

Introduction

This leaflet provides an overview of the various conformity assessment routes available under the MDR, helping you understand which pathway is most suitable for your device and ensuring a smoother journey to compliance.

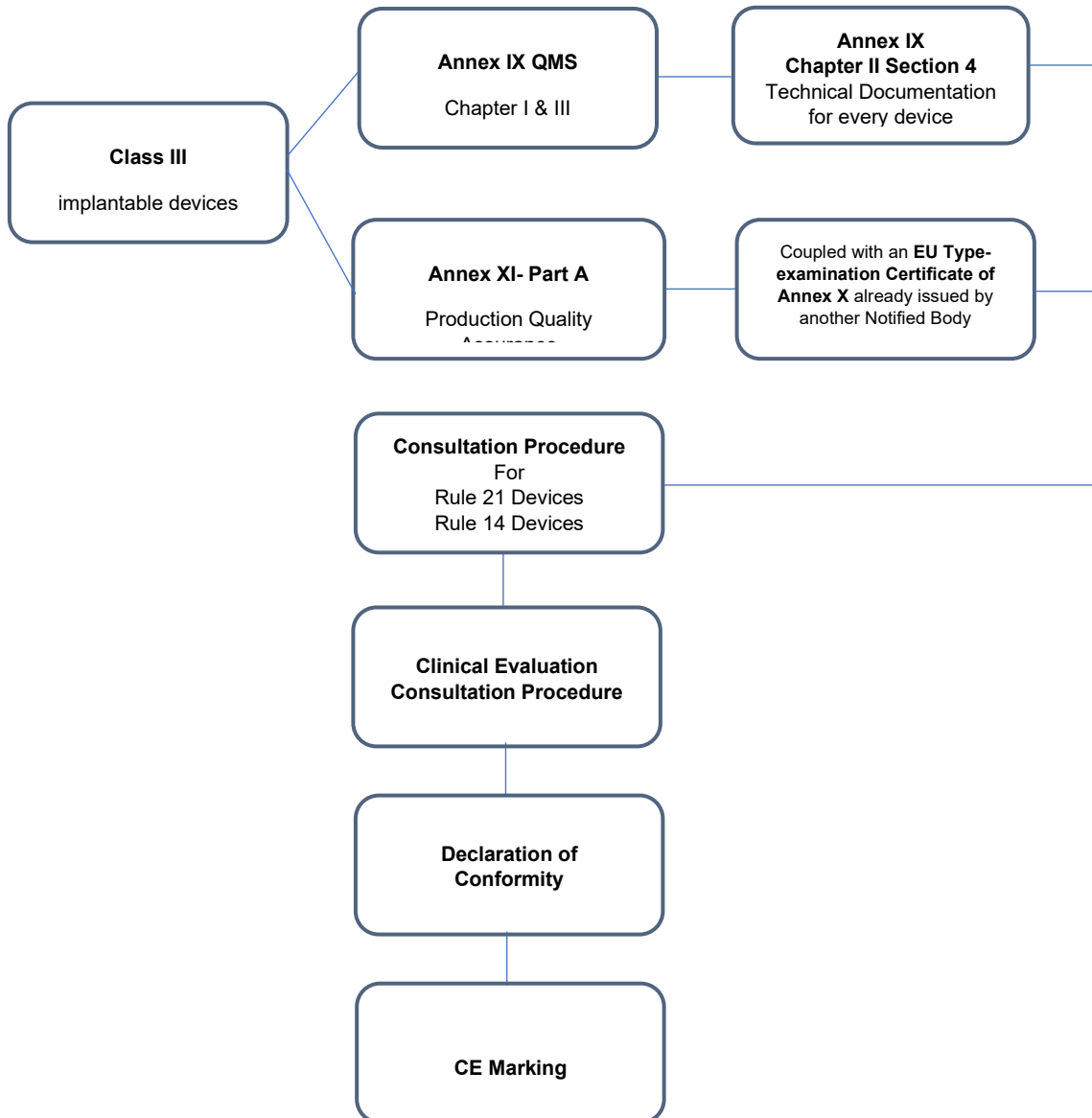
Definitions

- WET devices** : Well Established Technology Implants, i.e., sutures, staples, dental fillings and braces, tooth crowns, screws, wedges, plates, wires, pins, clips & connectors as per Article 52 of MDR.
- Rule 12** : All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa (such as Suction pump, feeding pumps, jet injectors for vaccination), unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb (such as infusion pumps, ventilators, Anesthesia machines, Dialysis equipment, blood pump for heart-lung machines, pressure regulators for medical devices)
- Rule 21** : Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:
- class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,
 - class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body (such as Na/Mg alginate, xyloglucan, Fat absorbers that are systemically absorbed, themselves or their metabolites)
 - class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities (such as Substance-based formulations for skin treatment, Salt water used as nose or throat sprays, Oral cough treatments achieving their intended purpose in the oral cavity as far as the pharynx)
 - class IIb in all other cases (such as Simethicone preparations for oral administration, Active coal for oral administration, Gel for vaginal moisturizing / vaginal lubricants, Eye drops for hydration, Ear drops, medical devices for oral administration, for the treatment of diarrhea, e.g., kaolin, diosmectite & Medical devices for oral administration, for the treatment of obesity, e.g., fructooligosaccharides, glucomannan)

Applicable Conformity Assessment Routes for Different Classes

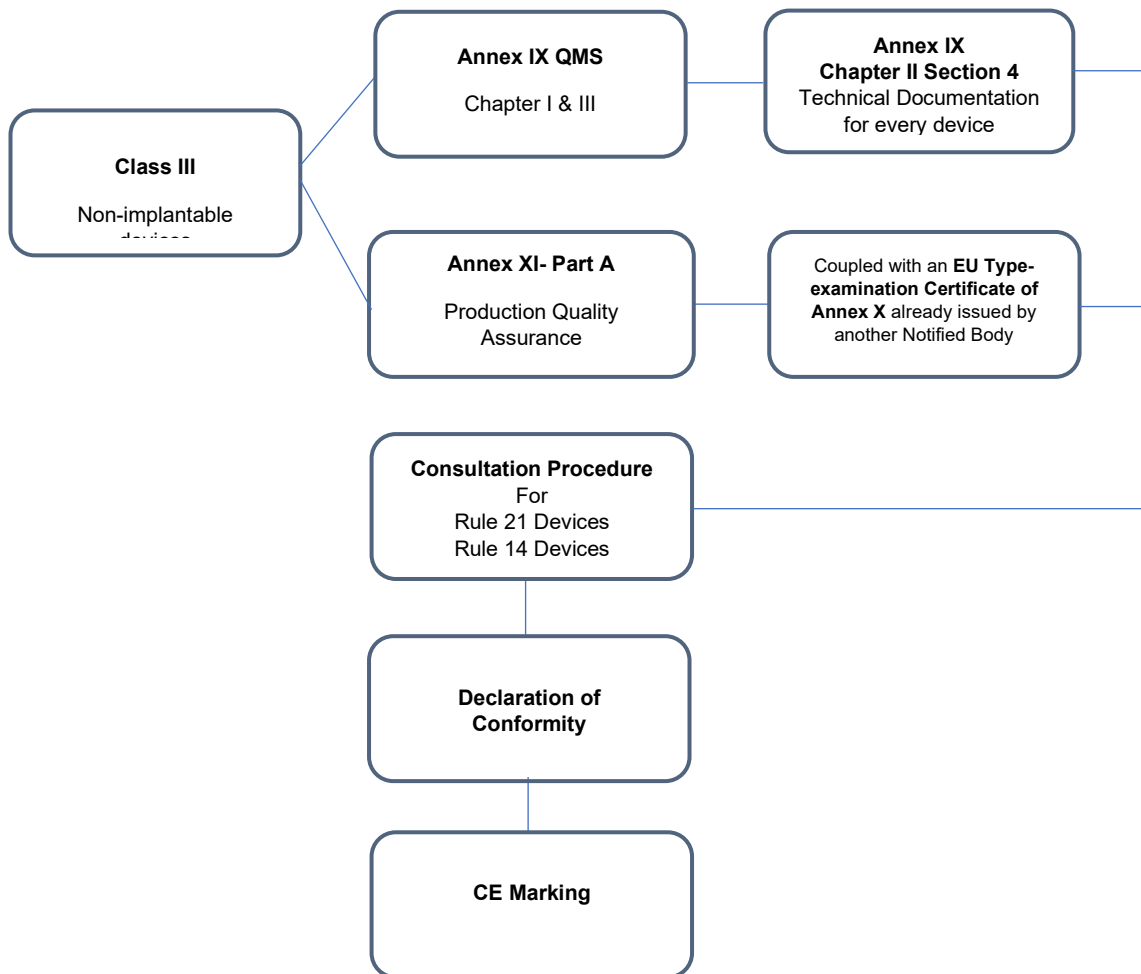
a. Class III Implantable Devices

Including devices with medicinal substances, Class III Rule 21 devices.



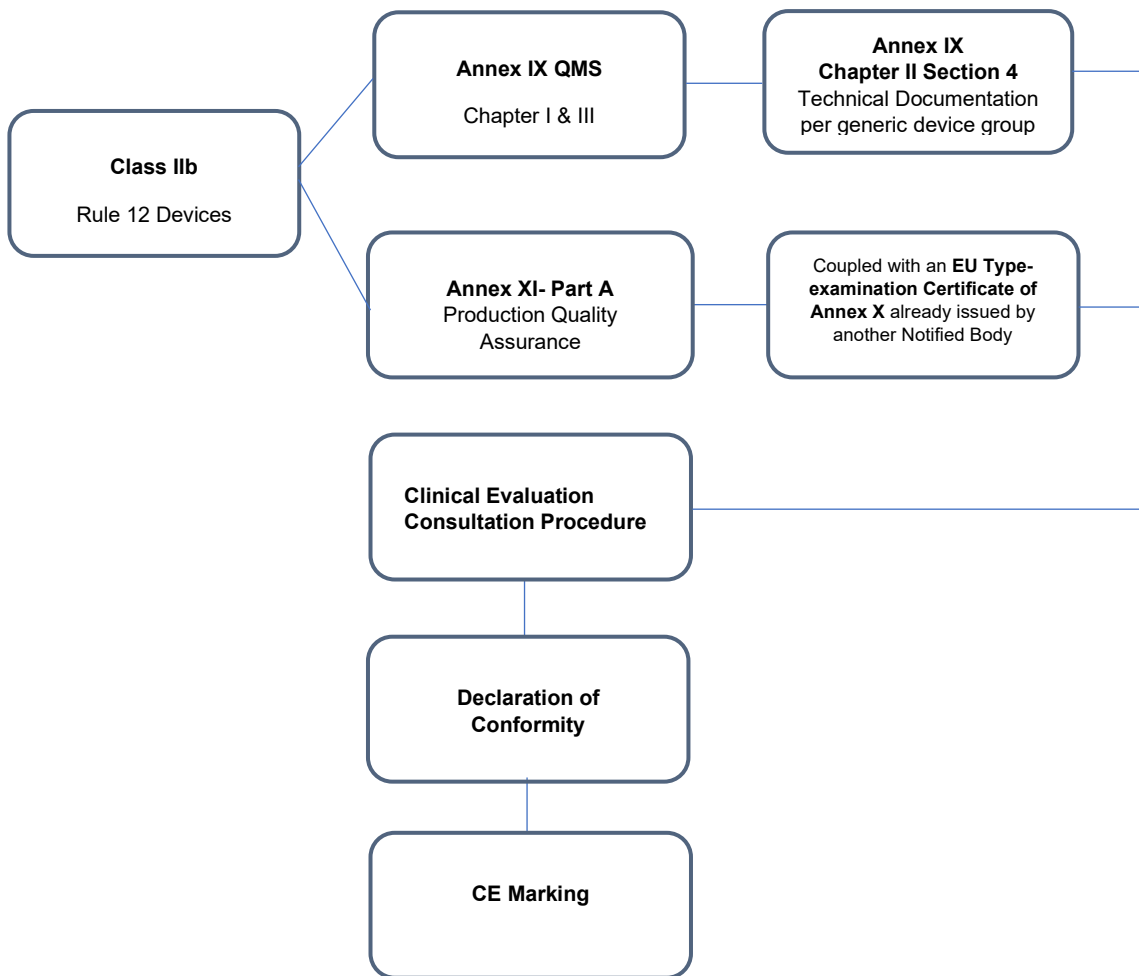
Class III Implantable Devices	TD Submission Requirements & Frequency
Technical Documentation	For every device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	Annually
Unannounced Audits	At least once within certification cycle

b. Class III non-Implantable Devices



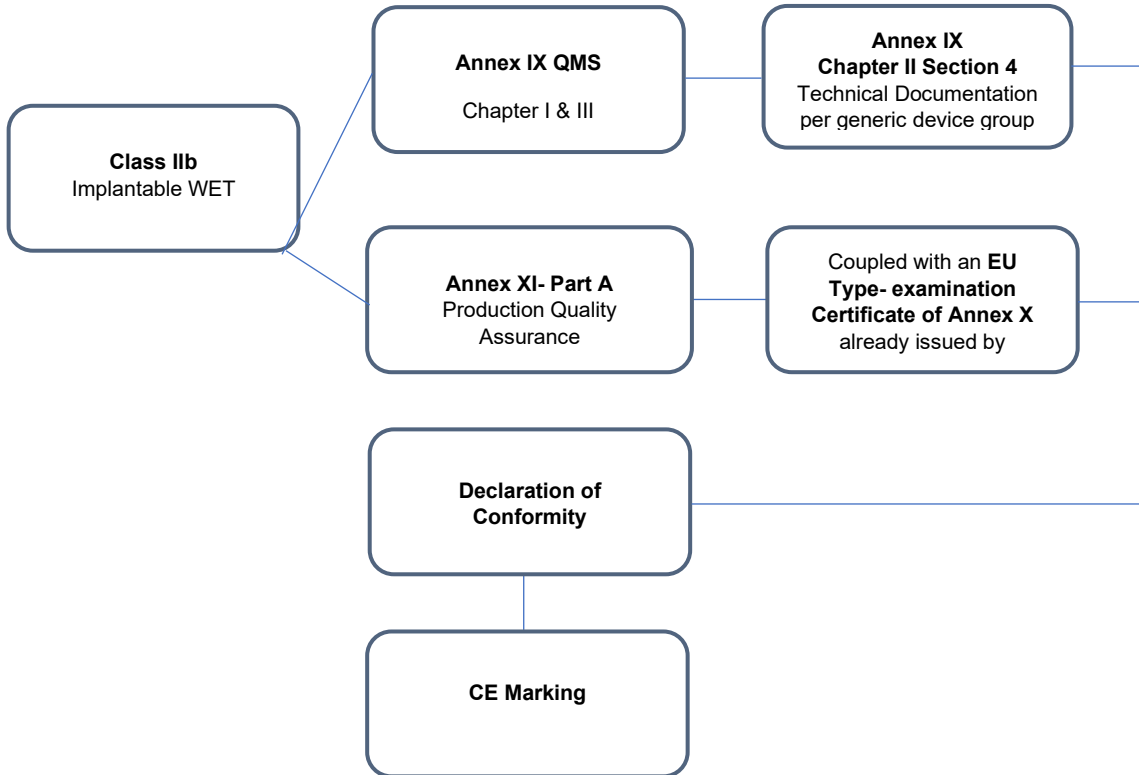
Class III Non-Implantable Devices	TD Submission Requirements & Frequency
Technical Documentation	For every device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	Annually
Unannounced Audits	At least once within certification cycle

c. Class IIb, Rule 12



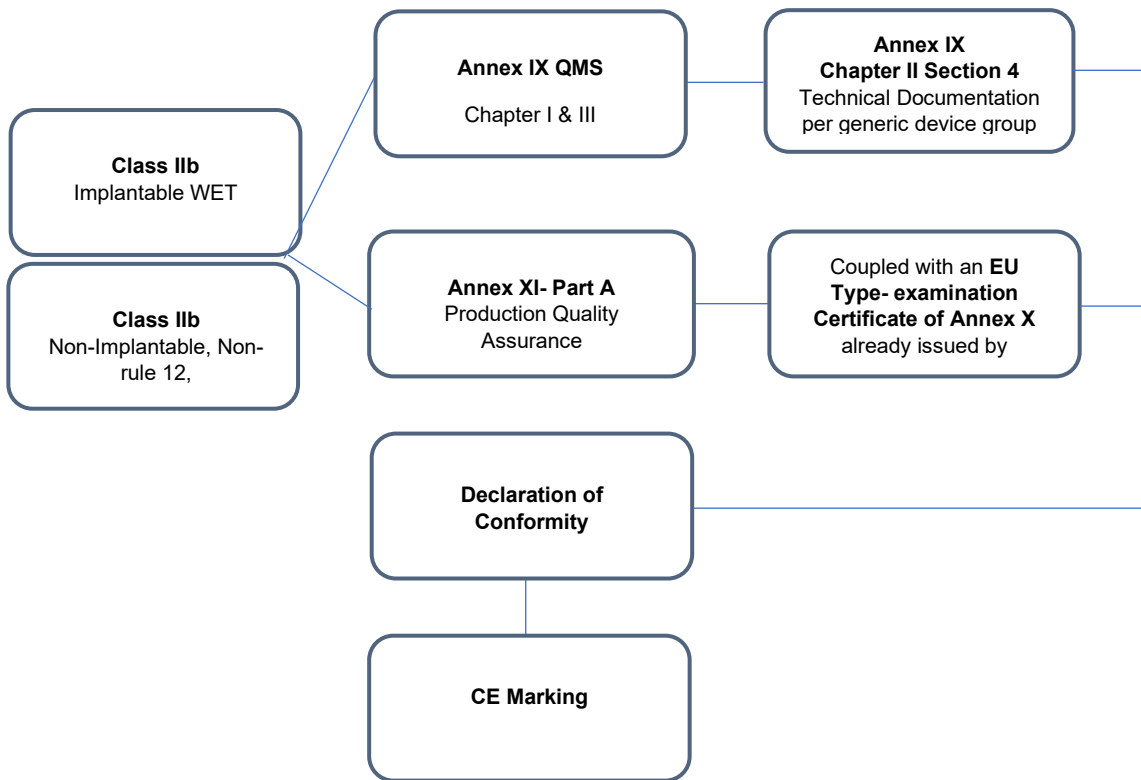
Class IIb, Rule 12	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	NA
Unannounced Audits	At least once within certification cycle

d. Class IIb Implantable, non-WET Devices



Class IIb- Implantable, Non-WET	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	Annually
Unannounced Audits	At least once within certification cycle

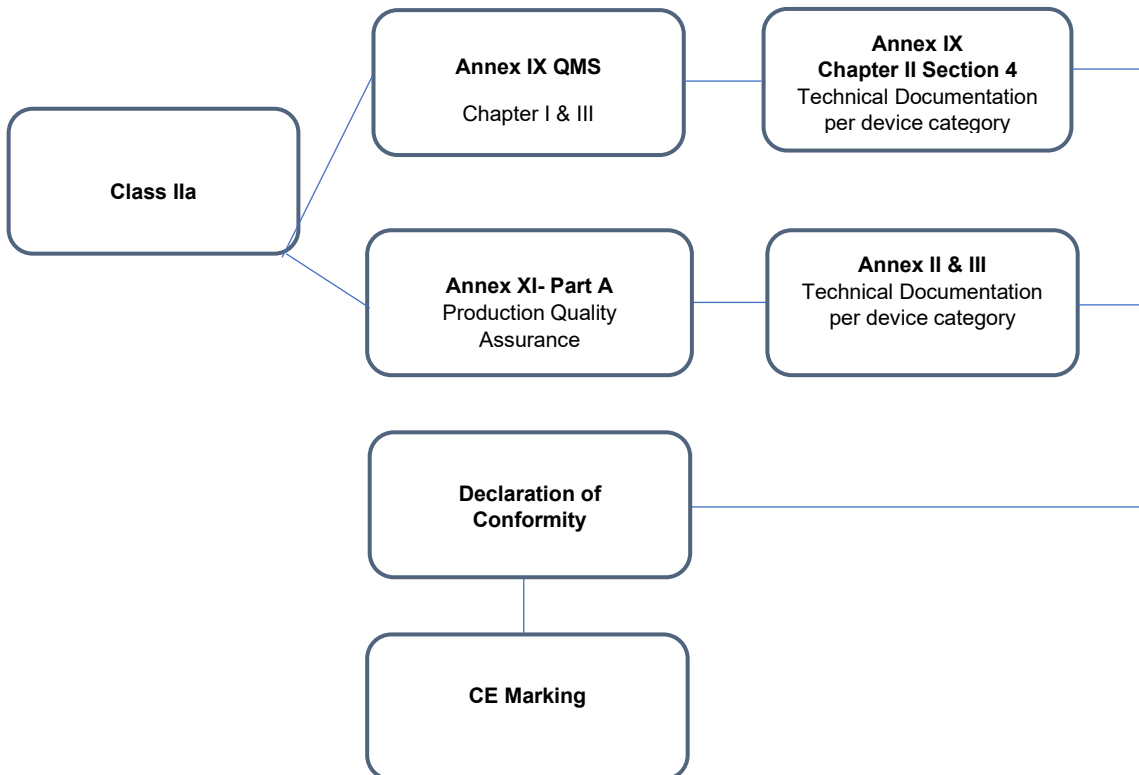
e. Class IIb Implantable-WET Devices & Class IIb Non-Implantable, non- rule 12,



Class IIb- Implantable-WET	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	NA
Unannounced Audits	At least once within certification cycle

Class IIb- Non-Implantable, Non-rule 12	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Annually (Via EUDAMED)
CER updates	Annually
PMCF Plan & Report (Article 61)	Annually
SSCP (Article 32)	NA
Unannounced Audits	At least once within certification cycle

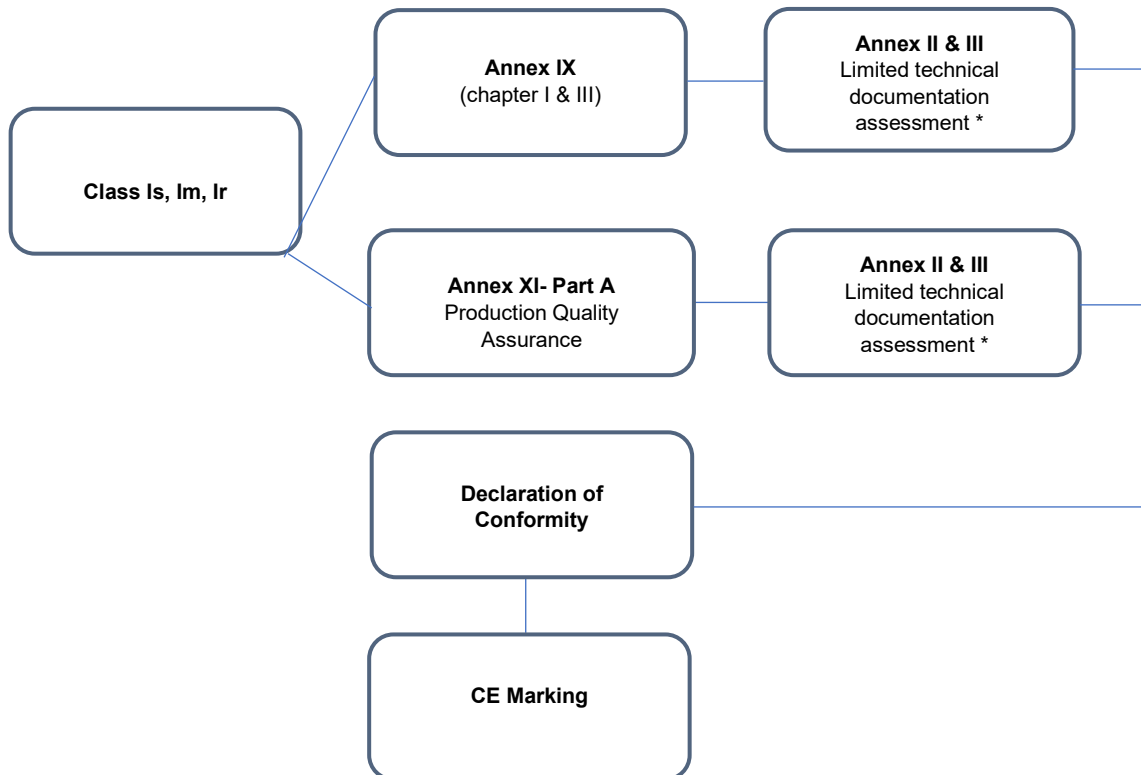
f. Class IIa Implantable, Class IIa Non-Implantable



Class IIa- non-implantable	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Every 2 years (Via EUDAMED)
CER updates	Every 2 years
PMCF Plan & Report (Article 61)	Every 2 years
SSCP (Article 32)	NA
Unannounced Audits	At least once within certification cycle

Class IIa- Implantable	TD Submission Frequency
Technical Documentation Assessment	Sample per generic device
PMS Plan & PSUR (Article 86)	Every 2 years (Via EUDAMED)
CER updates	Every 2 years
PMCF Plan & Report (Article 61)	Every 2 years
SSCP (Article 32)	Once in 2 years
Unannounced Audits	At least once within certification cycle

g. Class Is/Im/Ir



Class Is/Im/Ir	TD Submission Frequency
Technical Documentation Assessment	Updated when necessary and made available to the NOTICE upon request.
PMS Plan & PMS Report (Article 86)	Updated when necessary and made available to the NOTICE upon request.
CER updates	Updated as per Manufacturer's clinical evaluation plan
PMCF Plan & Report (Article 61)	Updated as per Manufacturer's PMS, PMCF plans
SSCP (Article 32)	NA
Unannounced Audits	At least once within certification cycle

* Technical Documentation review is limited to:

Class Is: aspects relating to establishing, securing and maintaining sterile conditions.

Class Im: aspects relating to the conformity of the devices with the metrological requirements.

Class-Ir: aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use

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