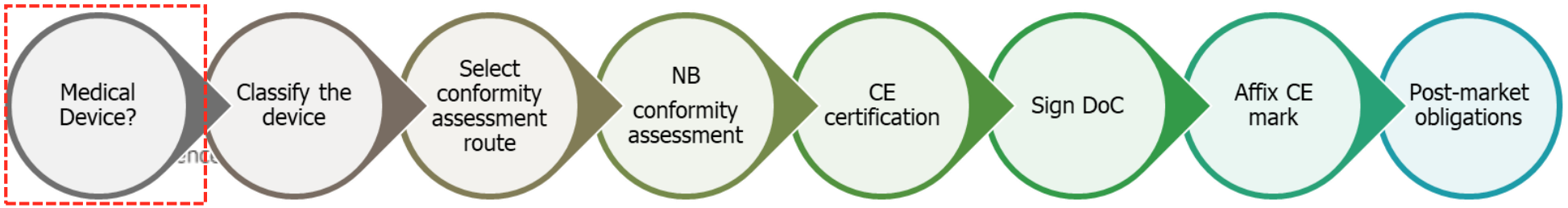
Does a product fall within the scope of the MDR?

- Articles 1 & 2 of MDR are key:
  - identify the inclusions and exclusions
  - Provide various definitions
  - Does the product fall within the definitions and scope?
    - If not, the product outside the scope of Regulation



What is a Medical Device? (Article 2.1)

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

For Humans

As intended by the manufacturer

Principal mode of action is not pharmacological, immunological, metabolic

Just as a reminder..

- The following devices/products need MDR certificates by 26 May 2020 for continued market viability

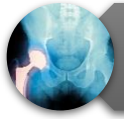

Class I re-usable surgical instruments


Software that was Class I under MDD and now up-classified


Devices utilising Human-tissue derivatives


Devices without a medical purpose – Annex XVI


Article 117 Drug/Device combinations


Custom-made Class III implants

~10 months left!

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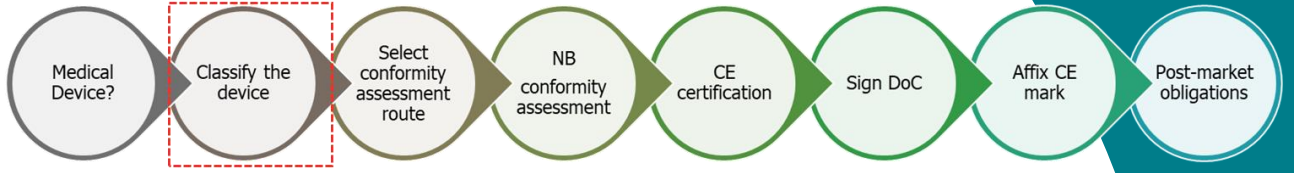
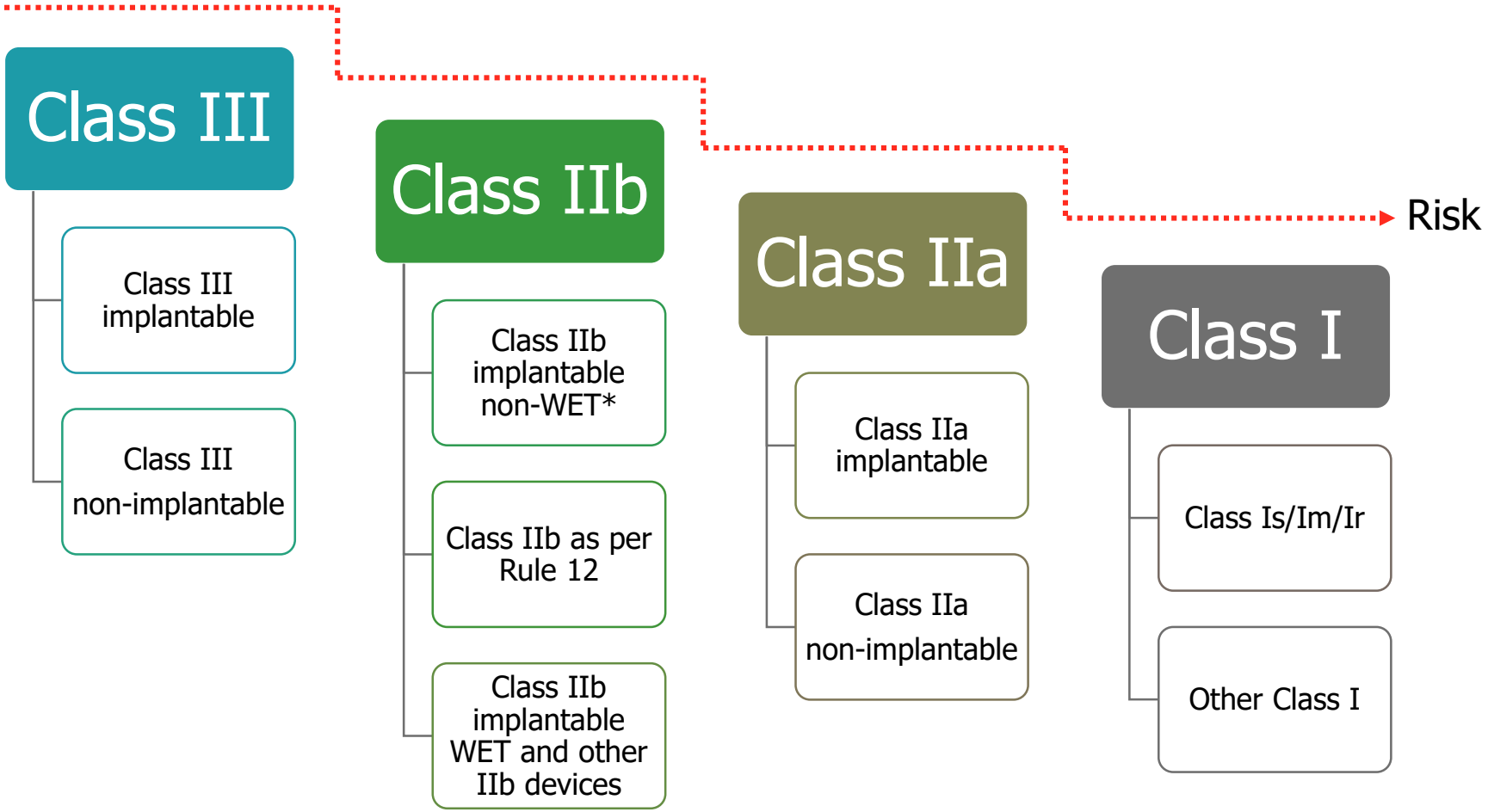
Classification under MDR

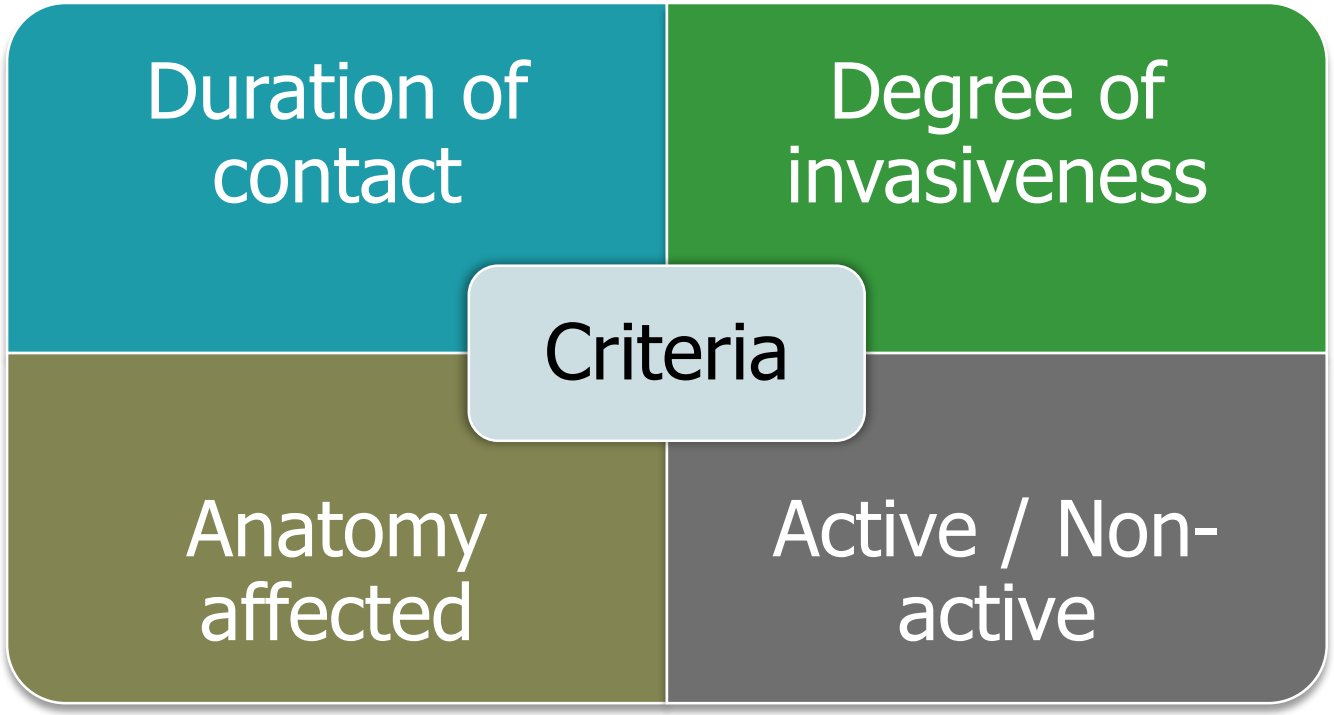




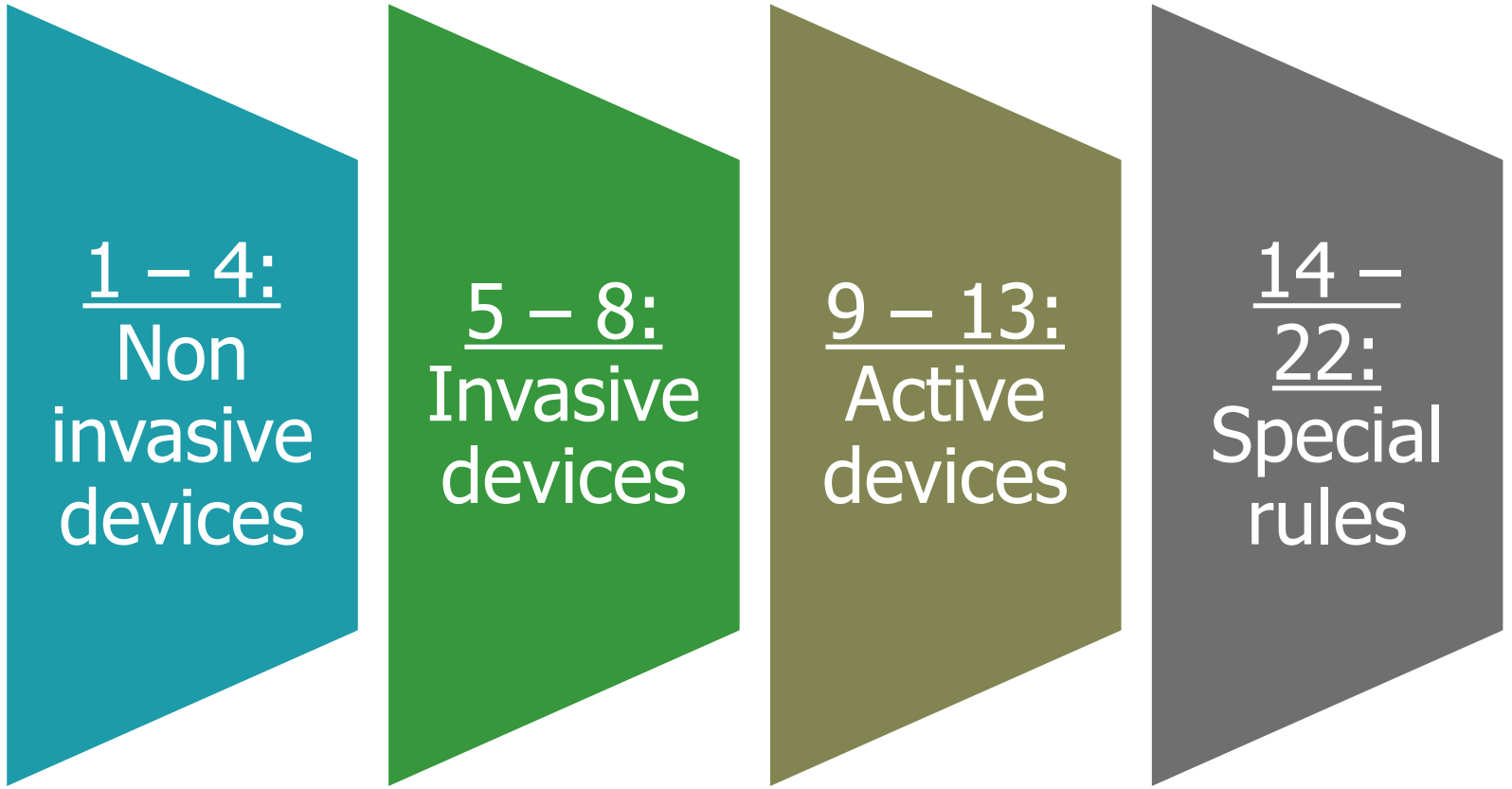
*WET – Well-established technologies (Article 52.4) - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

Annex VIII: Classification Rules

… Para 3.1: *"Application of the classification rules shall be governed by the intended purpose of the devices"*



Annex VIII: Classification Rules



Conformity Assessment Routes

Conformity Assessment

- *'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled – Article 2.40*

Requirements, and conformity assessment routes

– Articles 52, 54; Annexes IX, X, XI,

Dependent on device classification and some additional features (implantable; contains animal, human, medicinal substances etc)

Conformity assessment

Quality system based

+

Product assessment based

Special cases – Article 22, Annex XIII, Annex XV, Article 117

More than one route may be available for a given classification

Manufacturer chooses the conformity assessment route

NB to verify appropriateness and assess against the chosen annexes

Quality System Assessment Annexes

Annex IX, excl. Chapter II (Quality Management System):

- Focus on full lifecycle of the device (Design, manufacture and final inspection)
- ISO 13485
- Ensures there is a valid design process and that the device is manufactured, tested and inspected in compliance with the technical documentation

Annex XI Part A (Production Quality Assurance):

- Focus on manufacture and final inspection (excluding design)
- ISO 13485 (excluding design)
- Ensures device is manufactured, tested or inspected in compliance with the technical documentation

Product Assessment Annexes

Annex IX Chapter II (Assessment of Technical Documentation)

- Technical Documentation submitted for examination
- NB examines documentation
- One-off examination
- + module to demonstrate consistency of manufacture

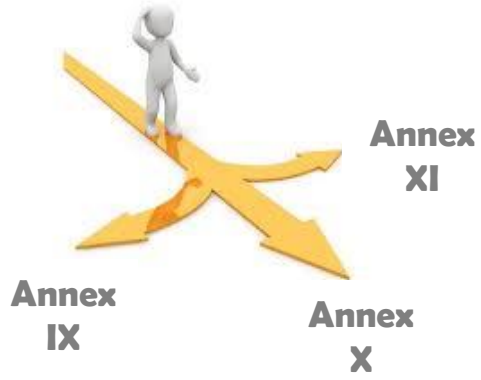
Annex X (Type Examination)

- Device + documentation submitted for examination
- NB tests device to check it meets a certain 'type' typically described in Harmonised standards
- + examines documentation
- One-off examination
- + module to demonstrate consistency of manufacture

Annex XI Part B (Product Verification)

- NB examines every individual device; Tests typically defined in harmonised standards
- Devices verified against Technical Documentation and EC type examination certificate if applicable

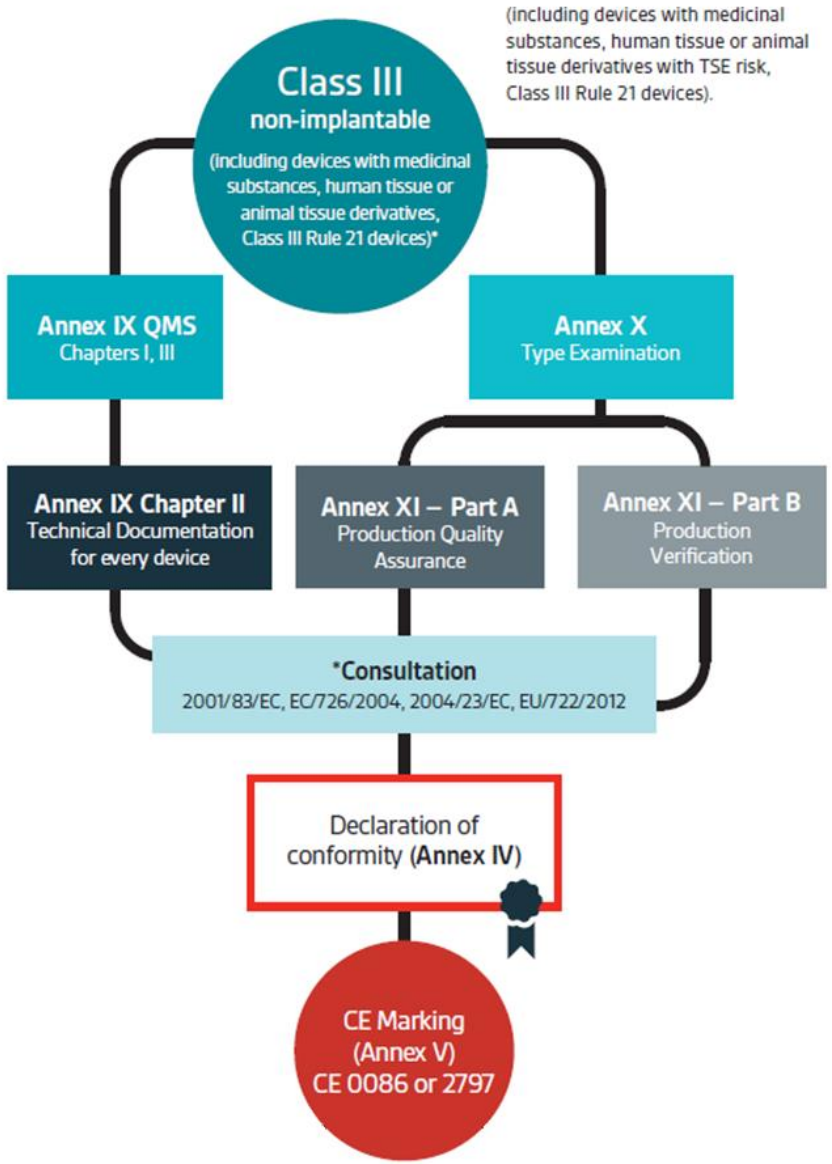
Conformity Assessment Routes



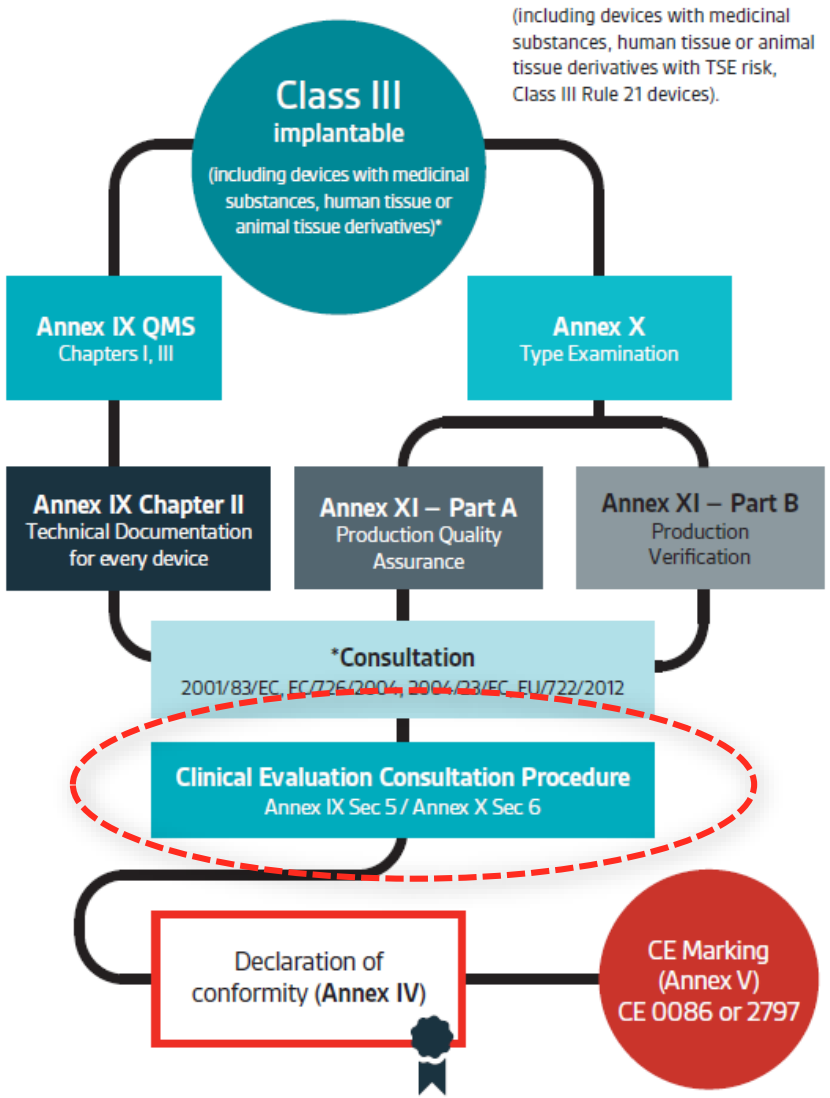
- MDD – MDR comparison

MDR	MDD	Focus of Annex
Annex IX Chapters I and III Quality Management System	Annex II excl Section 4 Full Quality Assurance	QMS based; Design, Manufacture, Final Inspection
Annex IX Chapter II Technical Documentation	Annex II Section 4 Design Examination	Product based; Documentation review
Annex X Type-Examination	Annex III Type Examination	Product based; Type testing + Doc review
Annex XI - Part B Product Verification	Annex IV Verification	Product based; Individual devices tested
Annex XI - Part A Production Quality Assurance	Annex V Production Quality Assurance	QMS based; Manufacture, Final Inspection
No equivalent	Annex VI Product Quality Assurance	QMS based; Final Inspection
Article 19 + Annex II, III	Annex VII Declaration of Conformity	For class I devices

Class III non-implantable devices



Class III Implantable devices



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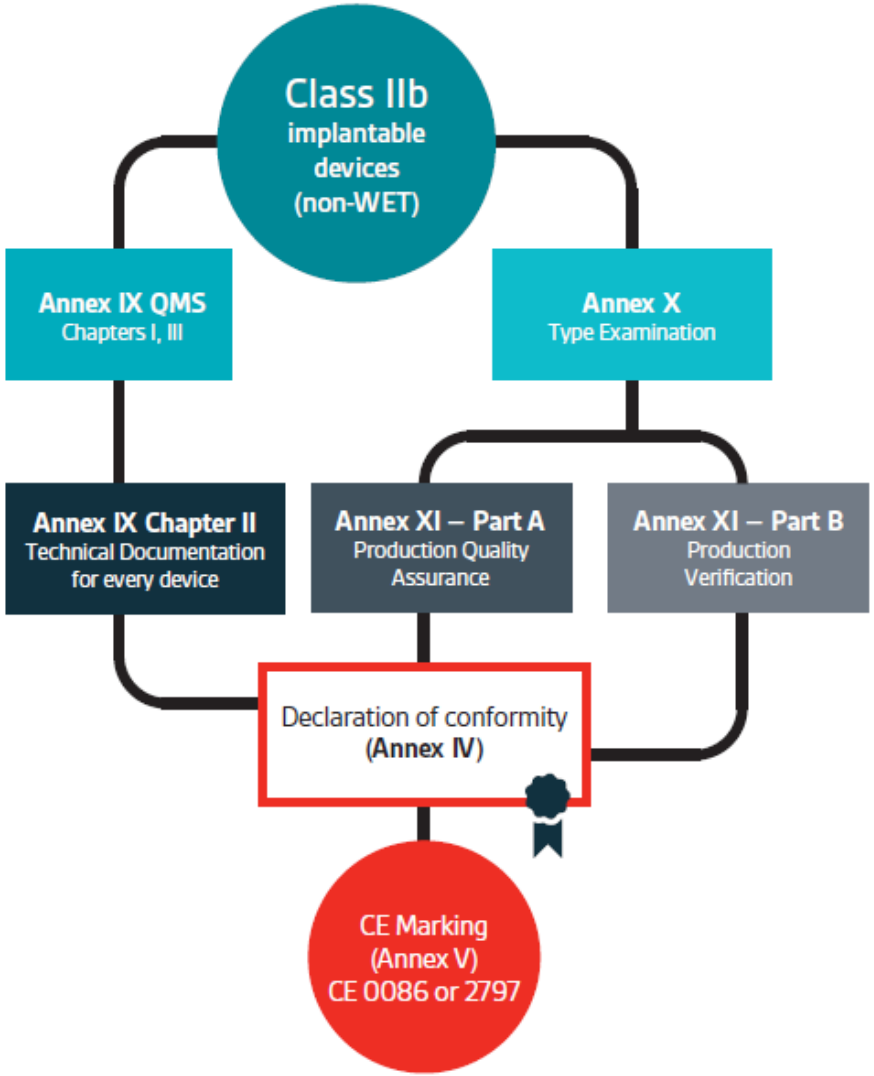
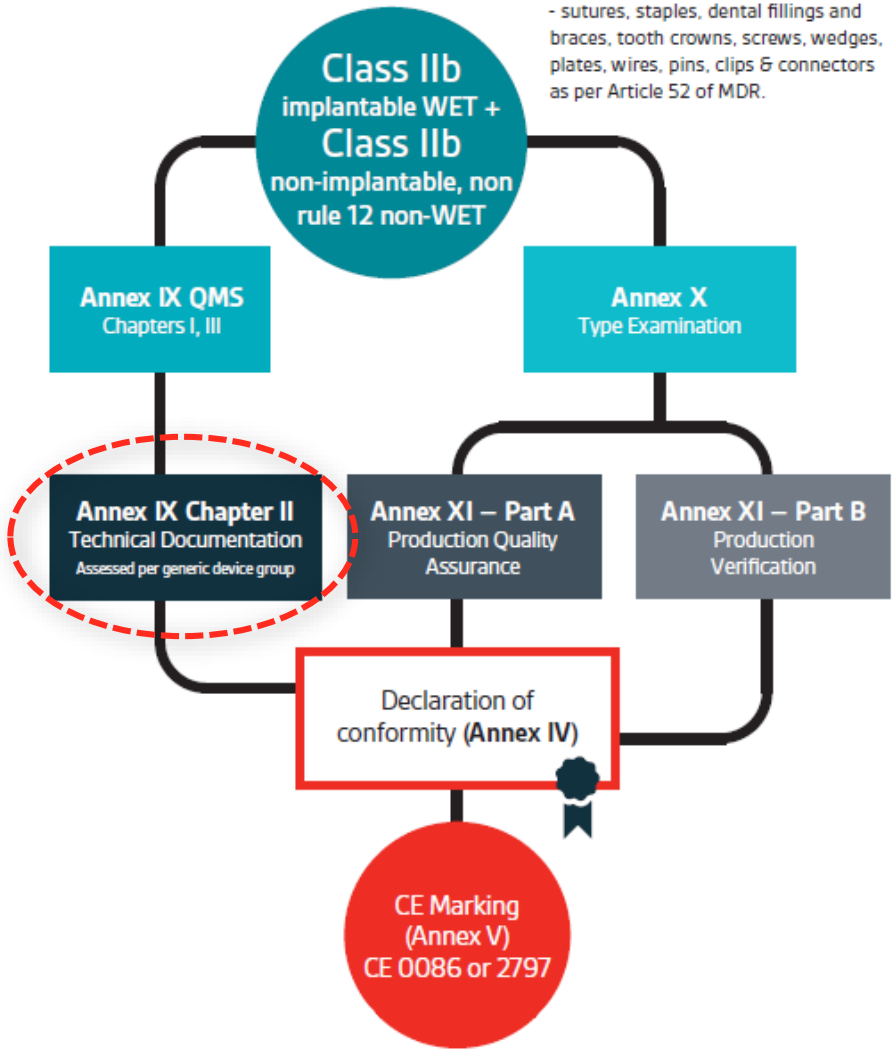
Class IIb implantable devices
(excluding WET)



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.



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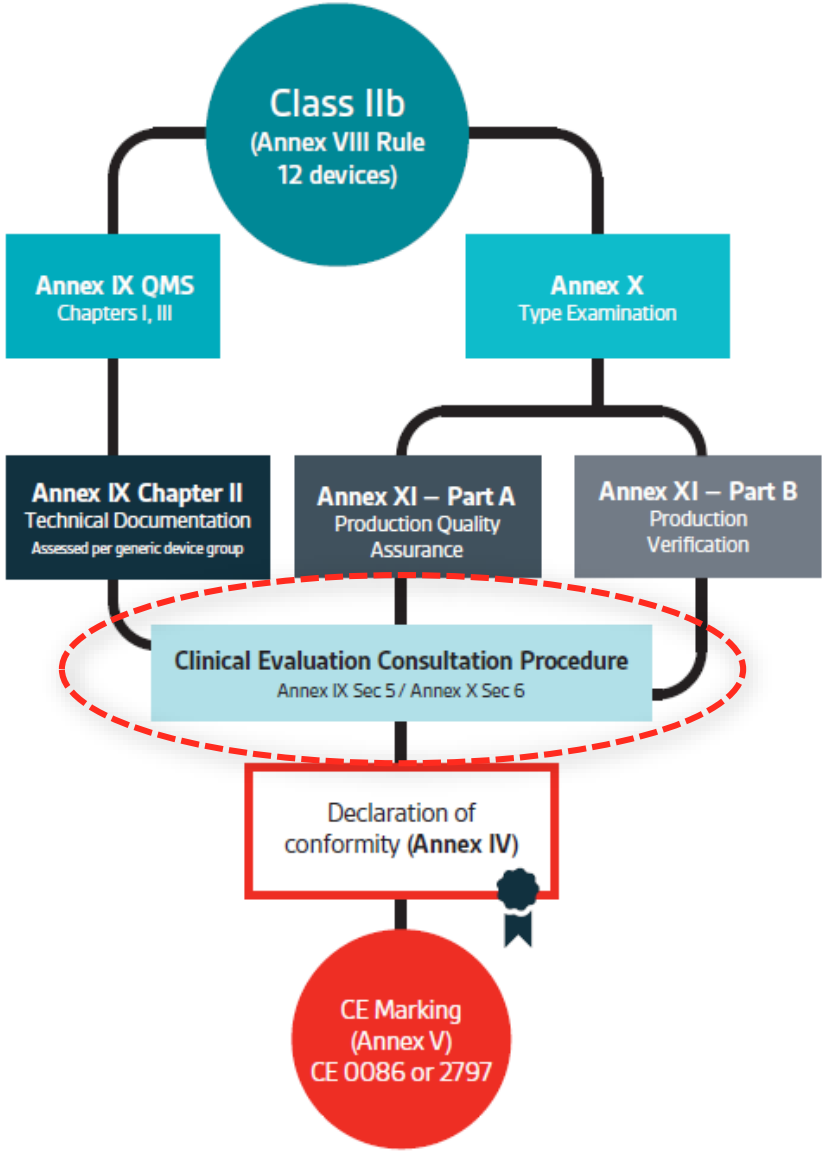
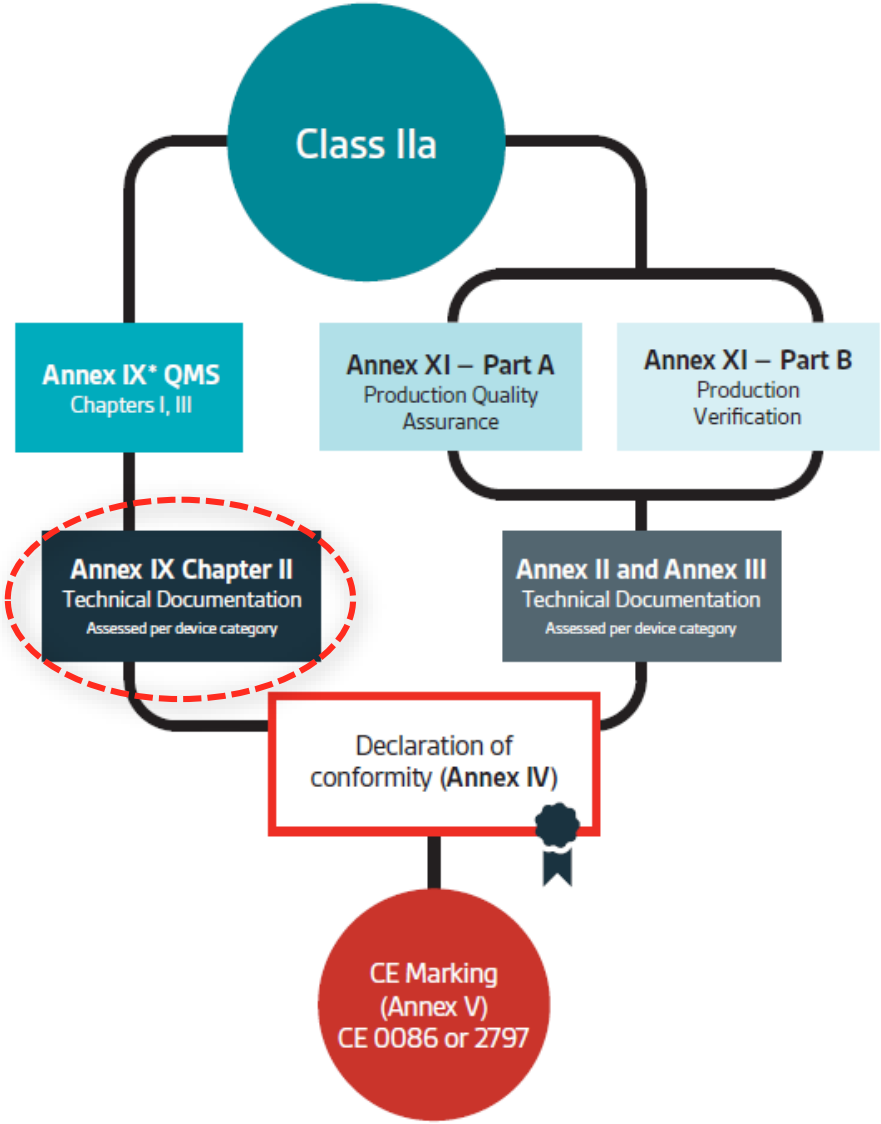
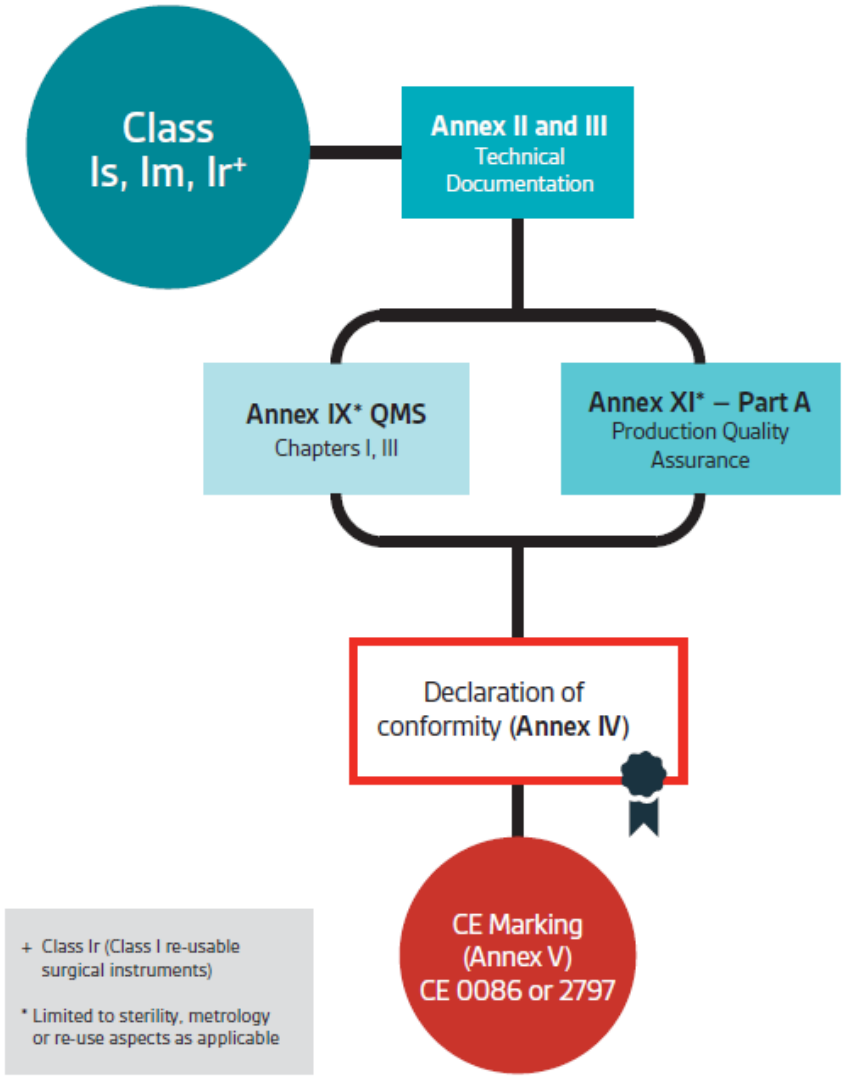
Class IIb Annex VIII Rule 12 devices



Class IIa devices



Class Is/Im/Ir devices

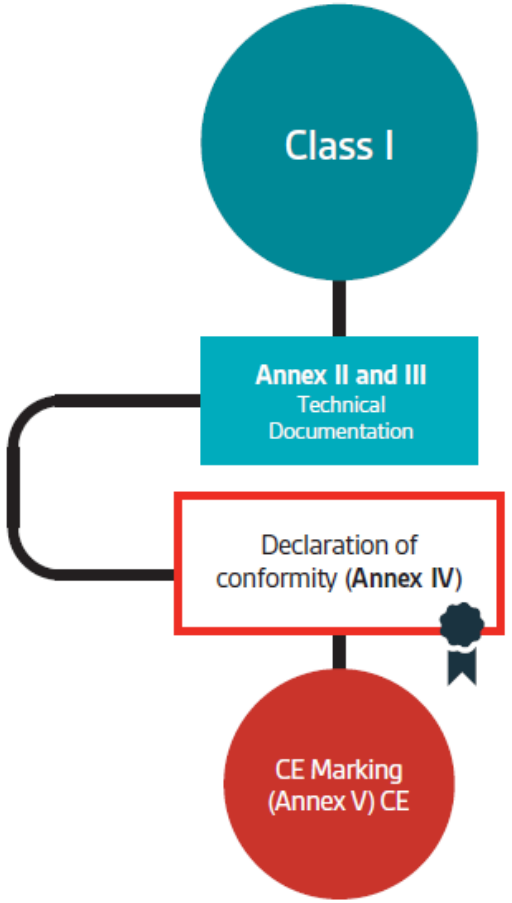


+ Class Ir (Class I re-usable surgical instruments)

* Limited to sterility, metrology or re-use aspects as applicable

Class I devices

(excluding Class Is/Im/Ir devices)



Note: No Notified Body involvement

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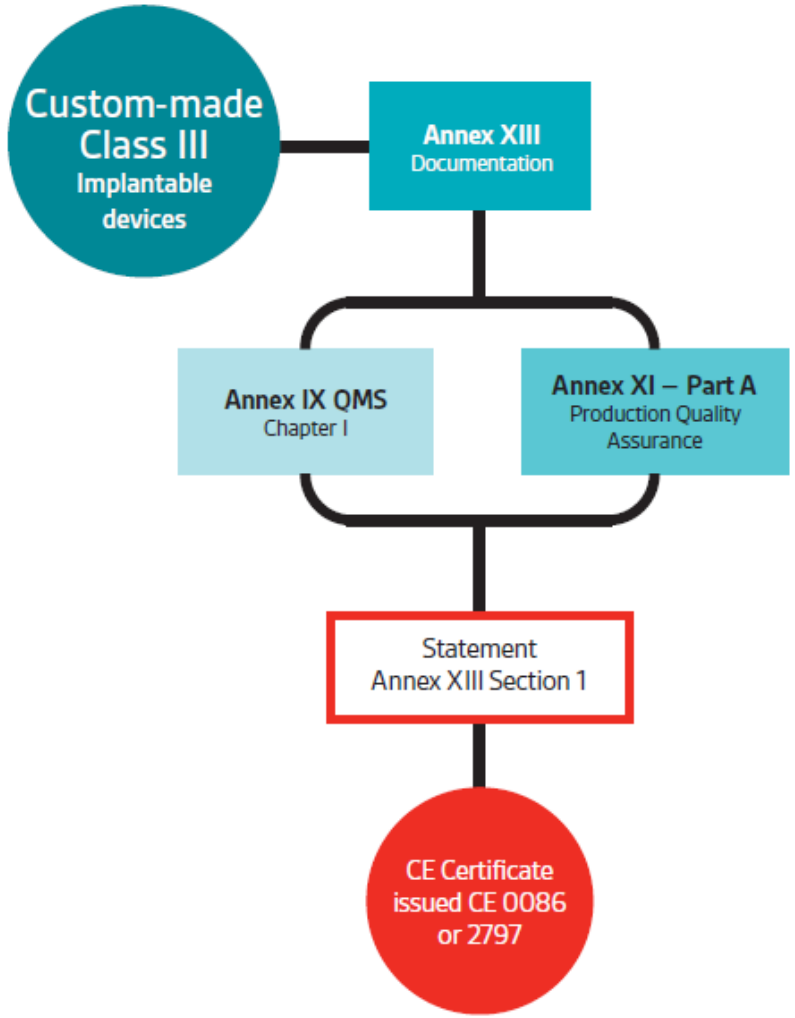
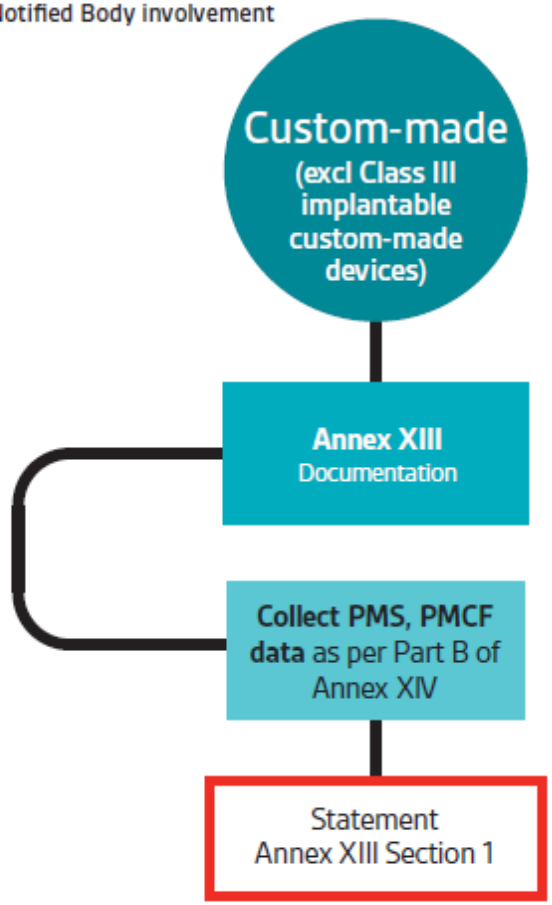
Custom-made Class III implantable devices



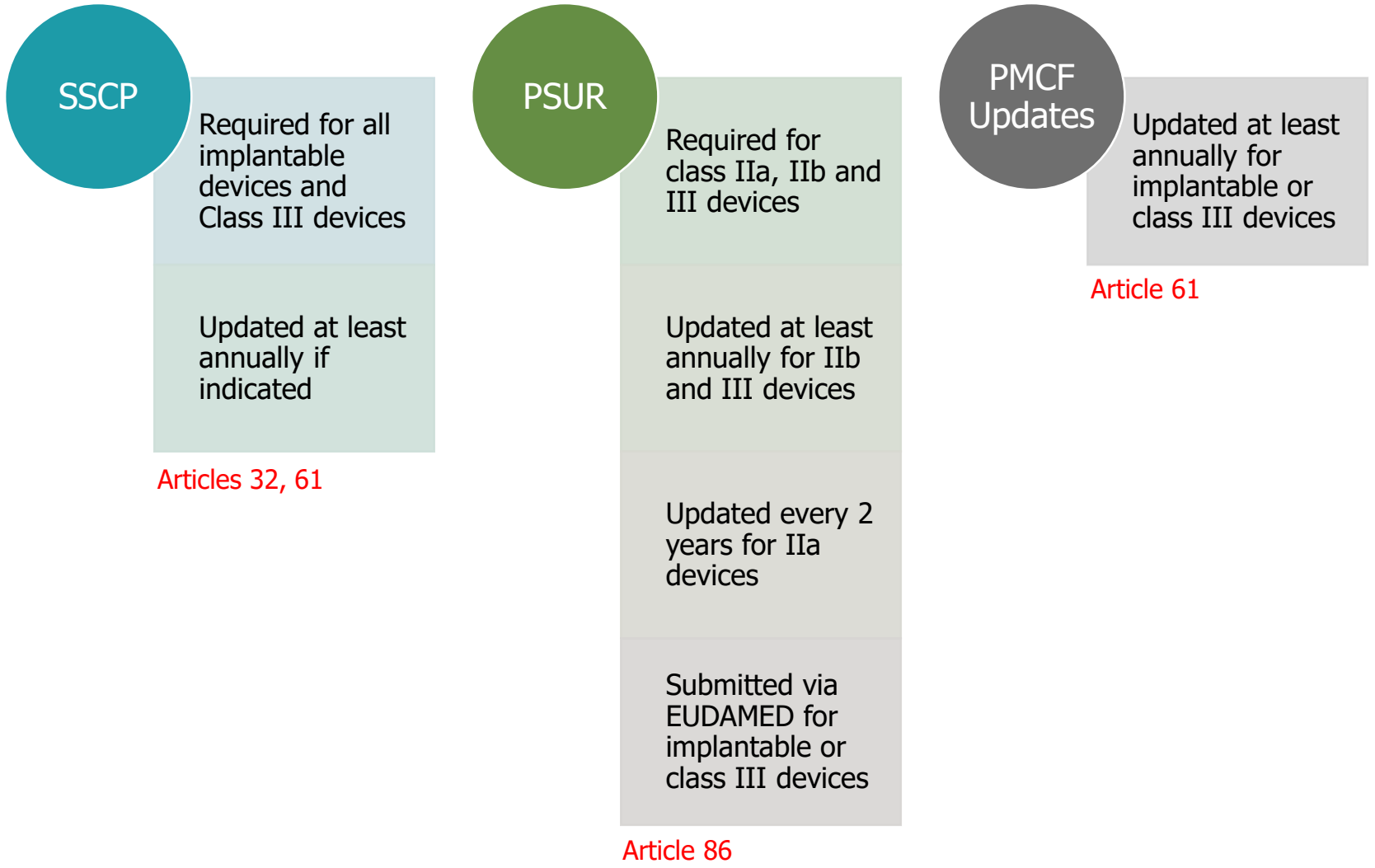
Custom-made devices

(excluding custom-made Class III implantable devices)

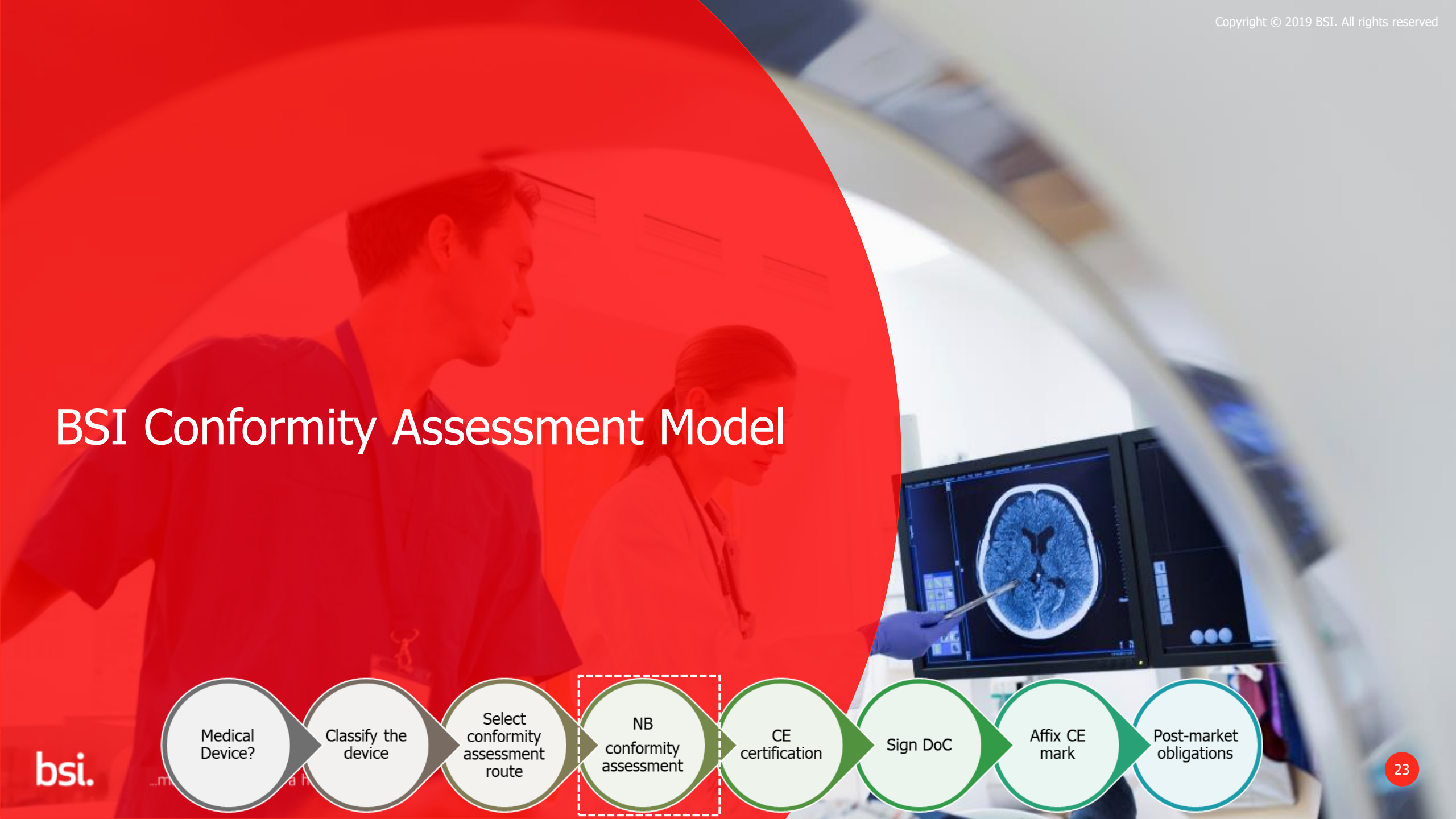
Note: No Notified Body involvement



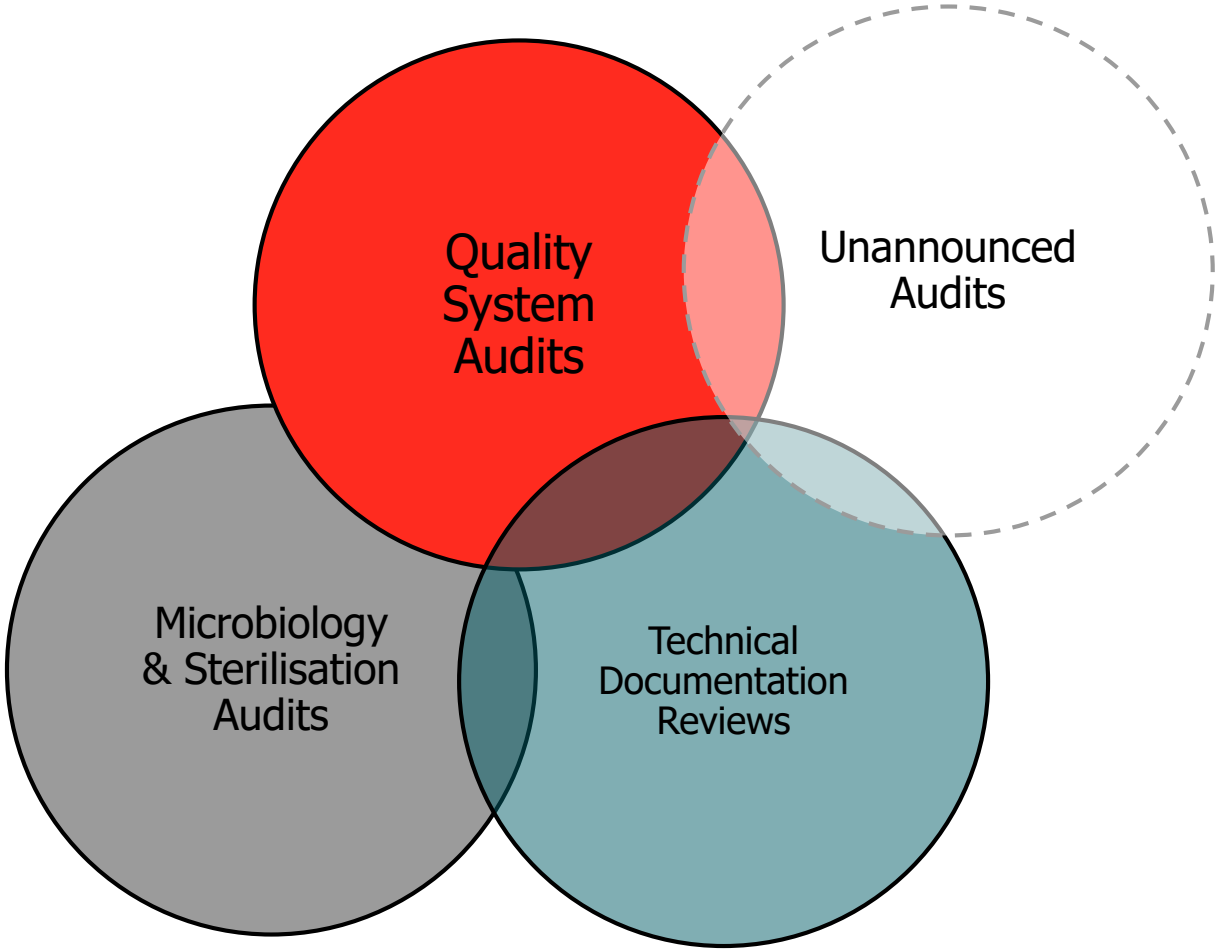
Some more pre-market and post-market requirements..



BSI Conformity Assessment Model



BSI conformity assessment

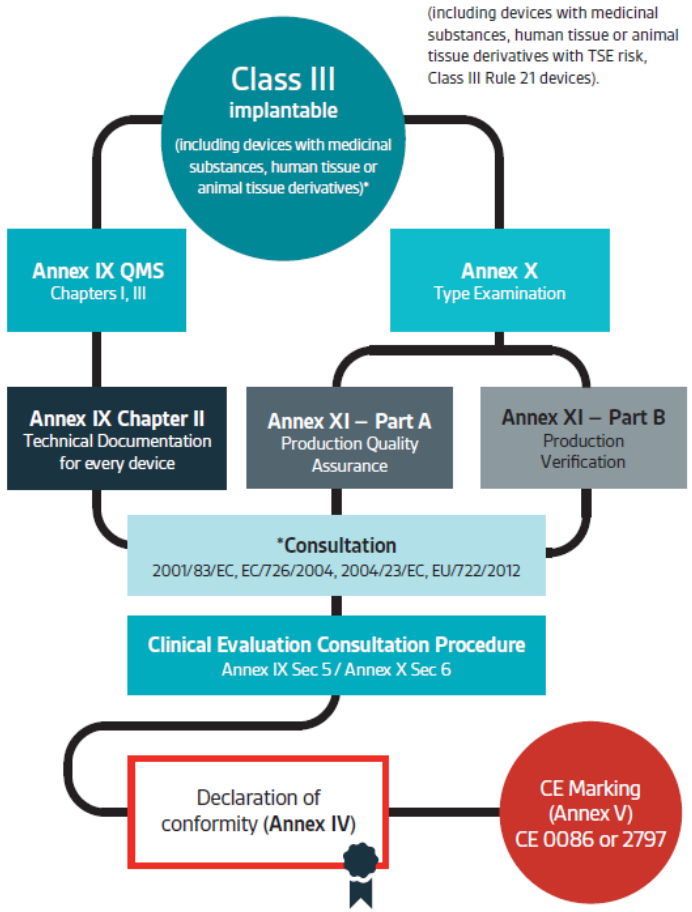


+Device Testing

- Type Examinations
- Product Verification

BSI Conformity Assessment – Class III implantable devices

Class III Implantable devices

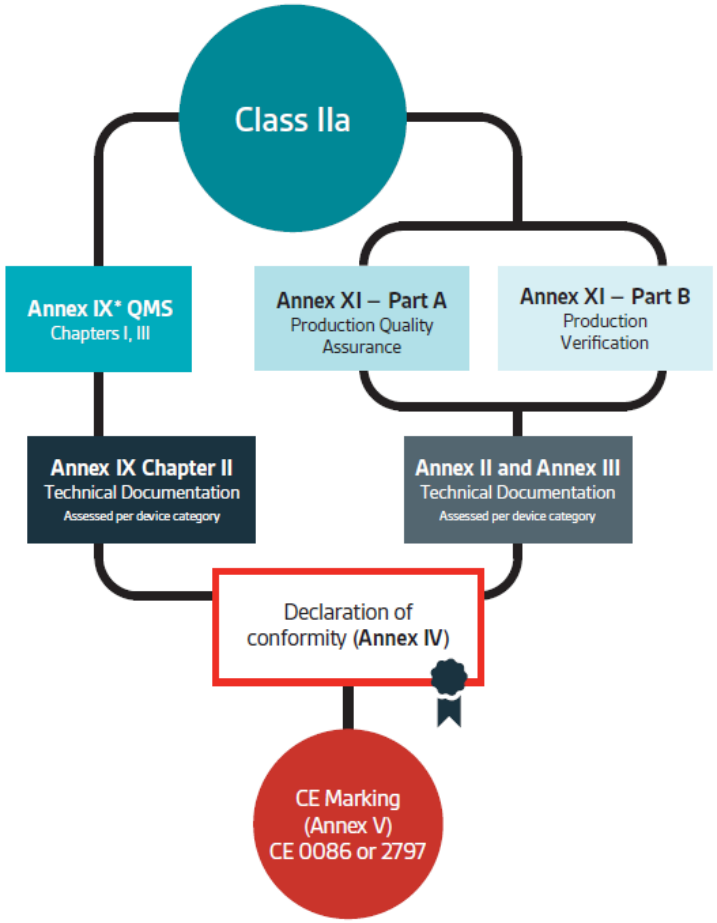


CLASS III IMPLANTABLE DEVICES

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				

BSI Conformity Assessment – Class IIa non-implantable devices

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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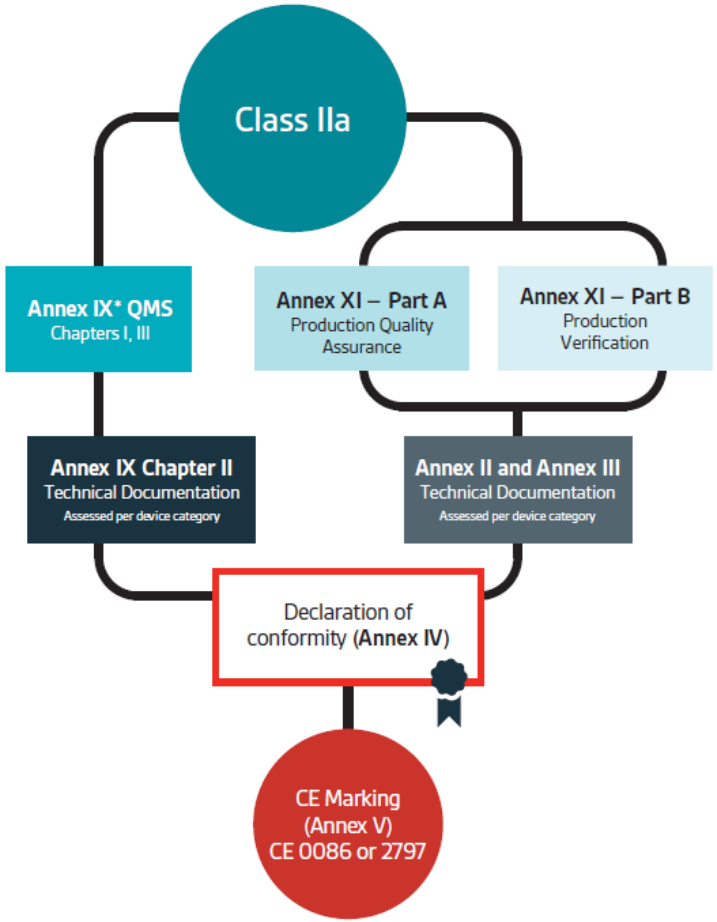
BSI Conformity Assessment – Class IIa implantable devices

Class IIa devices



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				

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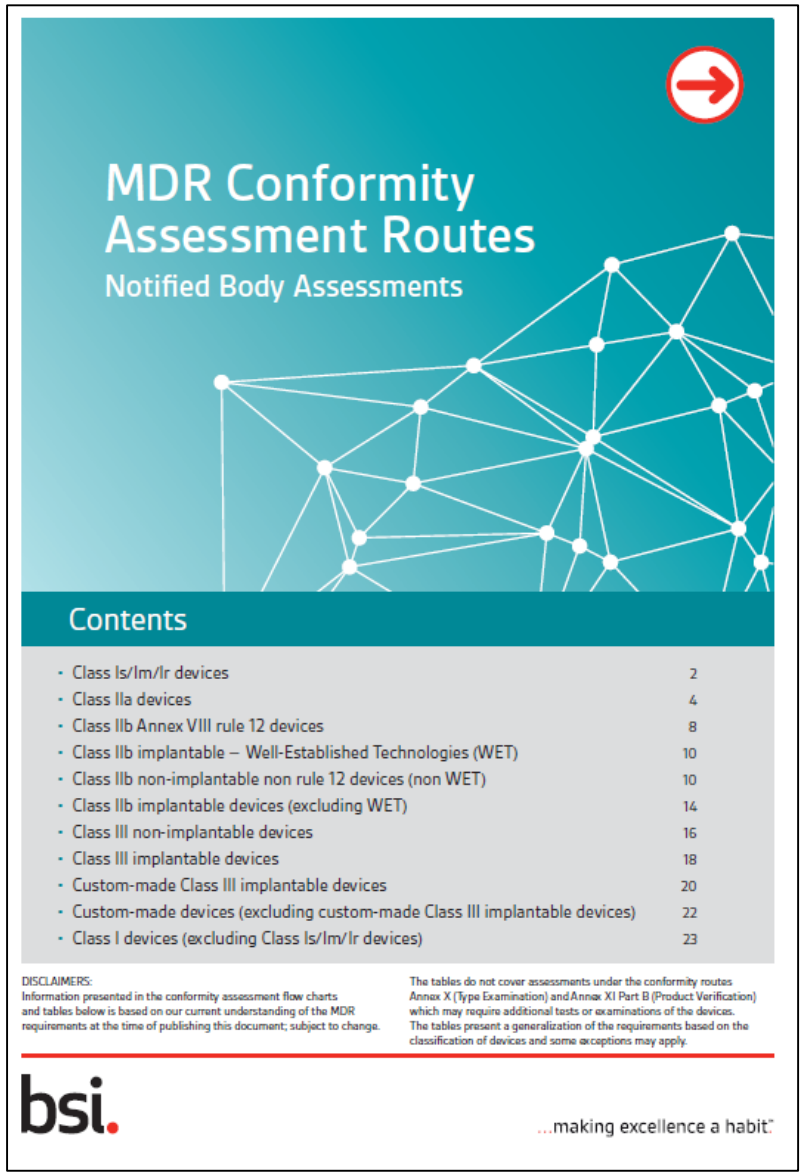

MDR Conformity Assessment Routes

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.

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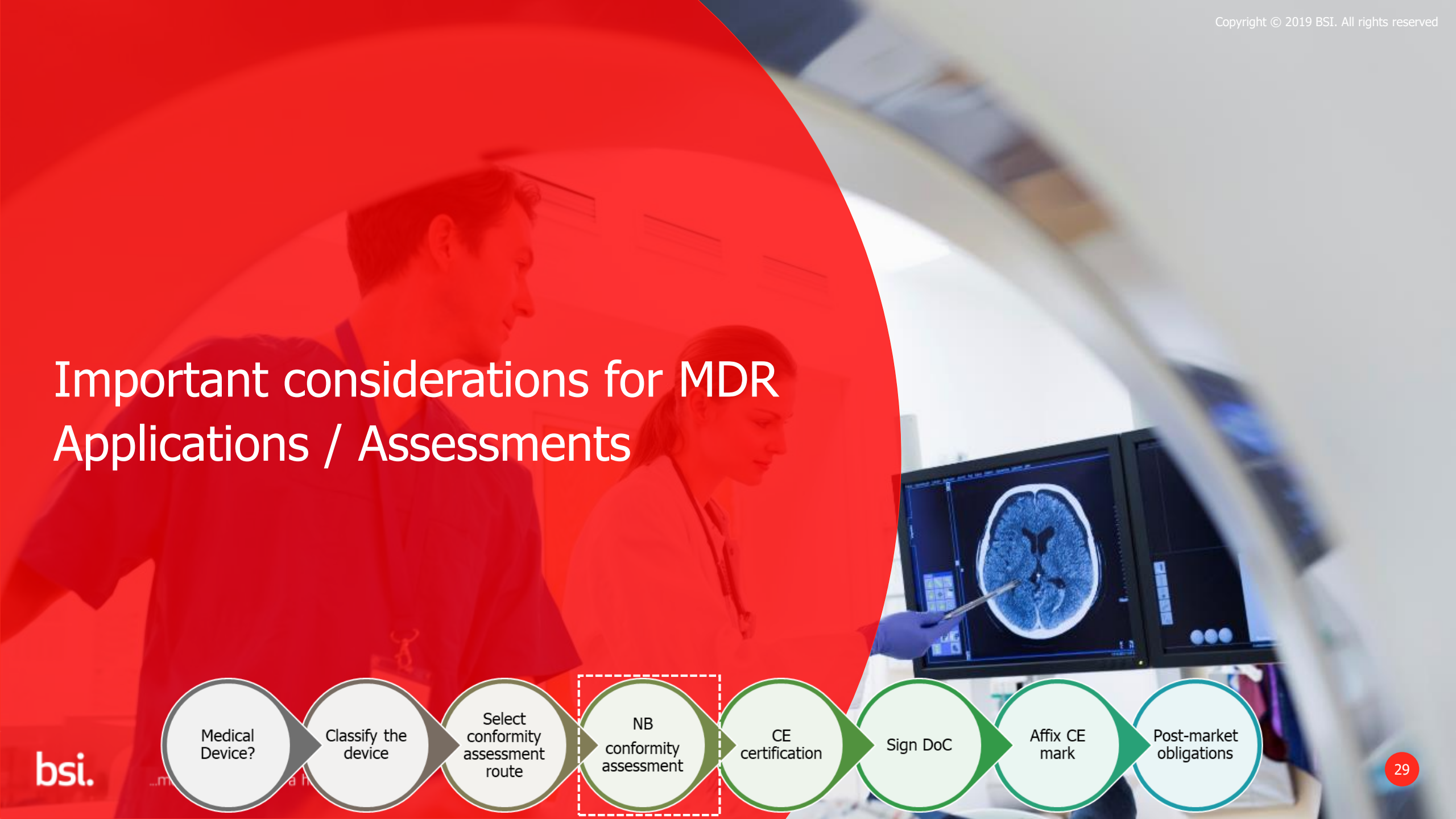
- All other classifications – Refer to the BSI guide

Important considerations for MDR Applications / Assessments

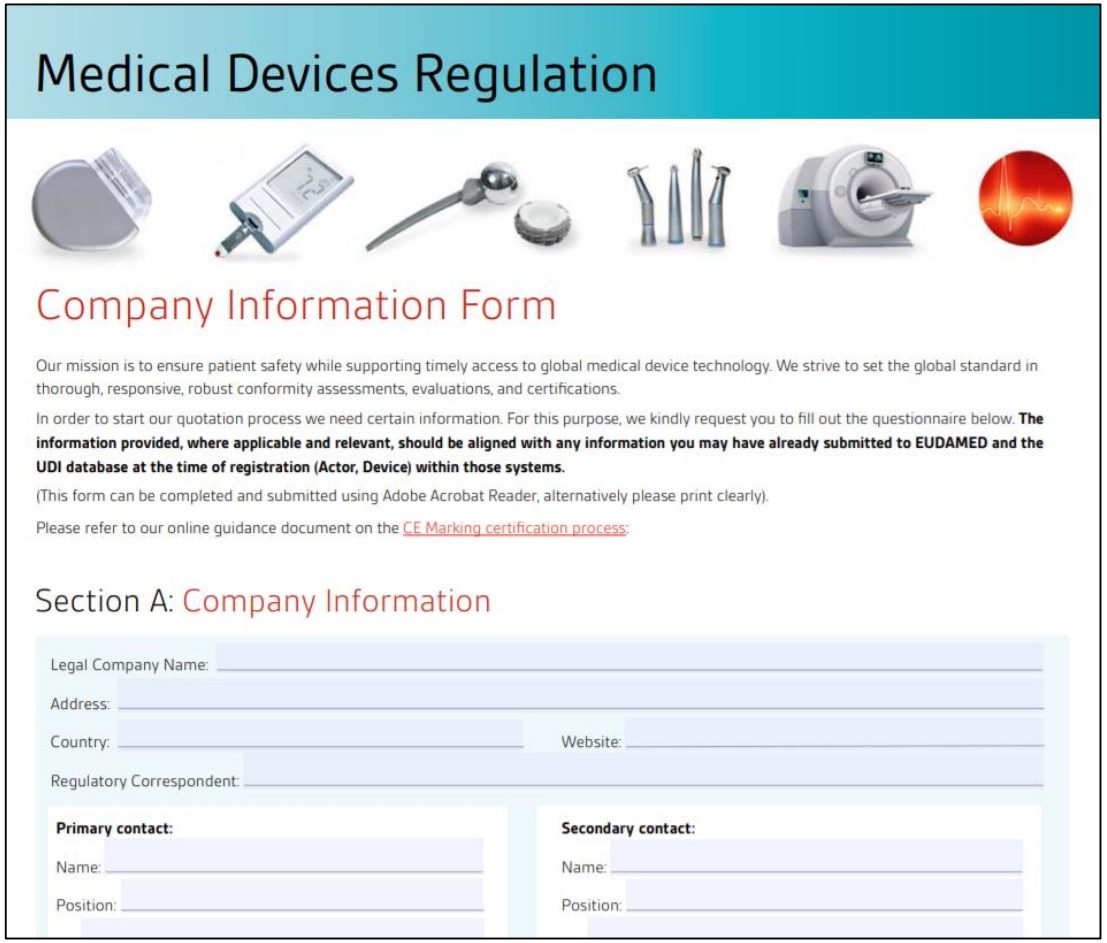


MDR Applications / Conformity Assessments

New applications to be submitted under MDR irrespective of whether those products have been previously certified under Directives

If an organisation consists of multiple legal entities marketing the same devices, separate applications will be required from each legal manufacturer with separate assessments conducted

NB will be requesting a few documents (quality manual, quality policy, PMS, vigilance procedures, sample PMCF plans etc) at the time of application



Medical Devices Regulation

Company Information Form

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations, and certifications.

In order to start our quotation process we need certain information. For this purpose, we kindly request you to fill out the questionnaire below. **The information provided, where applicable and relevant, should be aligned with any information you may have already submitted to EUDAMED and the UDI database at the time of registration (Actor, Device) within those systems.**

(This form can be completed and submitted using Adobe Acrobat Reader, alternatively please print clearly).

Please refer to our online guidance document on the CE Marking certification process:

Section A: Company Information

Legal Company Name:

Address:

Country: Website:

Regulatory Correspondent:

Primary contact:

Name:

Position:

Secondary contact:

Name:

Position:

MDR QMS audits

- All MDR audits must be treated as Initial audits
- Full in-depth QMS audit should be expected, but the emphasis will be on the new requirements introduced by MDR
  - Strategy for regulatory compliance, PRRC, UDI, Labelling, Implant Card, Clinical, SSCPs, PSURs, PMS/PMCF, Vigilance reporting, economic operators, translations etc
- Major gaps in control of subcontractors/suppliers may lead to verification audits at these entities even if they held valid certification
- Manufacturer's QMS must demonstrate capability to meet the MDR requirements
- Project plans in place for various devices with evidence of implementation available for at least a few devices

What about EUDAMED, UDI etc for which provisions may not be in place yet?

Is the manufacturer aware of the requirements?

Are there are documented plans in place to implement these new provisions (even if theoretical and manufacturer own created forms and templates)

Are they aware of the current guidance documents already published and is there any progress in implementing these?

Does the manufacturer have provisions and processes in place to monitor or screen for publication of key guidance documents?

sampling,

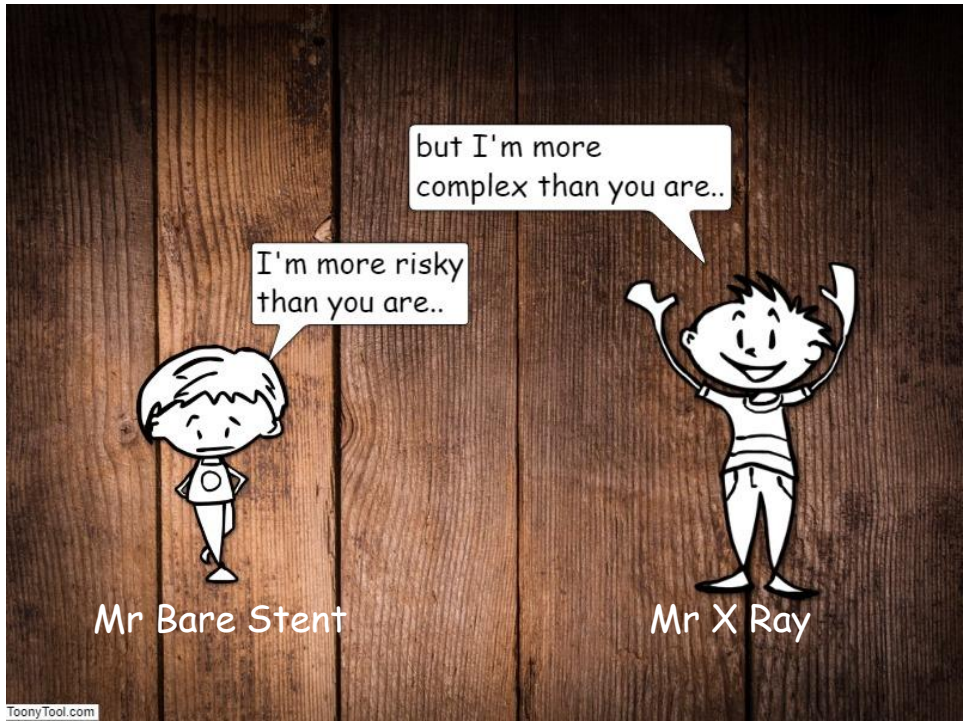
— evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

Annex VII section 4.5.1 on conformity assessment activities

MDR Technical Documentation Reviews

NB review format to be the same for all classifications of devices	All conformity routes cross-refer to Annex IX Section 4 for Tech doc reviews
Depth of review to be the same irrespective of the classification of the device	Proportionality to risk only via sampling of devices for IIa and certain IIb devices
Annex VII of MDR requires NBs to set time limits on conformity assessment activities	Tech doc reviews to be limited to 3 rounds of Q&A



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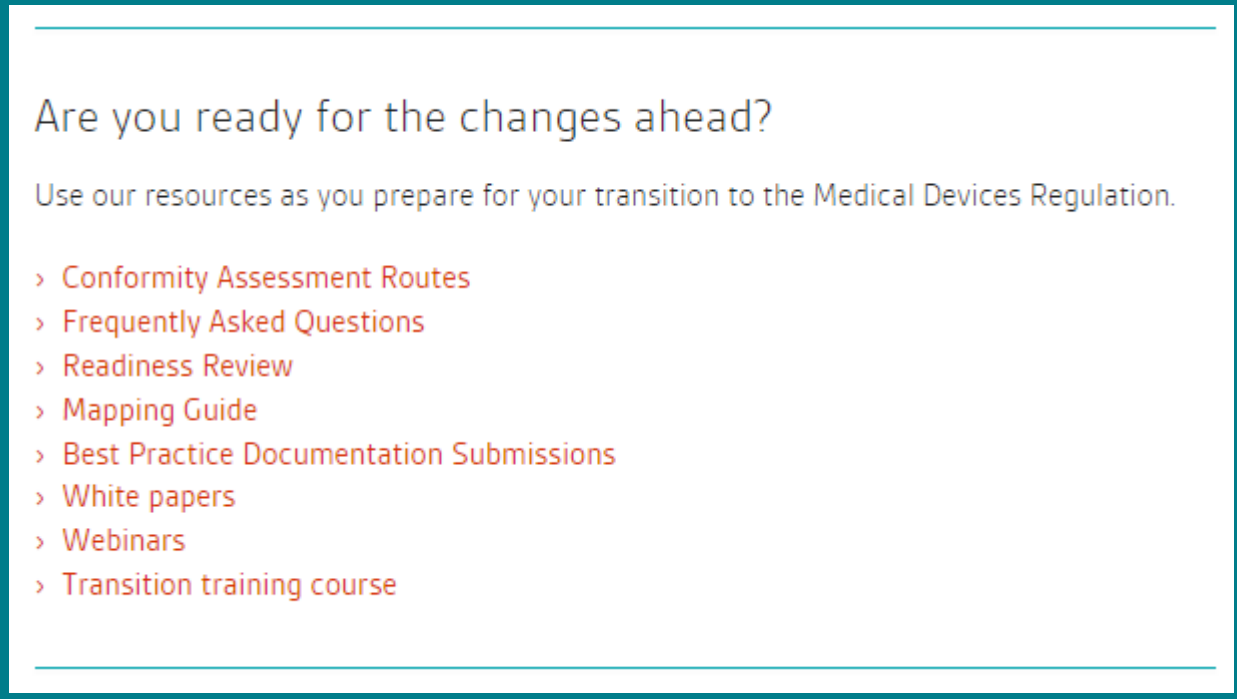
Other BSI Resources

https://www.bsigroup.com/en-GB/medical-devices/our-services/MDR-Revision/



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