Definition of Conformity Assessment available in Art. 2(40) of EU-MDR

'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

- More than one routes may be available for a given class of risk. They are described in Chpt. V, section 1, Art. 52
- The Manufacturer is free to choose any applicable routes

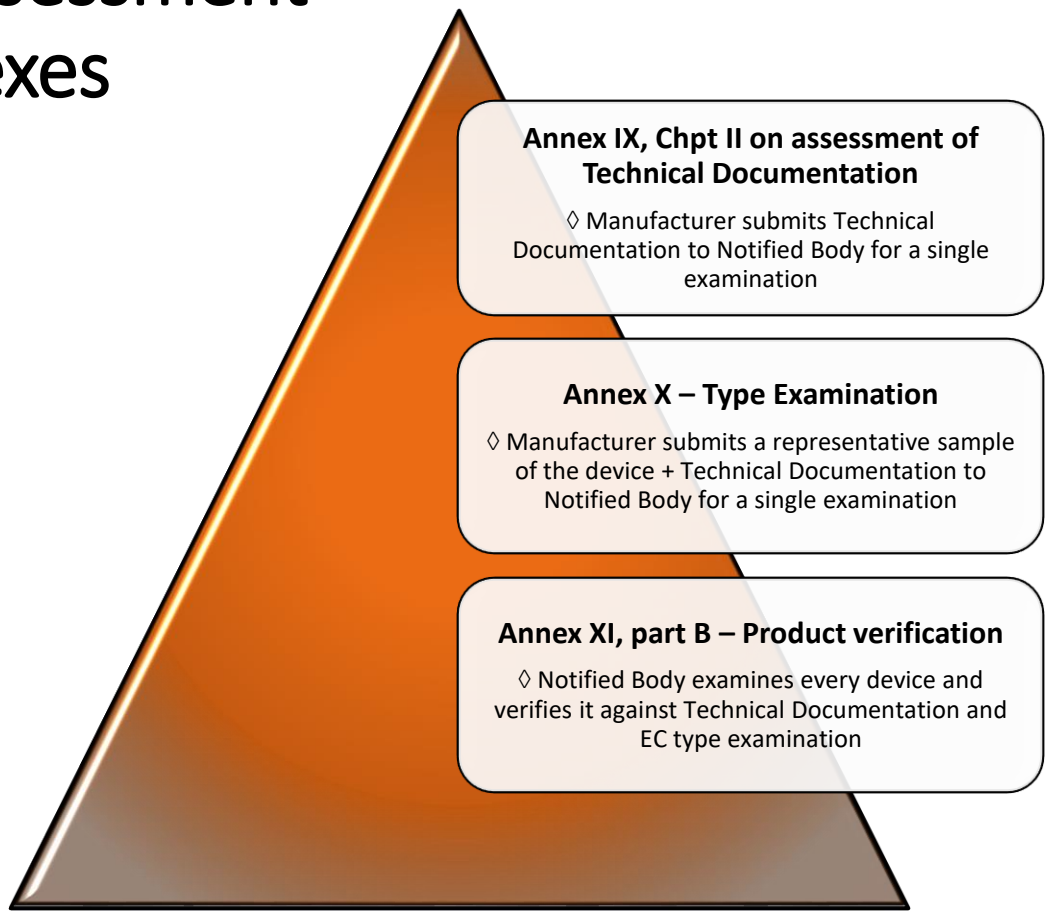
- Notified Body involvement is outlined in Art. 53
- Consultation procedure when, applicable for class IIb and class III devices is outlined in art. 54

- Annexes IX, X, and XI describe the various conformity assessment routes
  - Annex IX: QMS + Assessment of Technical Documentation
  - Annex X: Type Examination
  - Annex XI: Product Conformity Verification

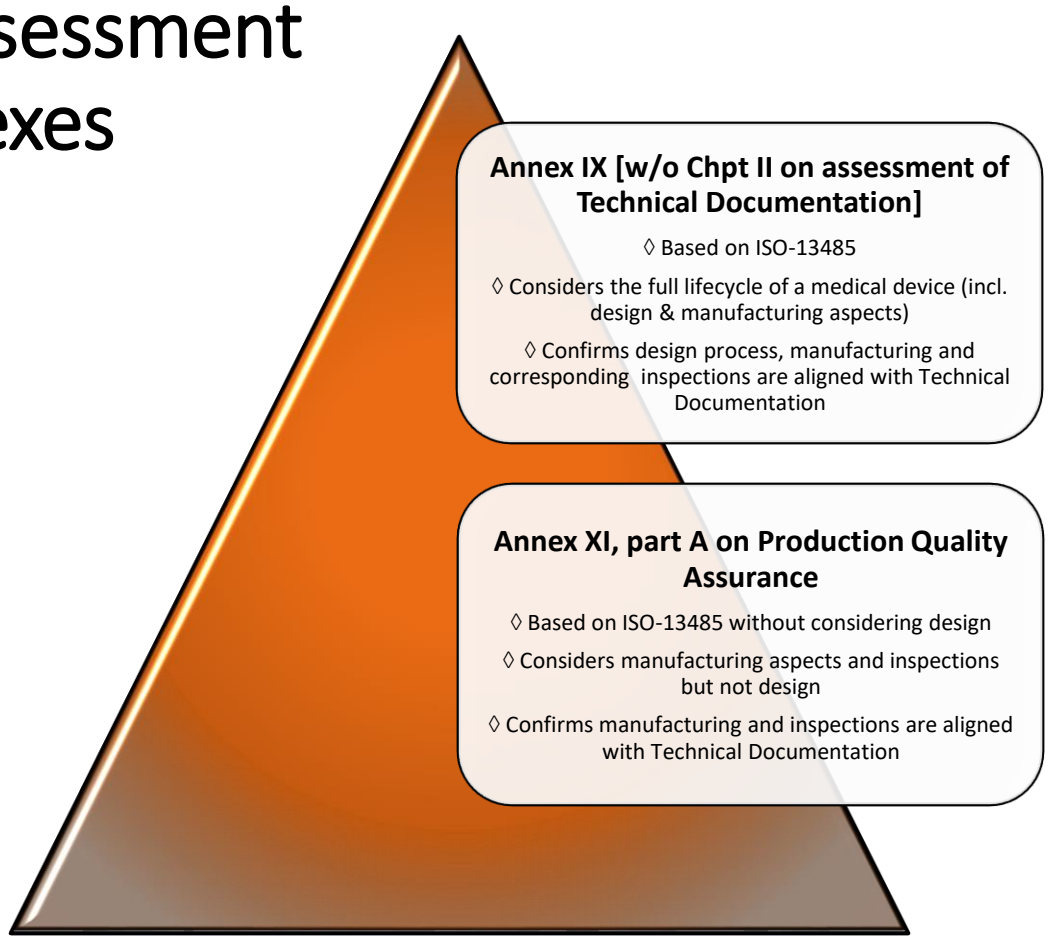
Differences in Conformity Assessment Routes between MDD and MDR

MDD	MDR	Comment
Annex VII (DoC)	Annexes II+II **+** Article 19 (DoC) Technical Documentation + PMS	Applicable to class I devices
Annex II w/o Section 4 Full Quality Assurance	Annex IX, Chpts. I & III Quality Management System + Assessment of Technical Documentation	Assessment of Technical Documentation: Class IIa: at least one representative device for each category of devices Class IIb: at least one representative device per generic device group Class IIb non-implantable: every device
Annex II Full Quality Assurance + Design dossier	Annex IX QMS + Assessment of Technical Documentation	Assessment of Technical Documentation: Class III: every device Note: Additional procedures apply for class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product (see Annex IX, section 5)
Annex III Type Examination	Annex X Type-Examination	Annex XI Part B (Product Verification) which may require additional tests or examinations of the devices.
Annex V Product Quality Assurance	Annex XI, part A Production Quality Assurance	-
Annex IV Product Verification	Annex XI, part B Product Verification	Annex XI Part B requires individual devices to be tested
Annexes III + VI Type Examination + Quality Assurance	N/A	No longer available option in MDR
Annexes IV +VII Declaration of Conformity +Product Verification	N/A	No longer available option in MDR

Product Assessment Annexes



Quality Assessment Annexes



Class I devices

Annex II and III
(Technical Documentation and PMS)

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Declaration of Conformity as per Annex IV

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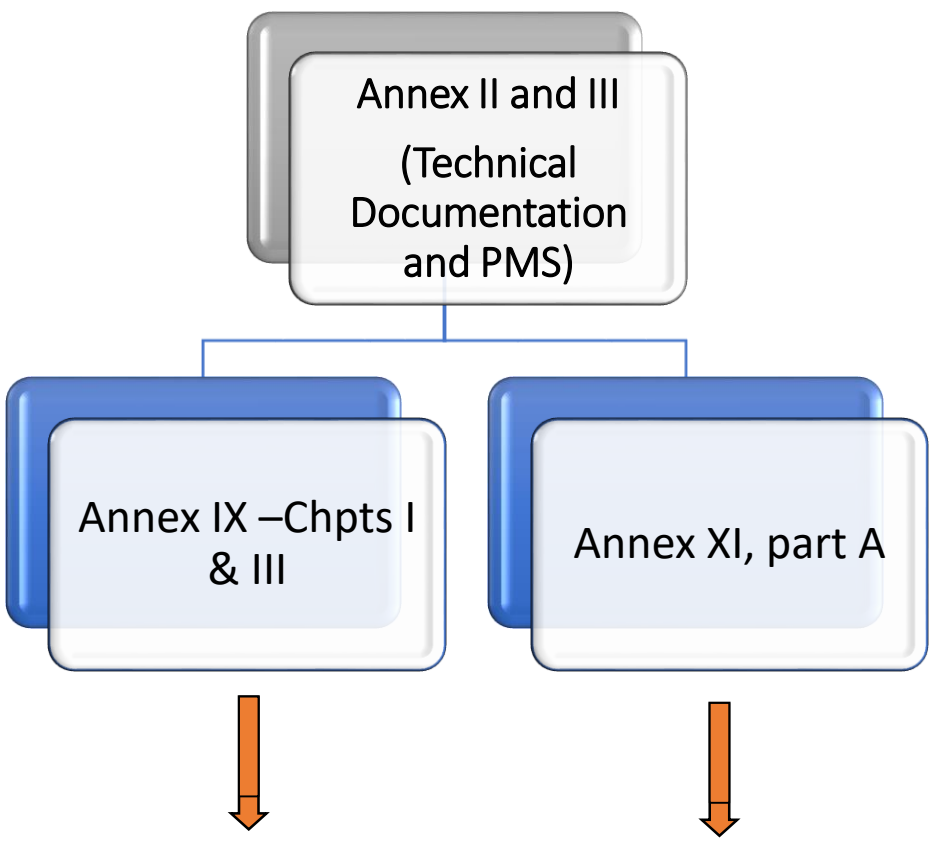
CE Marking as per Annex V

Class Is/Im/Ir devices



Clinical Evaluation Consultation

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Declaration of Conformity as per Annex IV

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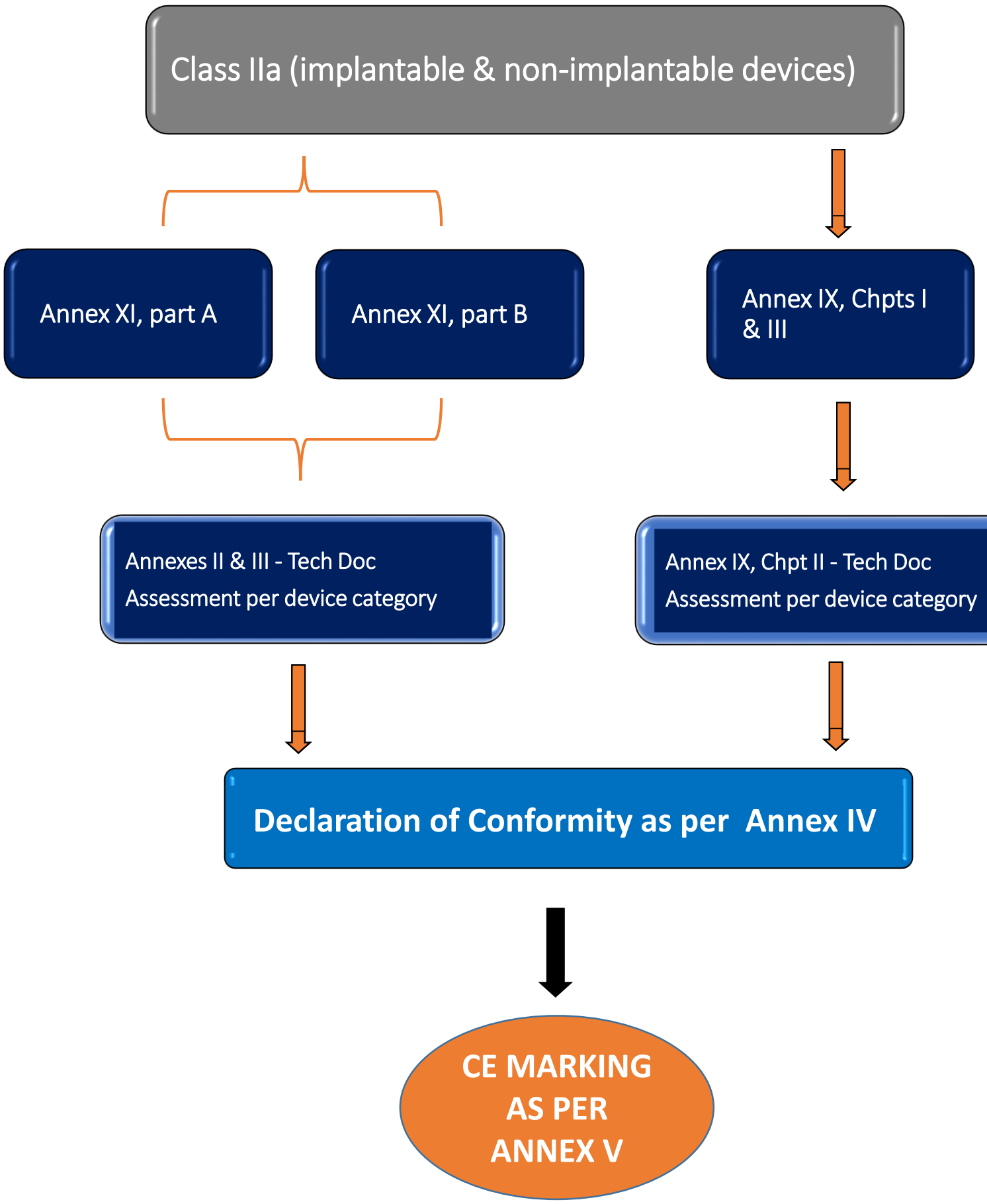
CE MARKING AS PER ANNEX V

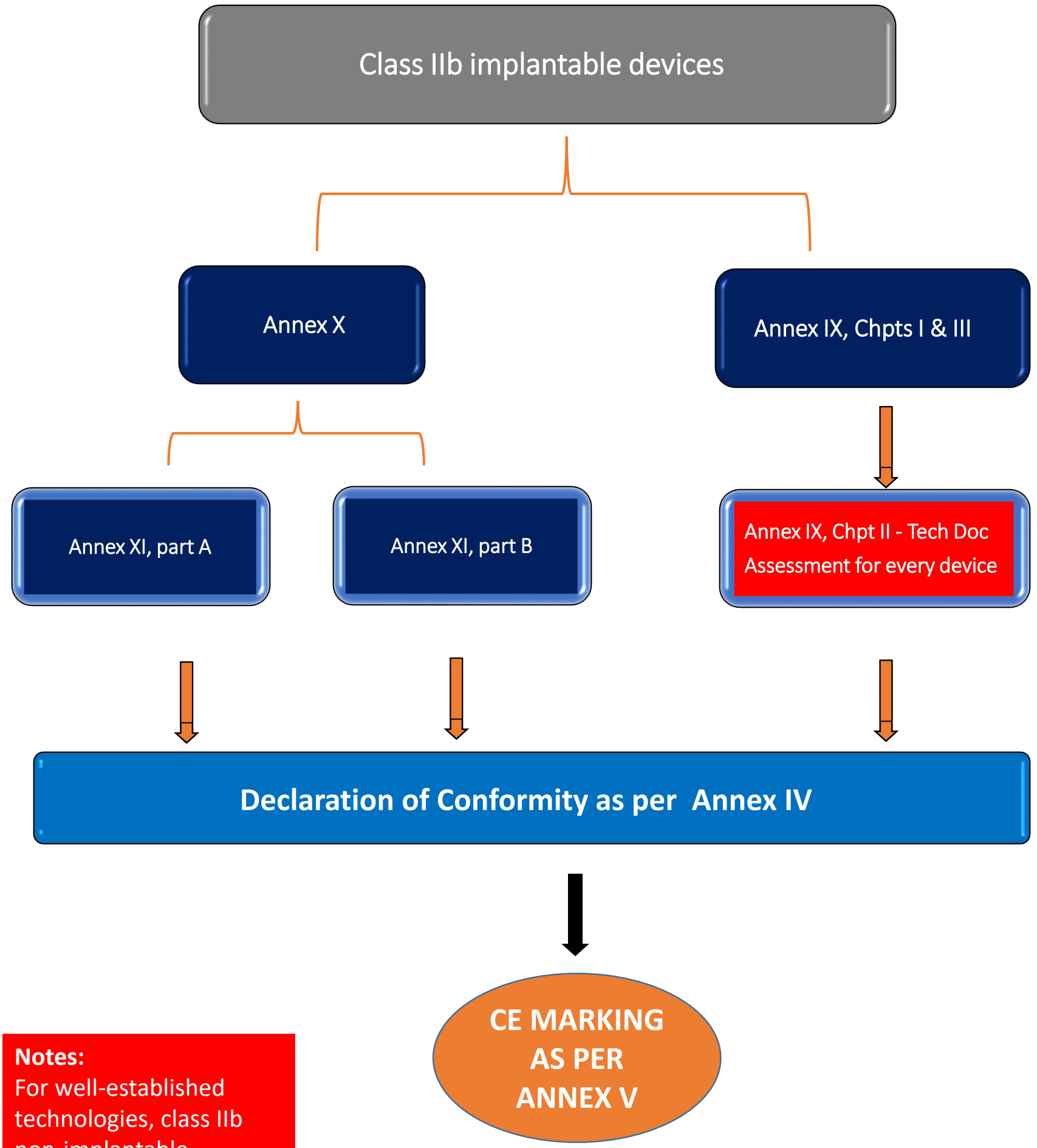
Notes:

- Class I devices are the only self-certified ones and the Manufacturer's obligation is to maintain and update Technical Documentation in compliance with Annexes II and III.
- Class Is / Im / Ir devices need to maintain a QMS to control production (Annex XI, part A) and/or special characteristics of each class (i.e. sterility, measuring functions, reusable features). Involvement of the NB will be a the QMS-control level

Class IIa devices



Class IIb implantable devices



Notes:
For well-established technologies, class IIb non-implantable devices, devices classified under Rule 12, assessment of Tech Documentation is performed per generic device group

Evnia
To Strive · To Seek · To Find

Class III non-implantable devices

Class III non- implantable devices

including medical devices incorporating medicinal substances, human or animal tissues derivatives with TSE and devices classified under Rule 21

- Annex X
  - Annex XI, part A
  - Annex XI, part B
- Annex IX, Chpts I & III
  - Annex IX, Chpt II - Tech Doc Assessment for every device

Consultation

- ❑ medical devices incorporating medicinal substances: 2001/83/EC
- ❑ medical devices incorporating human or animal tissues derivatives with TSE: 2004/276/EC and 2012/722/EC

Declaration of Conformity as per Annex IV

CE MARKING AS PER ANNEX V

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Class III implantable devices

Class III non- implantable devices

including medical devices incorporating medicinal substances, human or animal tissues derivatives with TSE and devices classified under Rule 21

- Annex X
  - Annex XI, part A
  - Annex XI, part B
- Annex IX, Chpts I & III
  - Annex IX, Chpt II - Tech Doc Assessment for every device

Consultation

- ❑ medical devices incorporating medicinal substances: 2001/83/EC
- ❑ medical devices incorporating human or animal tissues derivatives with TSE: 2004/276/EC and 2012/722/EC

Clinical Evaluation Consultation Procedure

- ❑ potential involvement of an expert panel to evaluate the clinical evaluation assessment report (CEAR) as per Annex IX, section 5/ Annex X, section 6

Declaration of Conformity as per Annex IV

CE MARKING AS PER ANNEX V

Note

The Clinical Evaluation Consultation procedure is not required in case renewals of certificates and/or in modifications of an already marketed device that will maintain the same intended purpose

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Custom-made class III implantable devices

Custom-made class III implantable devices

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Annex XIII

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Annex IX, Chpt I | Annex XI, part A

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Generation of Statement required by Art. 52(8) and Annex XIII, section 1

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CE MARKING AS PER ANNEX V

All custom-made devices except class III implantable devices

All custom-made devices except class III implantable devices

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Annex XIII

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Annex XIV, part B requirements for PMS and PMCF data collection

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Generation of Statement required by Art. 52(8) and Annex XIII, section 1