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MDR (EU 2017/745) Certification structure

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michael.maier@medidee.com

www.medidee.com

ISO 9001 & ISO 13485
Certified company

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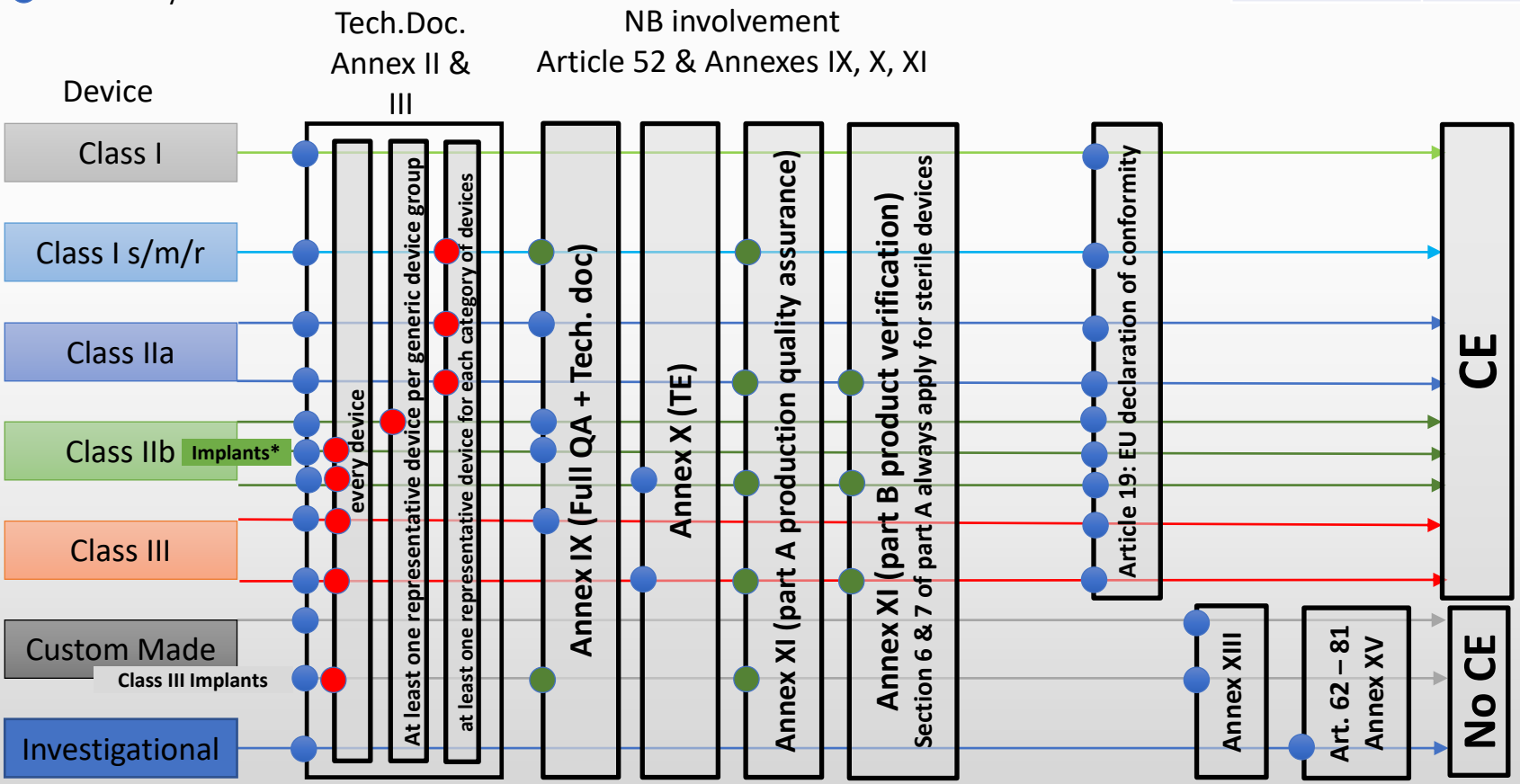
Tech Doc Requirements & NB review

MDR	MDD
Annex IX	Annex II
Annex X	Annex III
Annex II	Annex VII
Annex XI Part A	Annex V
Annex XI part B	Annex IV
…	Annex VI

- Tech. doc review by NB
- Choice of manufacturer, either of
- Mandatory



*except: except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

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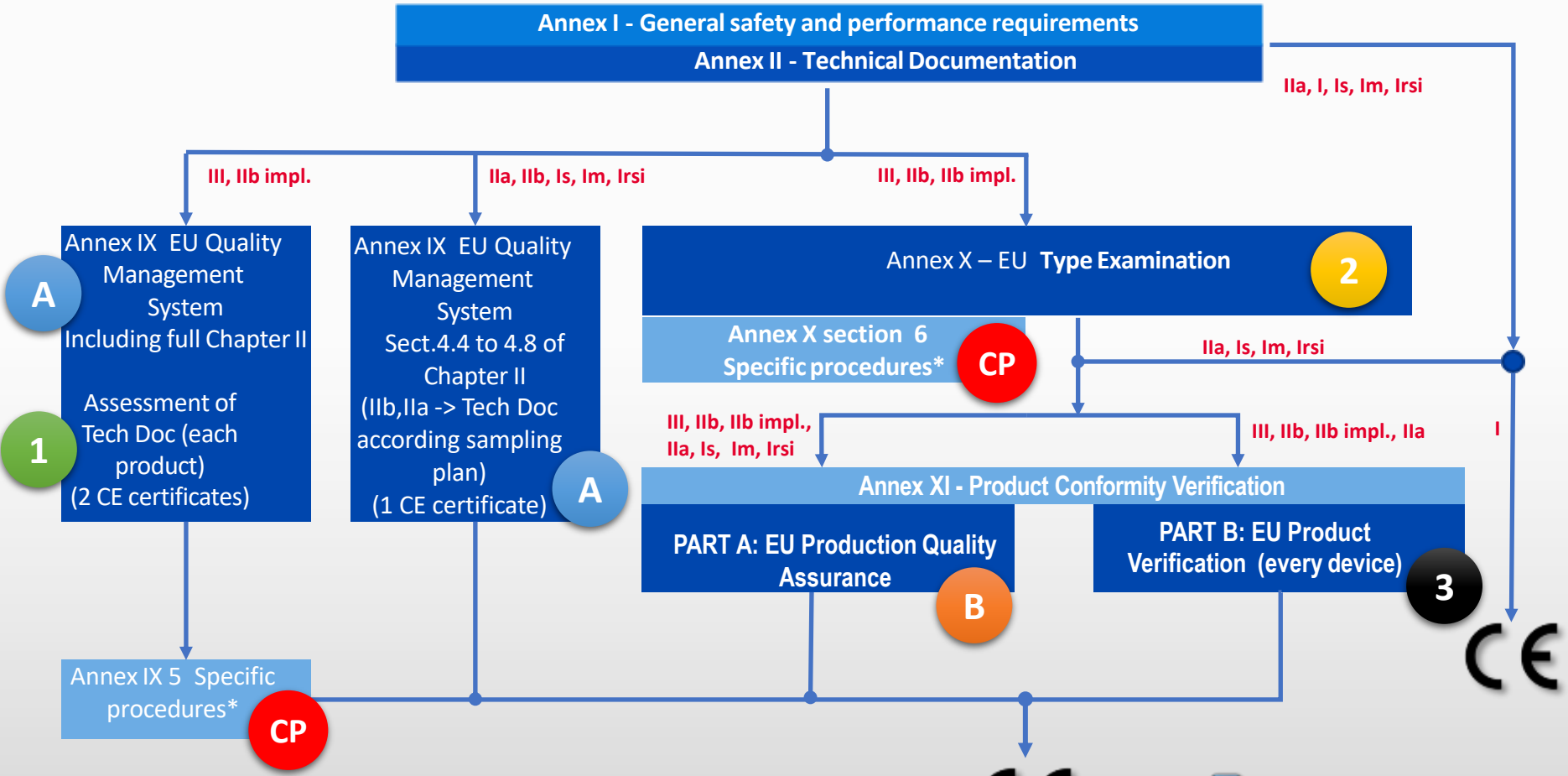
MDR Conformity Assessment Procedures



***Class III implantable devices, class III with incorporated medicinal product, class III utilising tissues or cells of human or animal origin, class IIb active devices intended to administer and/or remove a medicinal product**

medídee® MDR Certificates Annex XII + Opinion

Certificates (Product related)	Conformity assessment pathway reference	Covering…
EU technical documentation assessment 1	Annex IX – Chapter II	Tech doc review of Class III & IIb Implants* and scientific opinion of the expert panel for class III implants and IIb active devices admin./remove drugs; combi products; human tissue / animal tissue;
EU type-examination 2	Annex X to be combined with Annex XI - Part A OR Part B	Tech doc review of Class III & IIb and scientific opinion of the expert panel for class III implants and IIb active devices admin./remove drugs; combi products; human tissue / animal tissue;
EU product verification 3	Annex XI - Part B – Product verification certificate	Part B – all devices > class IIa and class IIa devices : «Batch verification» or «each device verification»
There is no certificate for consultation procedures – the NB has to consult with commission expert panel / CA / EMA		
Consultation Procedure Opinion CP	- Annex IX sect.5 or - Annex X sect.6	Specific procedures where an opinion of the commission expert panel /scientific opinion of CA is required. Clinical Consultation / Scientific Opinion CA / EMA

* Tech doc assessment for every device besides : sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors – assessment of at least one representative device per generic device group

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MDR Certificates Annex XII

Certificate (QMS related)	Conformity assessment pathway reference	Covering…
EU quality management system (A)	Annex IX – Chapter I	QMS including product design & development
EU quality assurance (B)	Annex XI - Part A – quality assurance certificate	Part A – all devices > class IIa and class IIa devices (+ aspects of sterility / measurement function / reprocessing for class I)

Conformity assessment pathway combinations = combination of certificates:

High Risk	Intermediate Risk (IIb)	Low Risk (I smr; IIa)
1 + A	A	A*
2 + B	2 + B	B
2 + 3	2 + 3	3

*** Full QMS can be choosen**

Only class IIa !

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Thank you for your attention!

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