Introduction of the Medical Device Regulation 2017/745 (MDR) for CE Marking

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By Royal Charter

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Benefits to you

Introduction the requirements of the European Medical Devices Regulation

Take the necessary steps for your organization to meet the MDR requirements

Maintain compliance to MDR and other/future documents related to Medical Device legislation

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Welcome

Introductions

Course aim

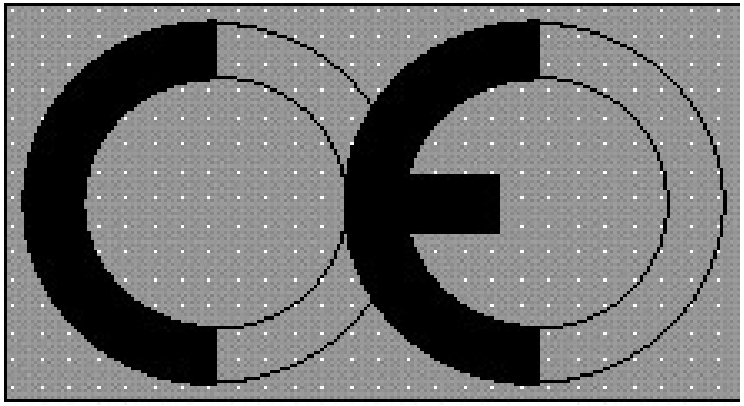
To provide the knowledge to requirements of the MDR in your organization, and to obtain and maintain CE marking for your product

Some Regulatory Background

What is CE Marking?

A legal mark

Affixed by manufacturer



Law defines appearance and size

Manufacturer's declaration

CE mark is not:

- A voluntary quality mark
- Owned by any particular company

Certification issued by Notified Bodies

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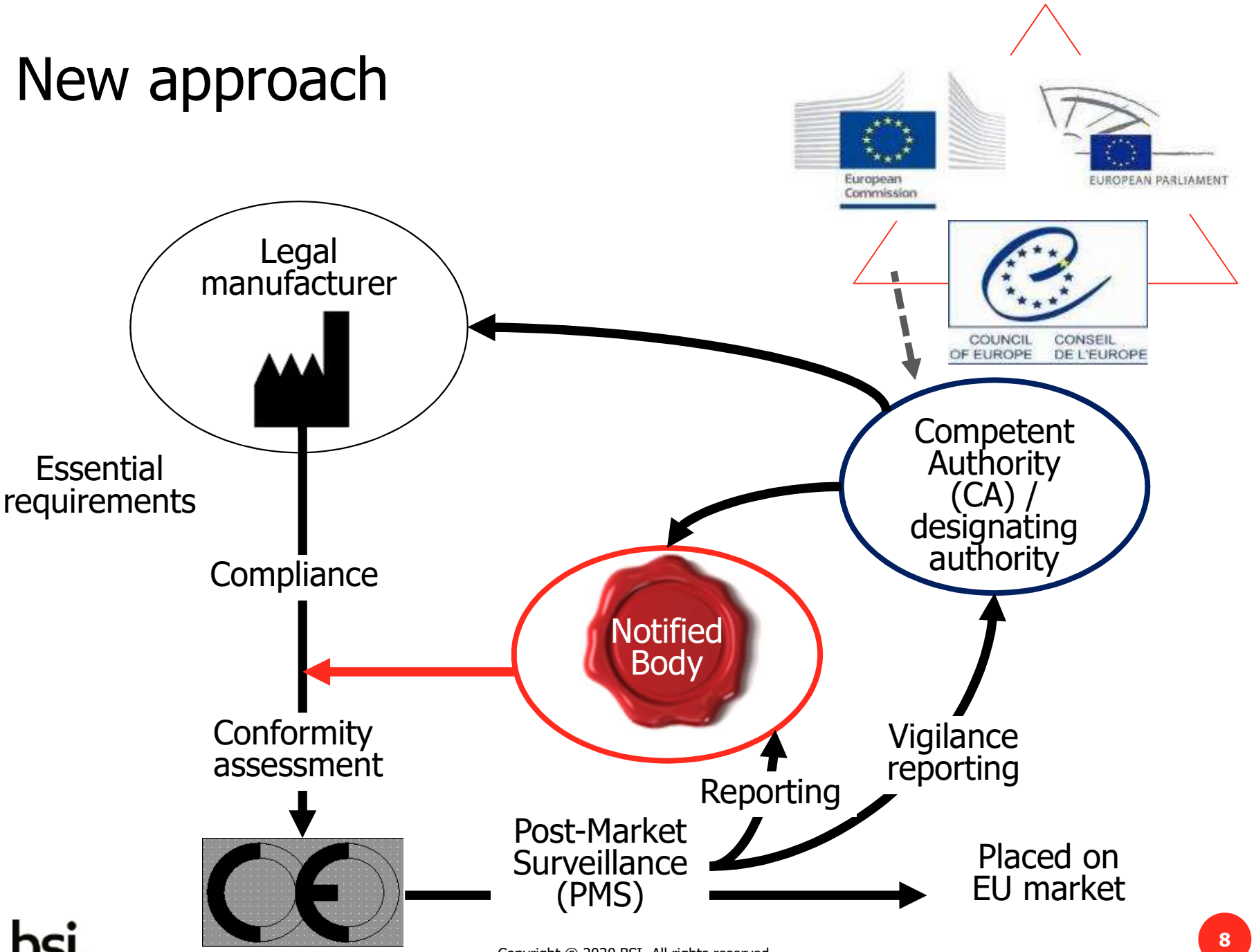
New approach



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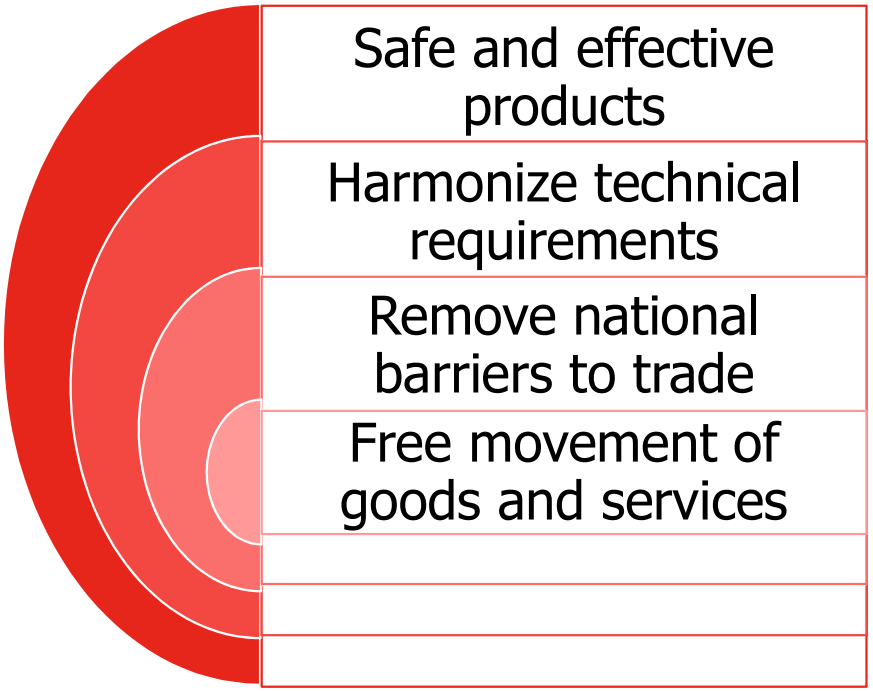
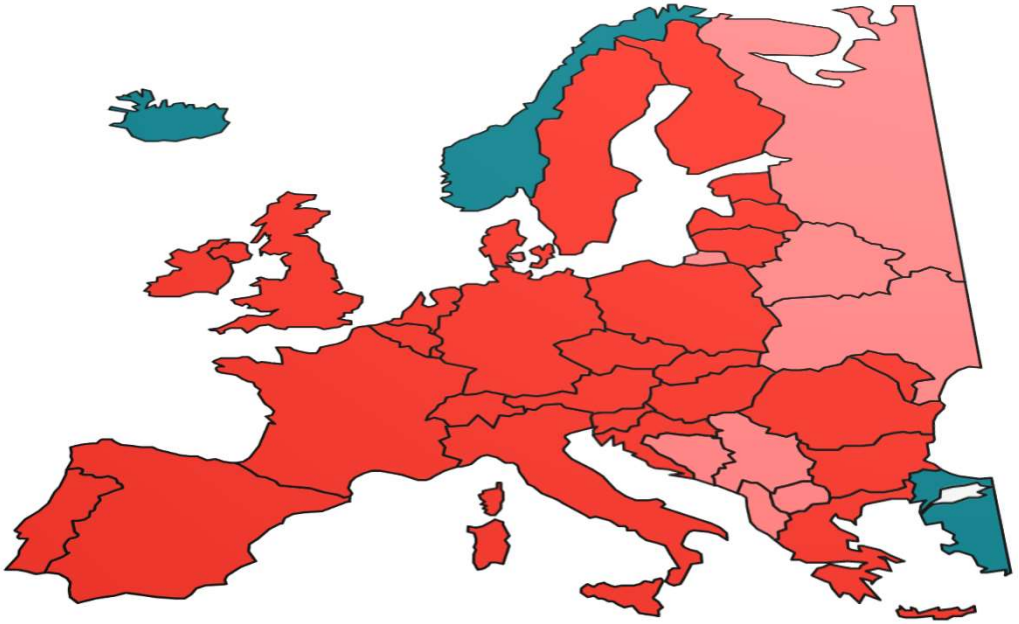
Where is CE marking mandatory?

Within EU, European Economic Area (EEA), Switzerland, Turkey





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MDD Amendments

Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L169, 12/07/1993)

Amended by:

M1 Directive 98/79/EC, 27 October 1998 (L331, 17/12/1998)

M2 Directive 2000/70/EC, 16 November 2000 (L313, 13/12/2000)

M3 Directive 2001/104/EC, 7 December 2001 (L006, 10/01/2002)

M4 Regulation (EC) No 1882/2003, 29 September 2003 (L284, 31/10/2003)

M5 Directive 2007/47/EC , 5 September 2007 (L247, 21/09/2007)

Medical Device Regulation: What will Change?

Many new requirements placed on all players in the sector, including regulators, manufacturers, suppliers, sub-contractors, importers, authorised representatives, distributors and healthcare institutions.

Recital (4) sets expectations

- **Key elements of the existing regulatory approach**, such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance **should be significantly reinforced**, whilst provisions ensuring **transparency and traceability** regarding in vitro diagnostic medical devices should be **introduced to improve health and safety**.

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Why Not a New Directive?
Directives vs Regulations: Relationship with National Legislation

- The Member States decide how and in what form Directives are put into local laws
- Many countries use their Consumer Protection legislation
- Regulations (MDR/IVDR) are law immediately throughout Member States once entered into OJ
- MDD, AIMD and IVDD slow to adapt to technical progress

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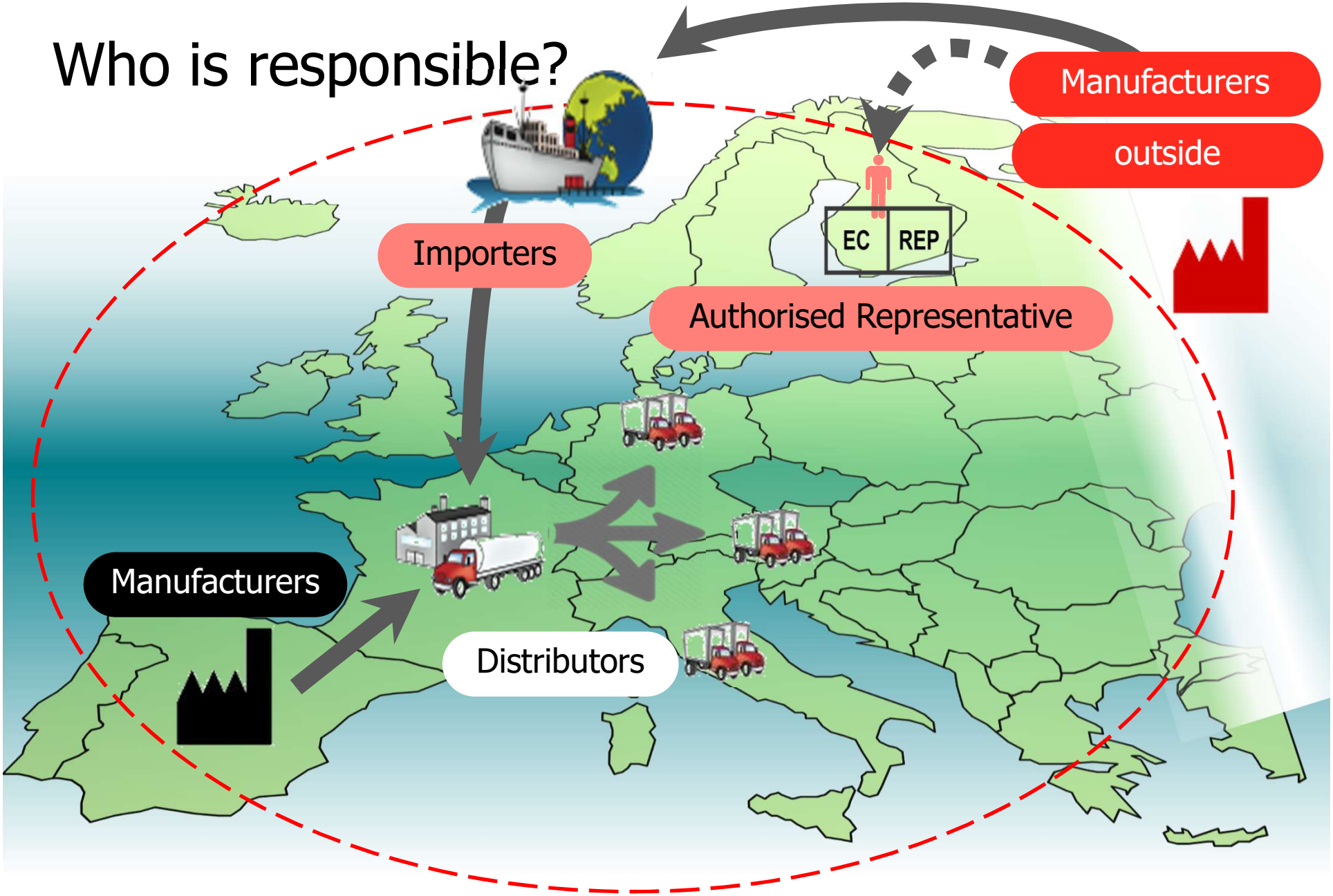
MDR 2017/745 and IVDR 2017/746: Top Level

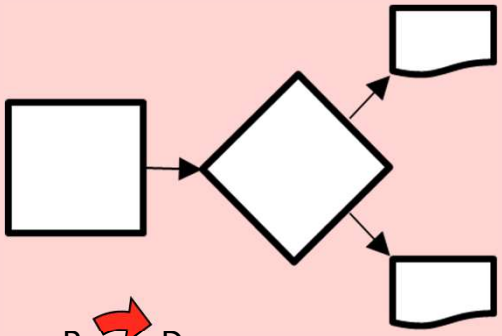
General obligations

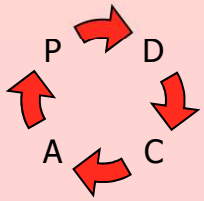
Who is responsible?



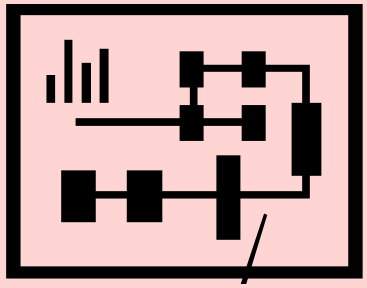
Most responsible: The manufacturer

Quality and Risk Management System



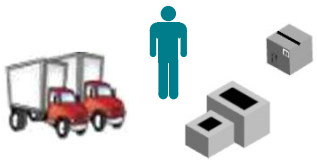


Conformity assessment Technical File



Post-market: Vigilance, Follow-up

Includes external resources



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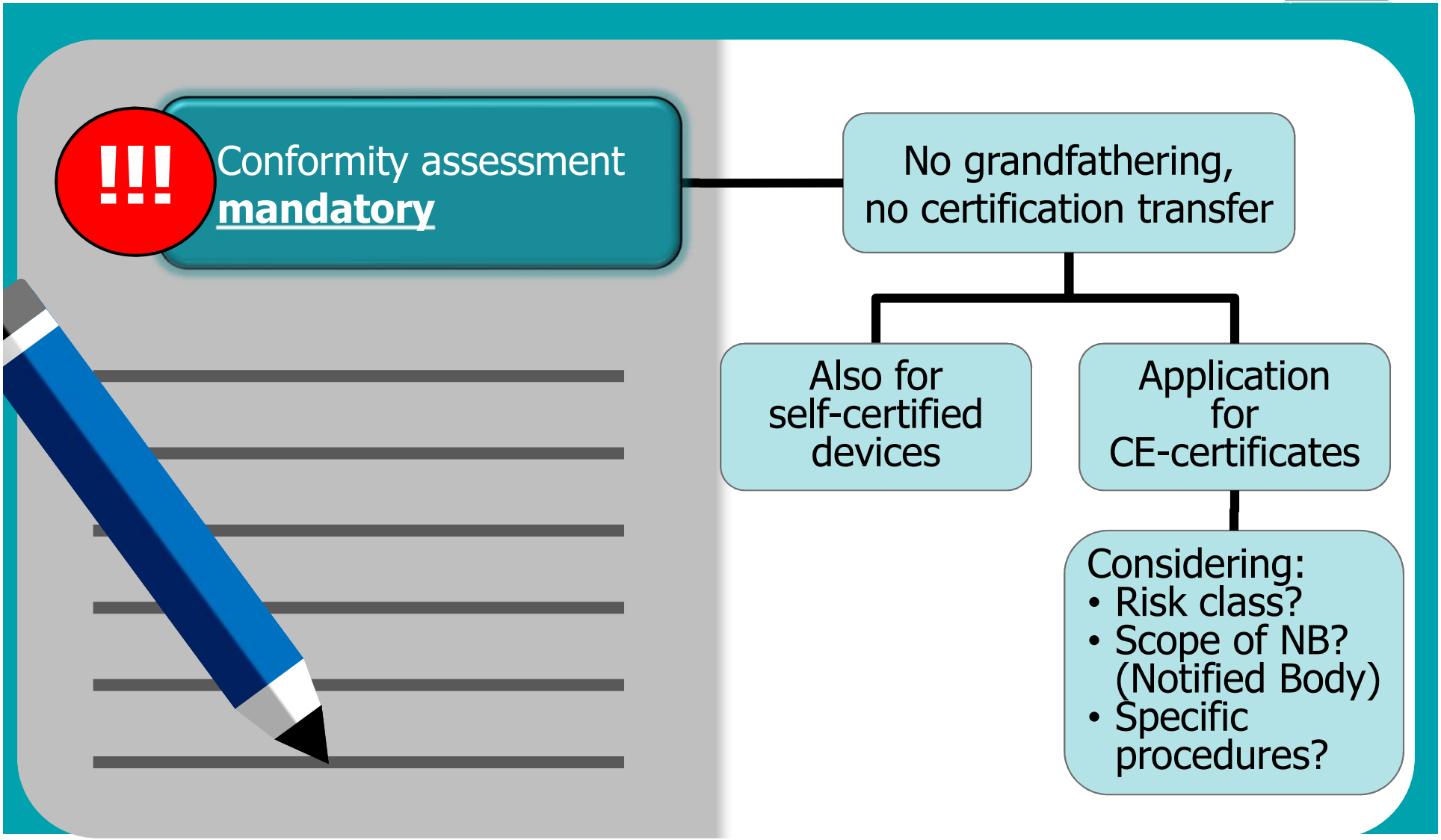
Conformity assessment is mandatory



MDR Designated Notified Bodies End of May 2020

Search Criteria:

Regulation (EU) 2017/745 on medical devices

Legislation: ALL

Procedure/ article or annex: ALL

Products:

Horizontal technical competence: ALL

SEARCH

Body type ▲	Name ▲	Country ▲
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Scope of the MDR

1	**Check device is within scope of MDR**	**(Chapter I, §1, §2, Annex XVI)**
2	Determine risk class of device and applicable MDR codes	(Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
3	Select conformity assessment procedure	(Chapter V, §52)
4	Maintain QMS	(Chapter II, §10)
5	Identify applicable safety and performance requirements	(Chapter II, §5, Annex I)
6	Assemble Technical Documentation	(Annex I, Annex II, Annex XIV)
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8	Assign Unique Identifications	(Chapter III, §27-34, Annex VI)
9	Complete Declaration of Conformity and affix CE mark	(Chapter II, §19 =>Annex IV) (Chapter II, §20, =>Annex V)
10	Post-market surveillance and updates	(Chapter VII, §83 to 86, Annex XIV => Annex III)

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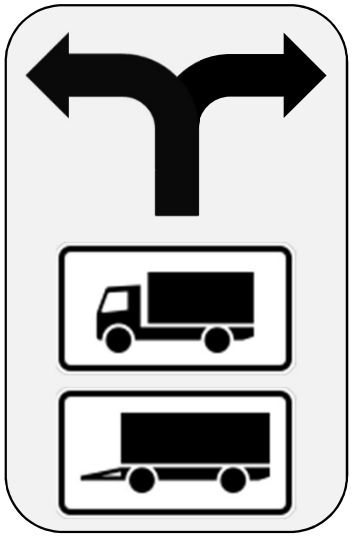
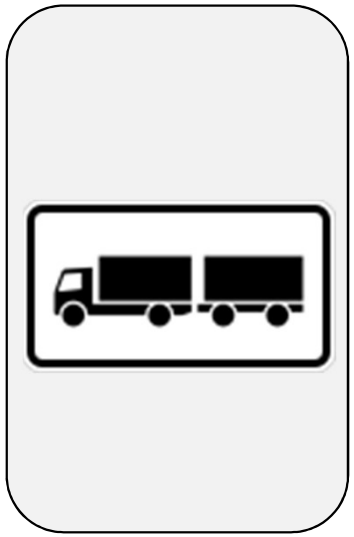
Relation of MDR to other Union Legislation

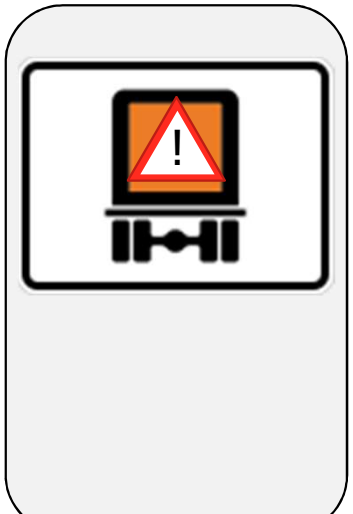


'One or the other'
Products covered by other Union legislations excluded

But devices in annex XVI (without Medical Purpose) included



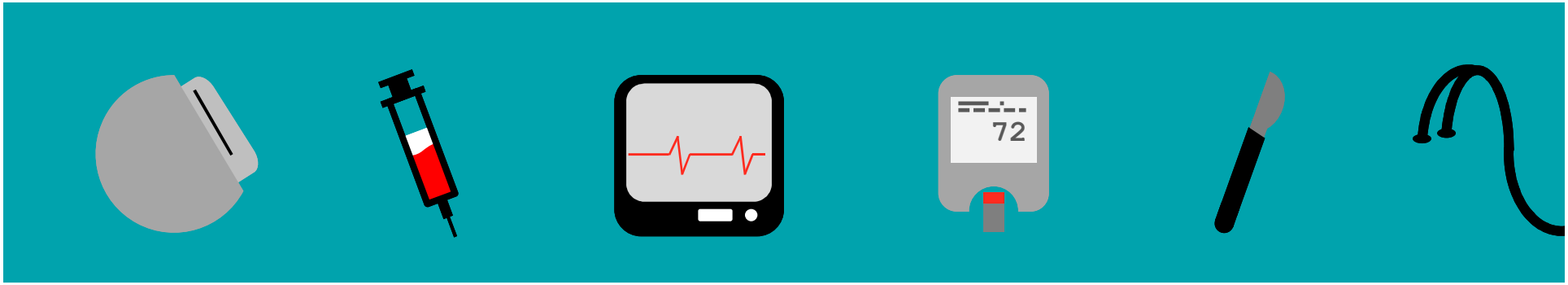
'Combinations'
Product parts must fulfil applicable parts of respective Union legislations



'Plus this'
Device must additionally fulfil other Union legislation

Definition: Medical device and accessories

'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.



'Accessory for a medical device':

- Enable the medical device(s) to be used, or
- Assist the medical functionality

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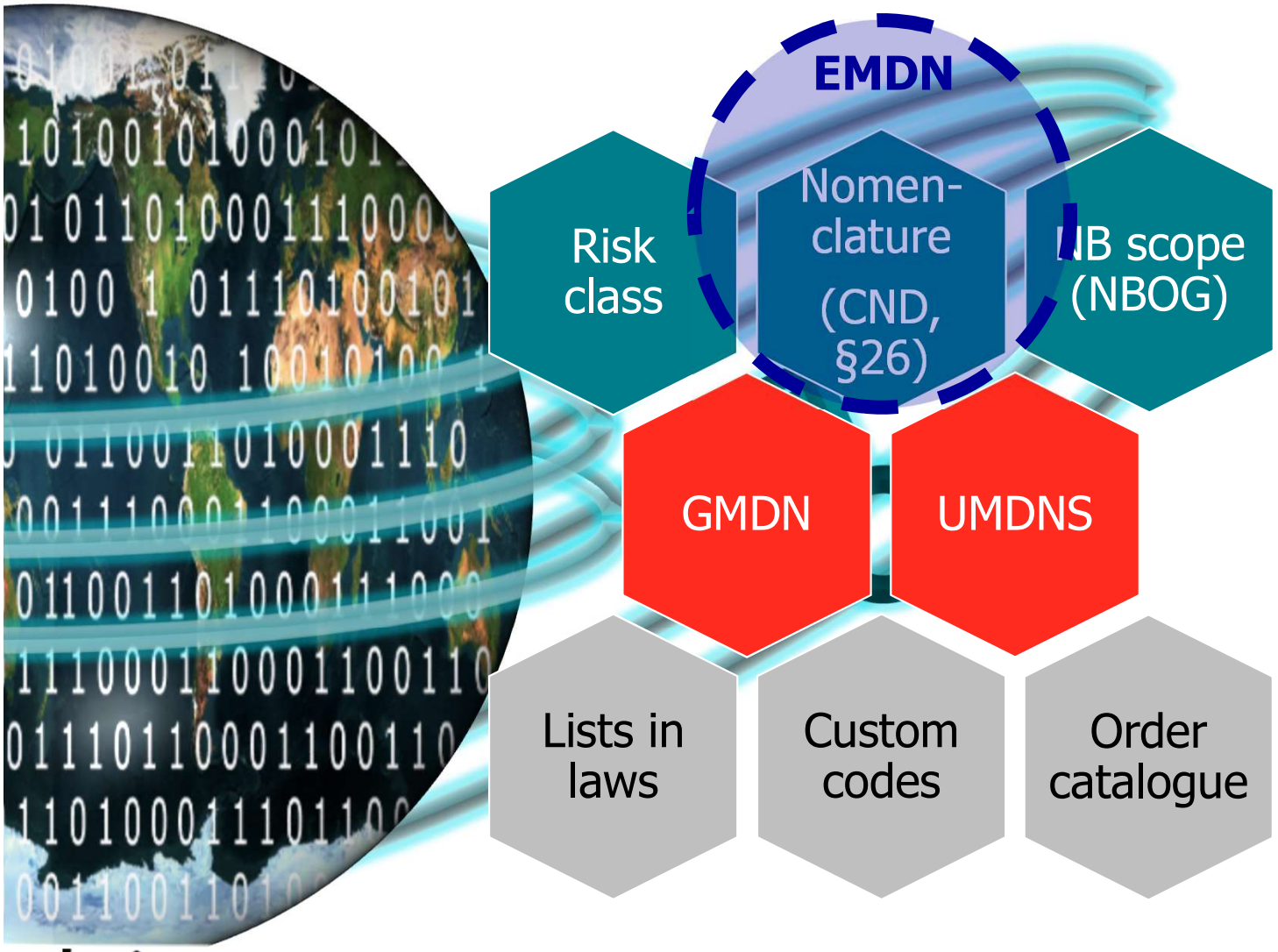
Different codes for Medical Devices



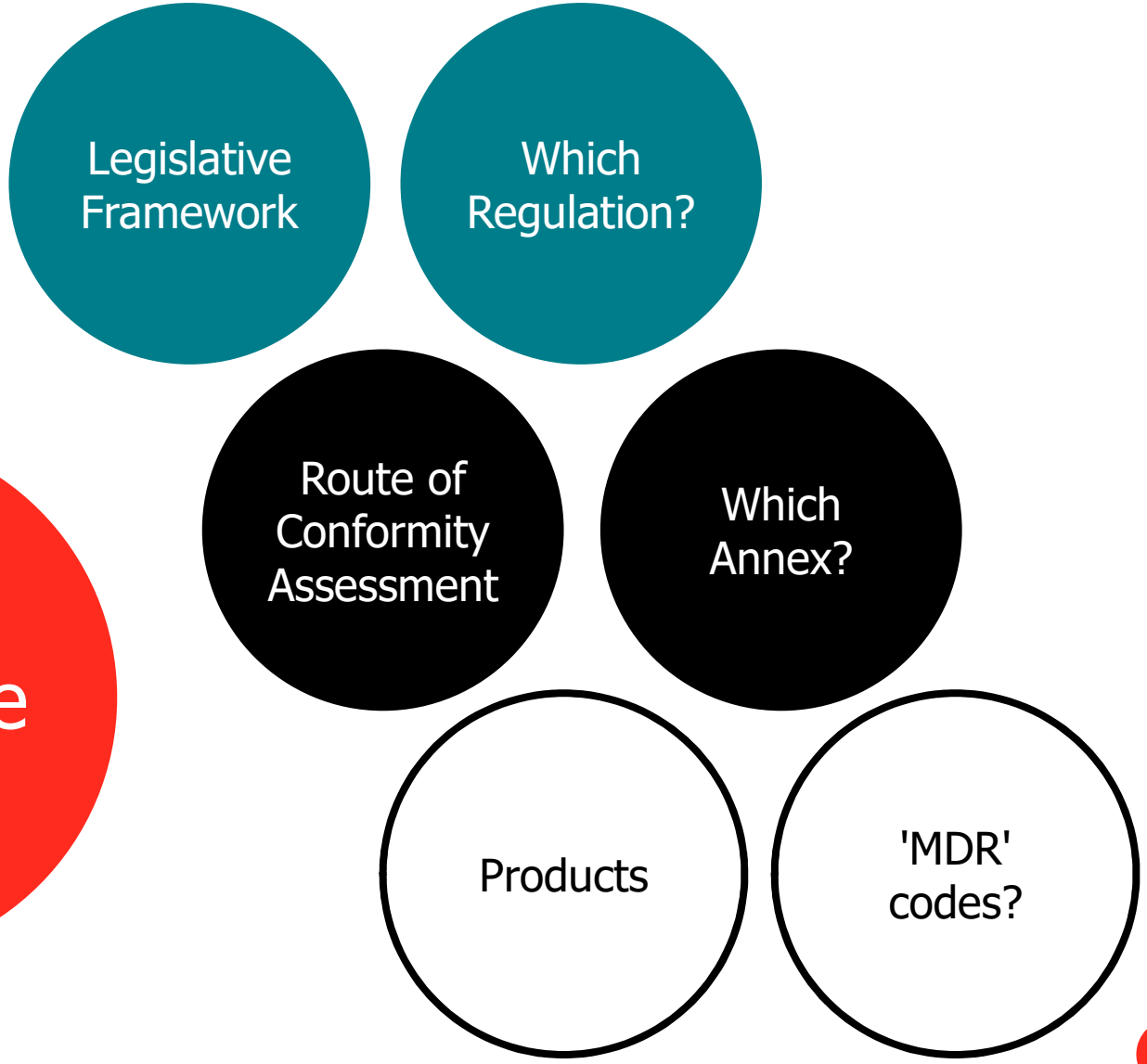
Within EU

International

Local

Is the Notified Body competent?

This depends on:



If not: Certificate is void!

MDR Codes: MDCG 2019-14, Explanatory note on MDR codes December 2019

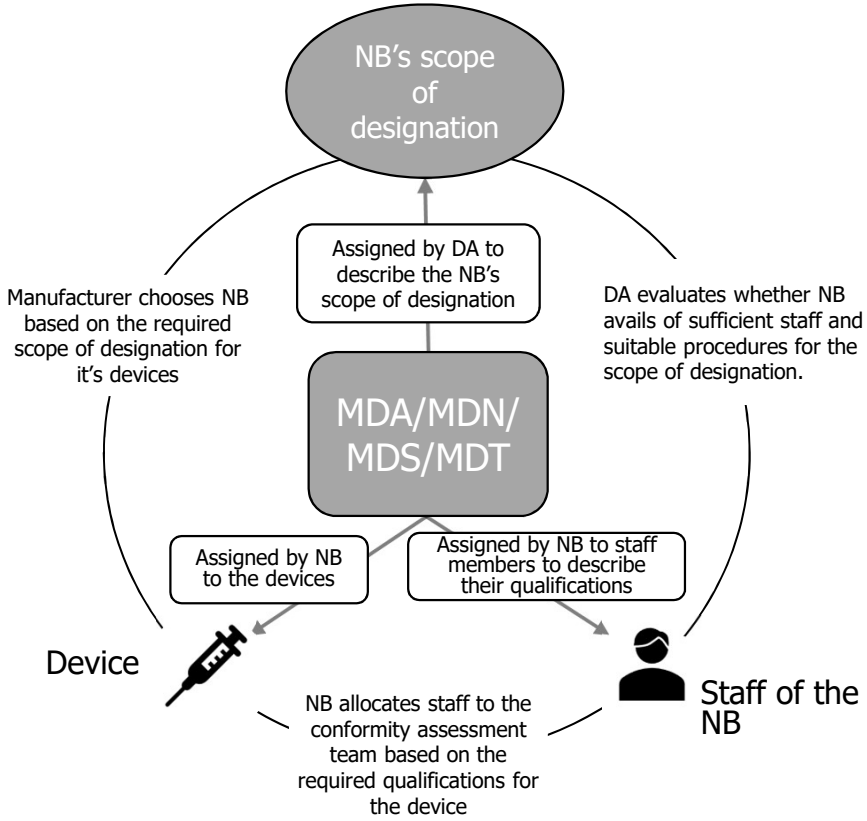
Main use to define the notified body scope of designation

Also used by the notified body to:

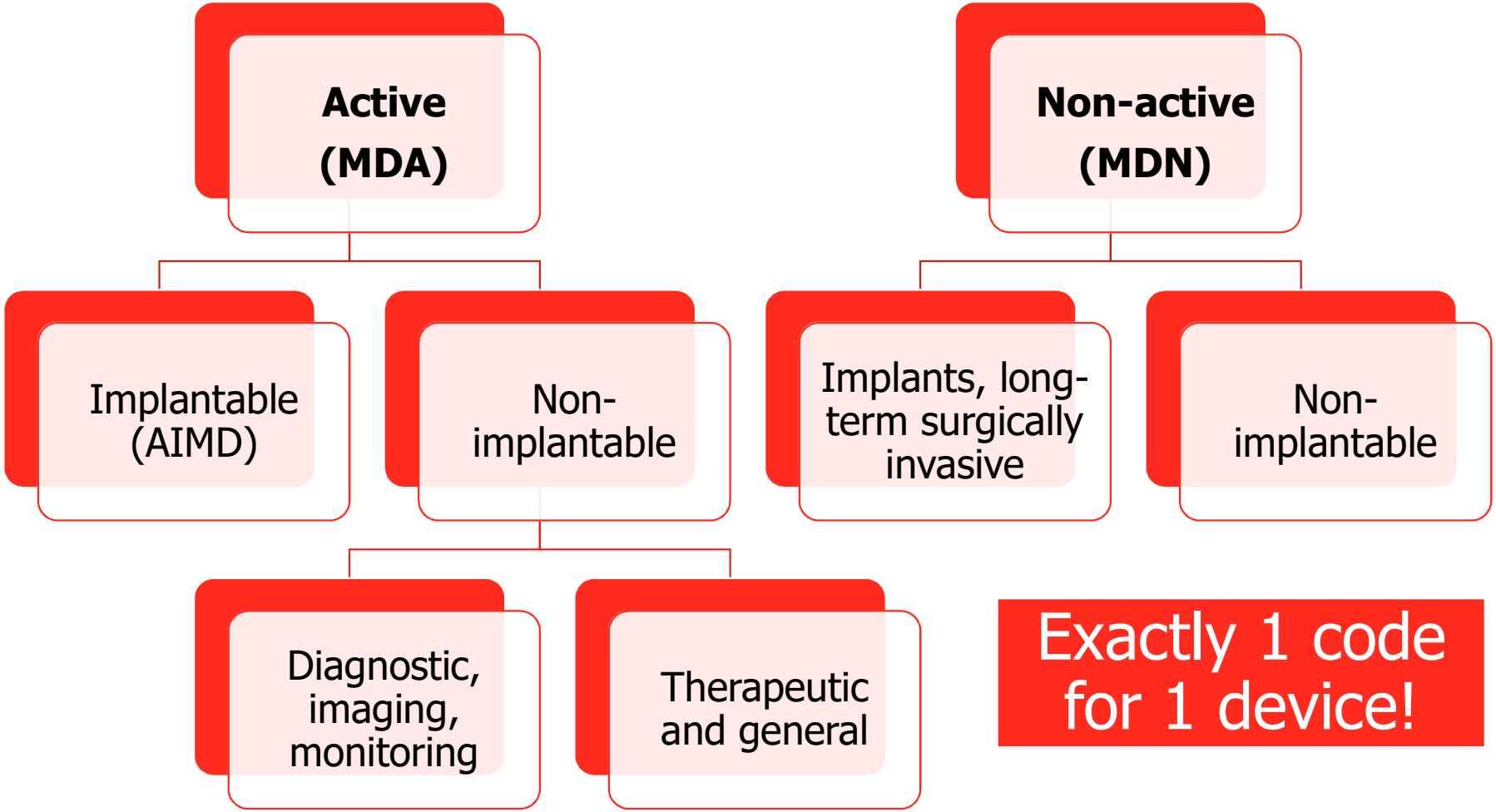
- Describe the individual qualification of the NBs staff members
- Describe the qualification required for assessing a device

Codes assigned to devices within the conformity assessment procedure

Reference: Commission Implementing Regulation (EU) 2017/2185.

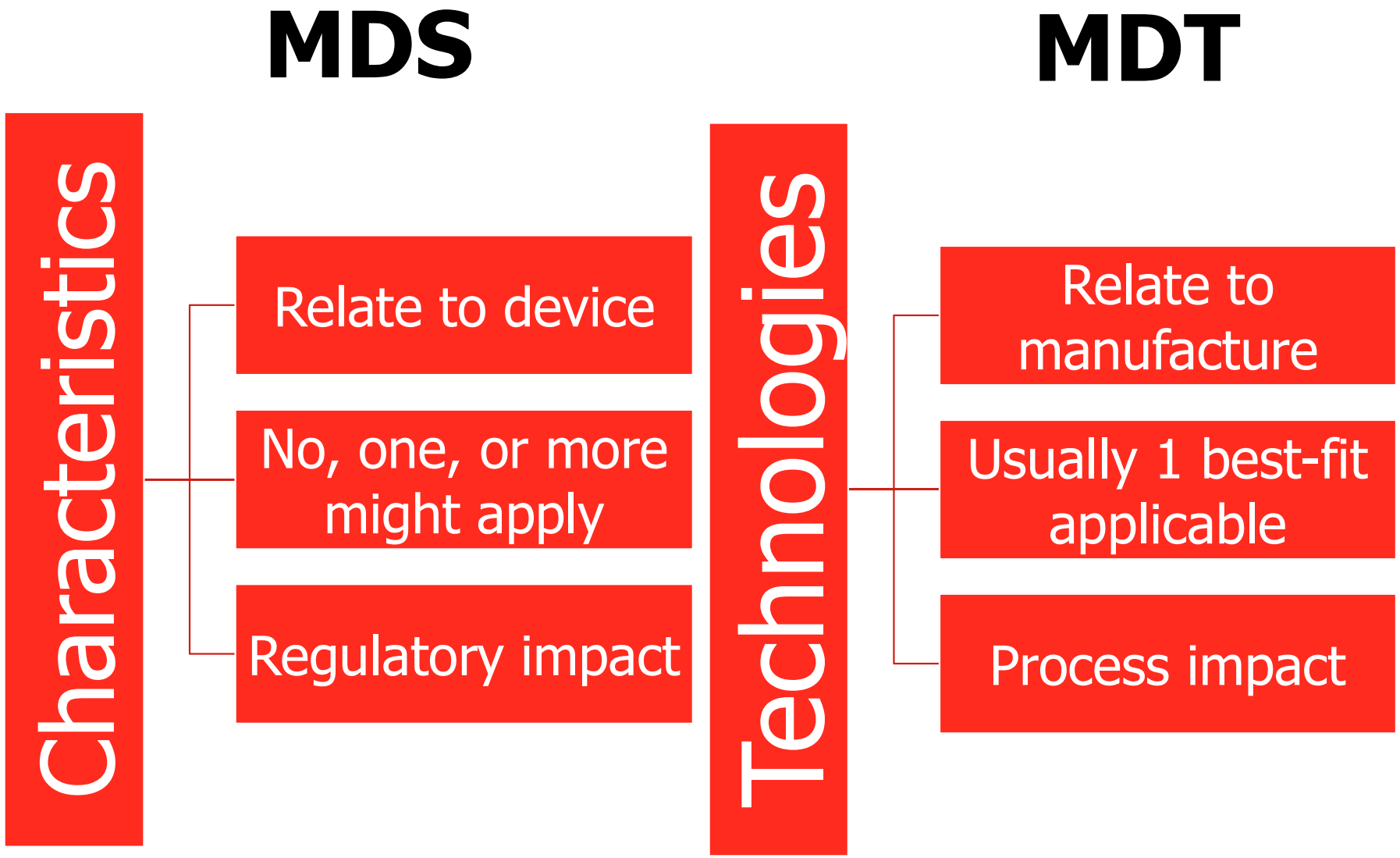


Code on design/intended purpose (MD*)



Reference: Commission Implementing Regulation (EU) 2017/2185.

Horizontal codes for designation of NB



Determine risk class and applicable MDR codes

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
2	**Determine risk class of device and applicable MDR codes**	**(Chapter V, §51 => Annex VIII)** **(Article 38, Regulation 2017/2185)**
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22 rules in the MDR: Annex VIII

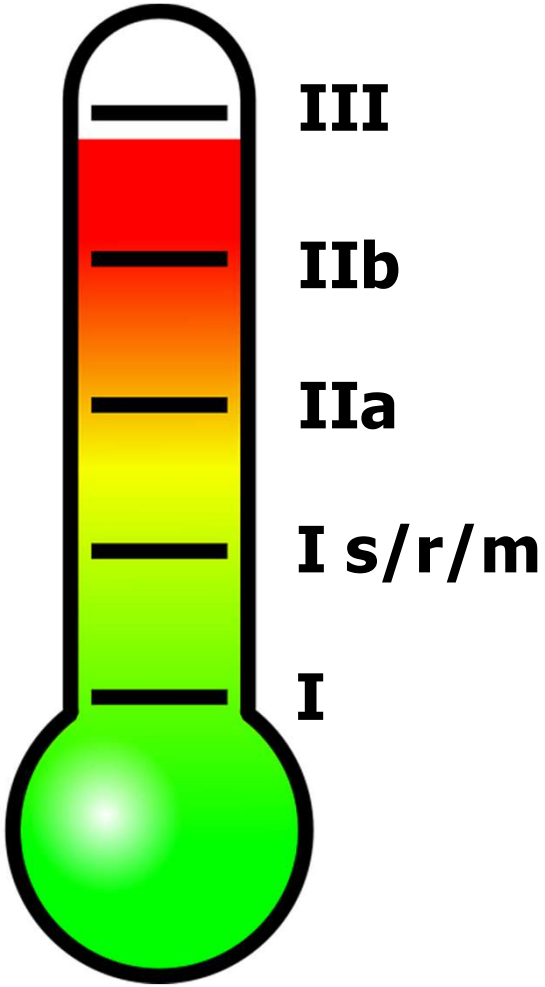
The table below sorts the classification rules.

Rules	Examples
1 to 4 non-invasive	    
5 to 8 invasive	     
9 to 13 active	    
14 to 22 special rules	   

Classification rules: Criteria in the MDR

Criteria	Possible instances e.g.
Invasiveness	Indirect contact – skin – invasive – surgically invasive
Duration of use	Transient – short term – long term - implantable
Energy	Passive – active
Overall intention	Diagnostic – therapeutic – closed loop
Special concerns	Materials composition – indication of use.

Risk-based classification under MDR



The higher the risk, the more scrutiny

s/r/m = sterile re-usable measuring

Select conformity assessment procedure

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Conformity Assessment

What
§2 (40)

The **process demonstrating** whether the requirements of this Regulation relating to a device have been fulfilled

Devices …shall be **designed and manufactured** in such a way that,…., they are suitable for their intended purpose.

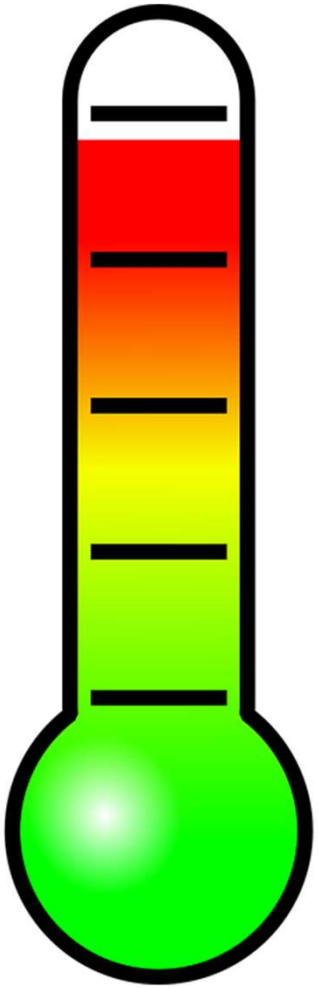
How
Annex I (1)

They shall be **safe and effective**…

The higher the risk, the more assessment

Sampling increases

Individual devices
Narrowing product families
Broad product families



Assessors accumulate

Commission
Competent Authority
Notified Body
Manufacturer

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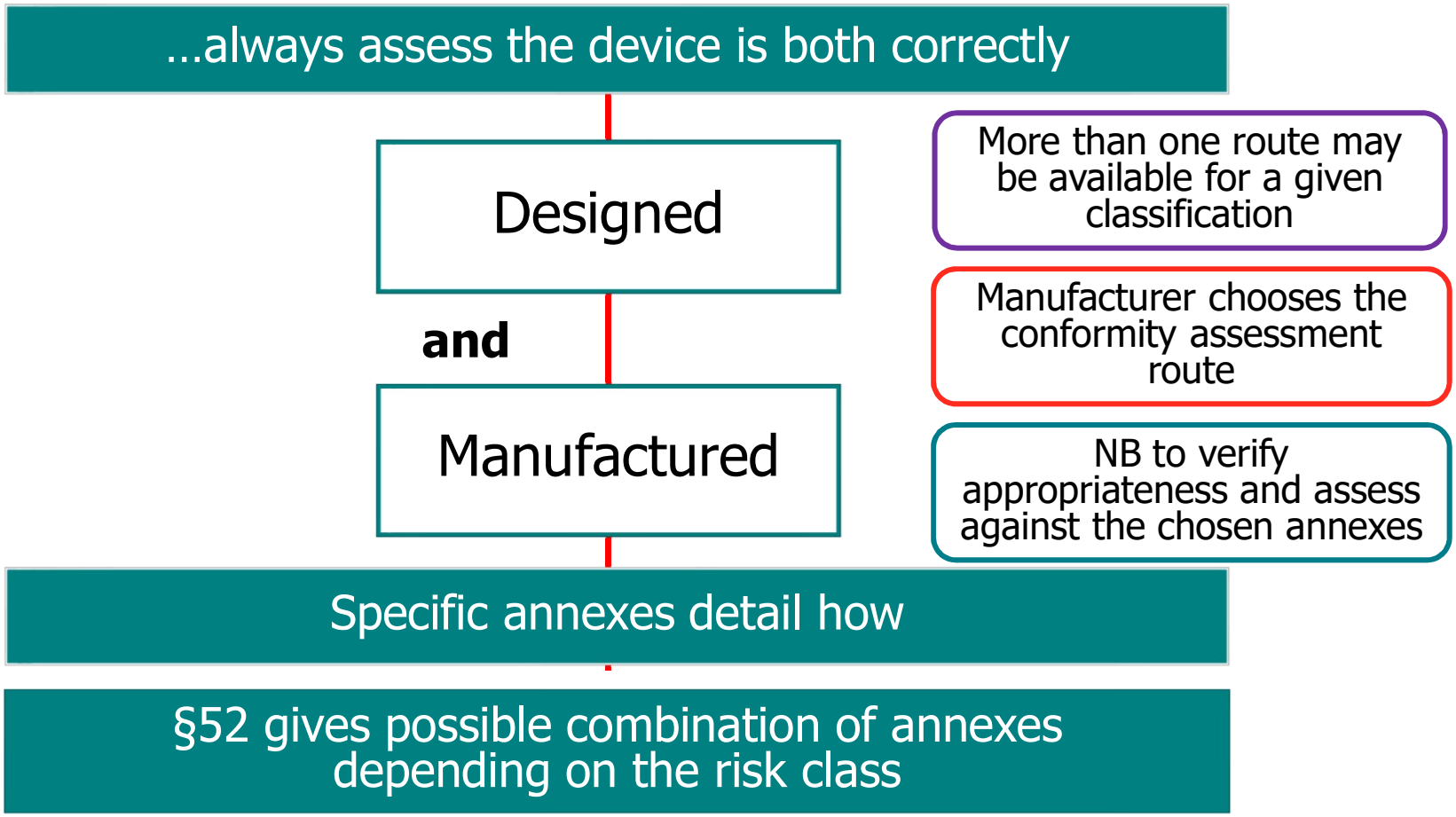
Conformity assessment procedures…



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

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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

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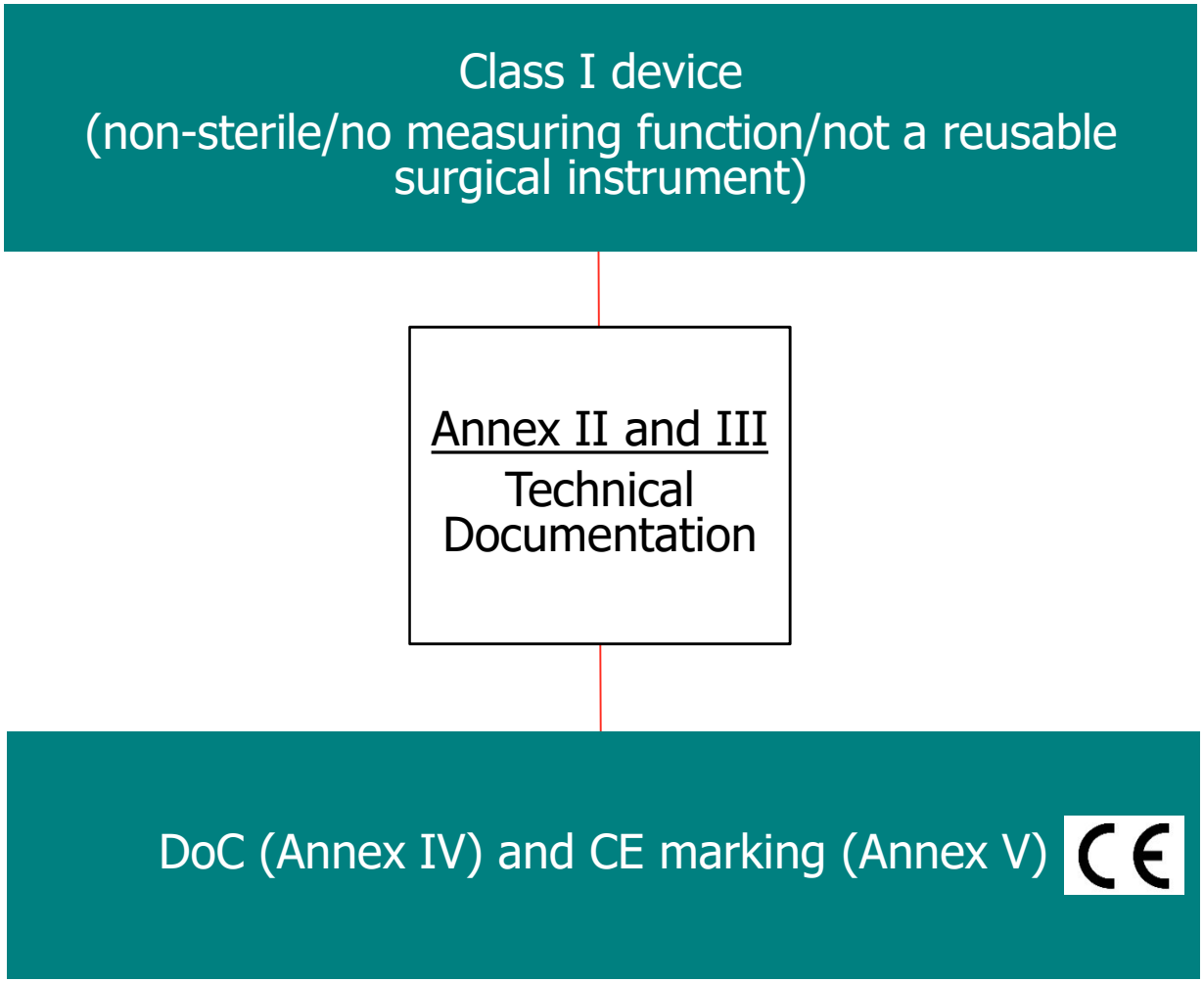
MDD and MDR Conformity Assessment Routes Compared

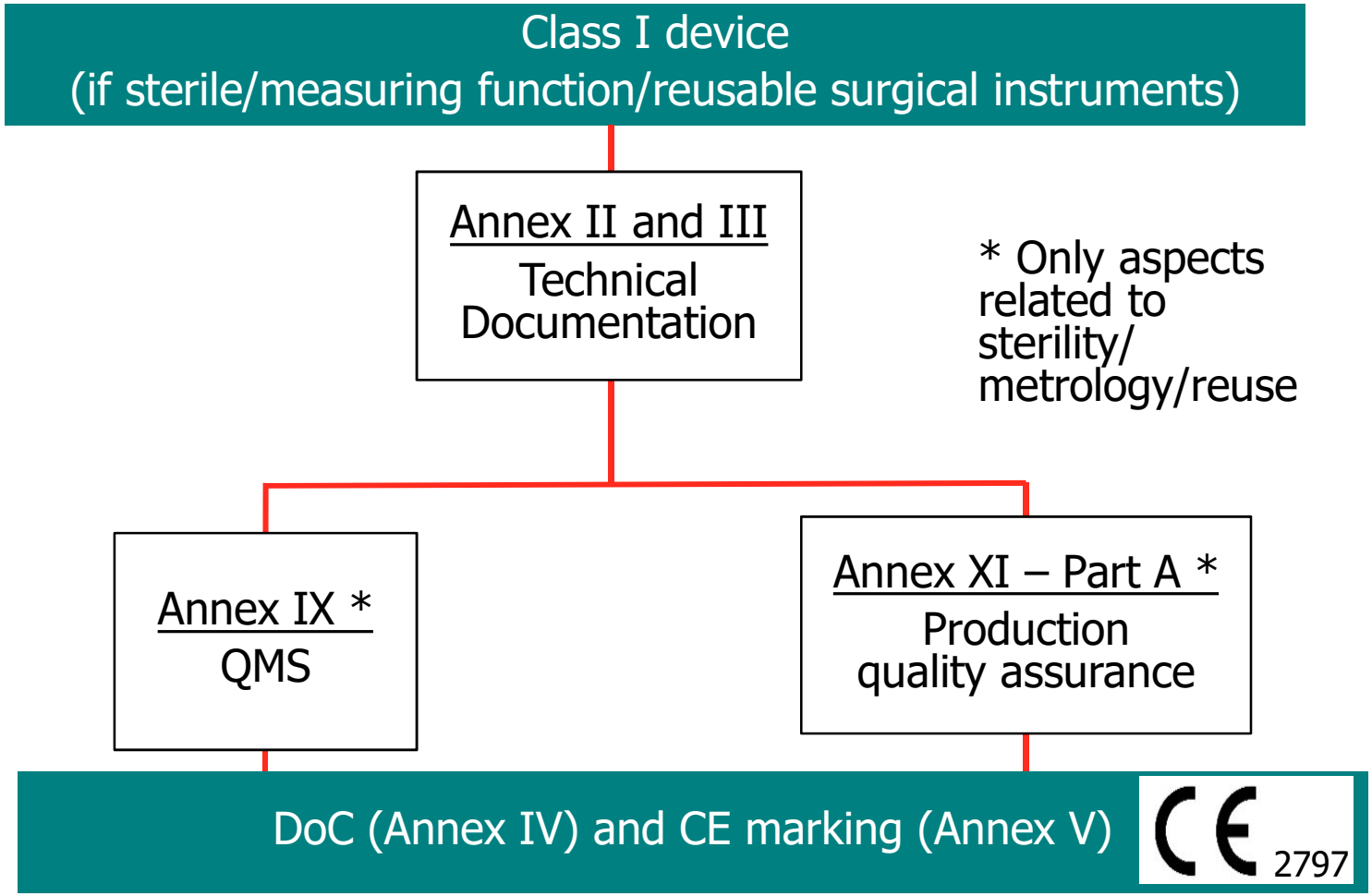
MDR	MDD	Focus of Annex
Annex IX Chapters I and III Quality Management System	Annex II excl Section 4 Full Quality Assurance	QMS based; Design, Manufacture, Final Inspection
Annex IX Chapter II Technical Documentation	Annex II Section 4 Design Examination	Product based; Documentation review
Annex X Type-Examination	Annex III Type Examination	Product based; Typ
Annex XI - Part B Product Verification	Annex IV Verification	
Annex XI - Part A Production Quality Assurance	Annex V Production Quality Assurance	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

Certificates based on Annex IV of the directive will become void in 2022

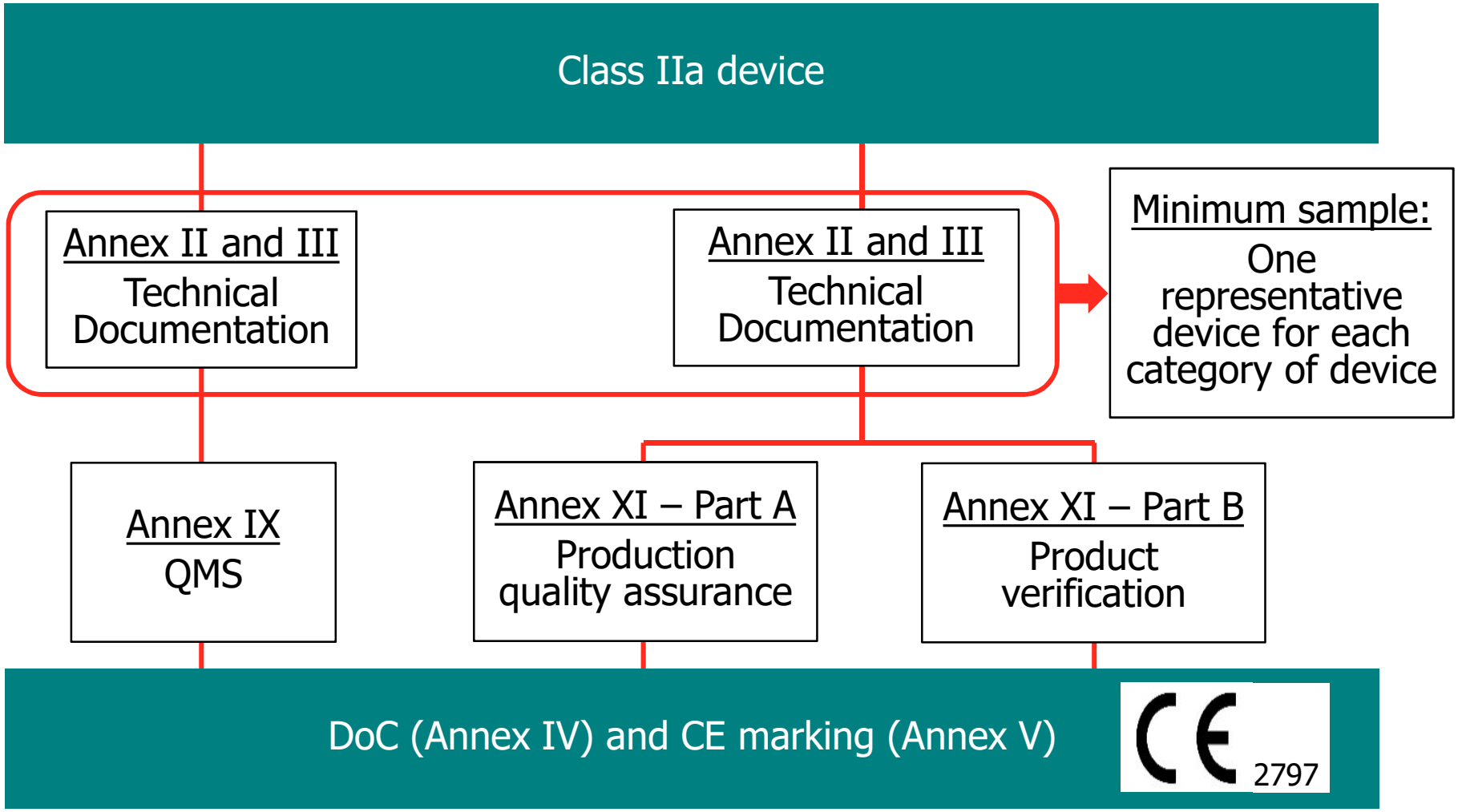
MDR Conformity Assessment Route Class I



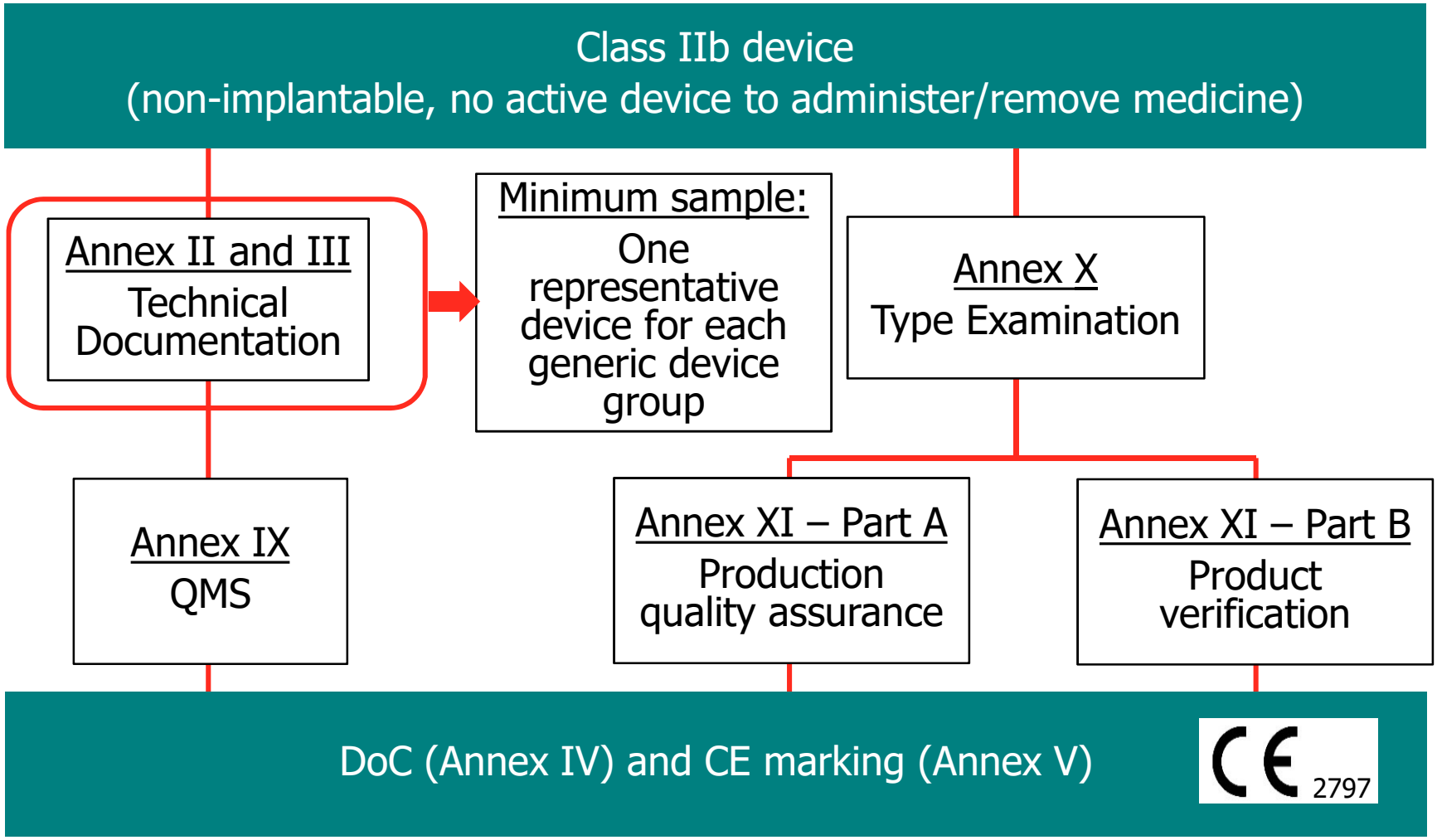
MDR Conformity Assessment Route Class I smr



MDR Conformity Assessment Routes Class IIa

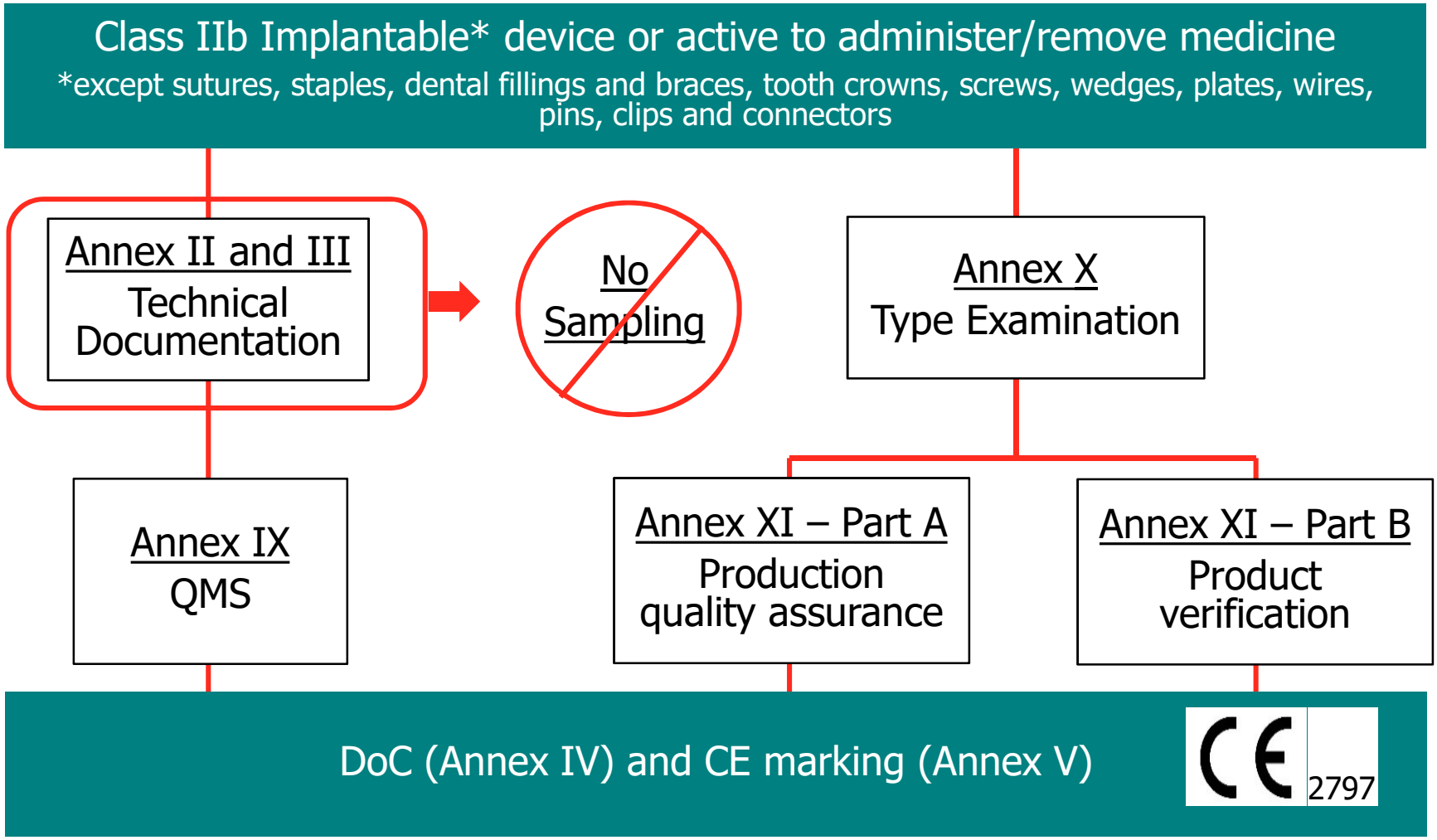


MDR Conformity Assessment Routes Class IIb

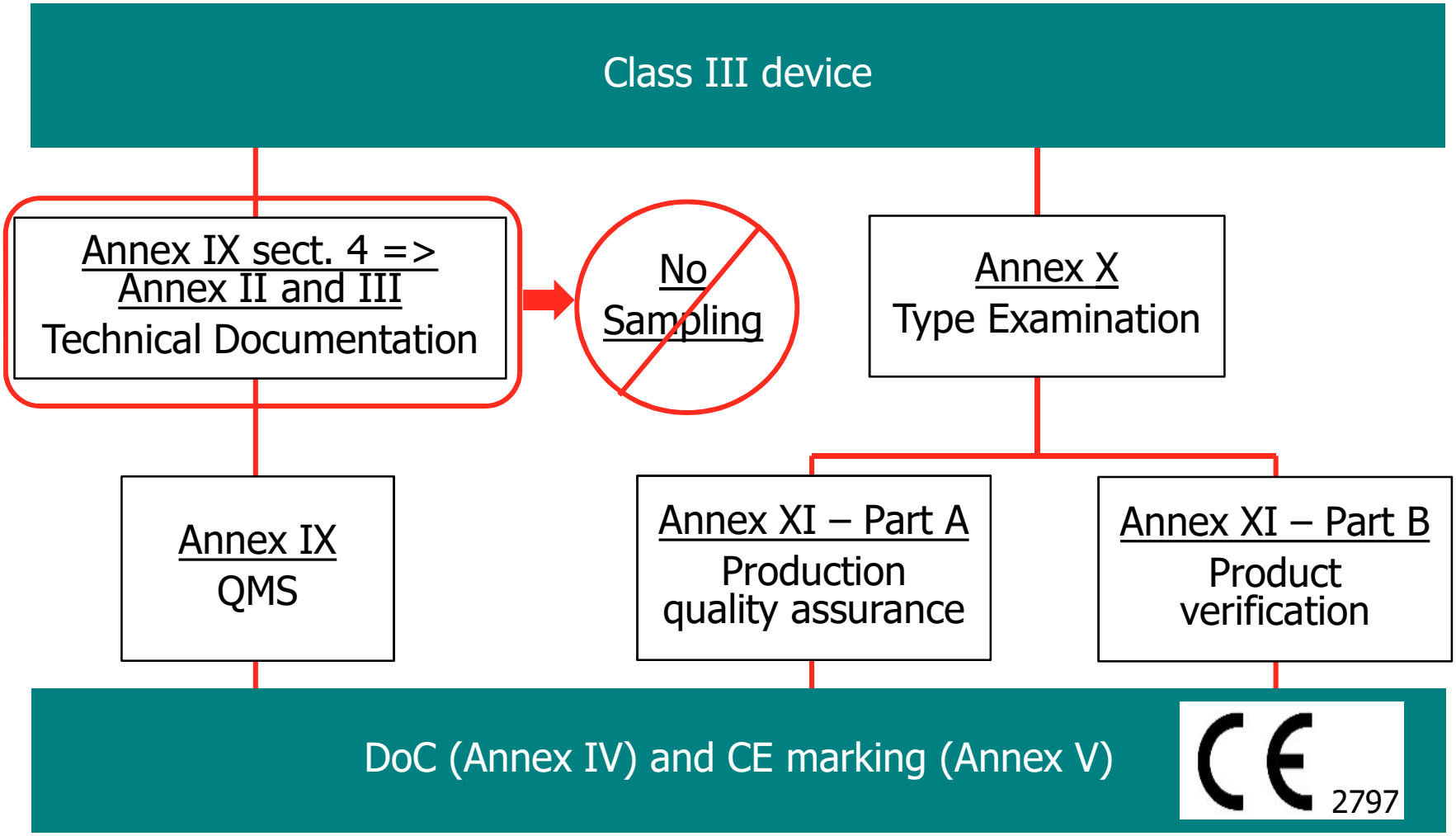


MDR Conformity Assessment Routes Class IIb

Implantable* device or active to administer/remove medicine



MDR Conformity Assessment Routes Class III Device



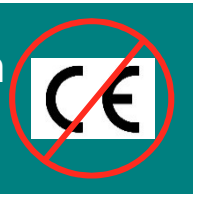
MDR Conformity Assessment Route Custom Made Devices (except Class III implantable)

Custom made devices (except Class-III-implantable)

Annex XIII
Documentation
(instead of TD)

Annex XIV – Part B
Experience gained in post-production
including from PMCF

Name of person authorized to make out prescription, name of healthcare institution and name of particular patient and meets requirements of annex I



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MDR Conformity Assessment Route Class III Implantable Custom Made Devices

Class III Implantable – Custom made devices

Annex XIII
Documentation (instead of TD)

Annex IX
QMS

Annex XI – Part A
Production quality assurance

Name of particular patient, name of person authorized to make out prescription and name of healthcare institution and meets requirements of annex I

CE 0086

All Routes to Conformity require:

Technical documentation controlled

Sub-contractors/suppliers defined and controlled

Conformity assessment by a NB (except Class I, Custom-made non class III implantable devices)

Higher the risk -> More involvement of NB + involvement of other entities (CA, Expert panels etc) for some high-risk devices

All routes should give equivalent assurance of compliance

Specific additional procedures under the MDR: Additional actors to involve

Classified as	Incorporates	Composed of	Manufactured using
Implantable class III Commission → Expert panel	**Medicinal substances** Medicinal Product authority (local or EMA)	**Systematically absorbed substances** Medicinal Product authority (local or EMA)	**Cells or tissues of human origin** Competent authority for cells/tissue
Active IIb to administer/remove medicinal product Commission → Expert panel Article 54 Clinical Evaluation Consultation Procedure (CECP)	**Blood derivatives** EMA as Medicinal Product authority		**Cells or tissues of animal origin** Coordinating competent authority → CA of member states (see 722/2012/EU)

Don't forget about eventual combination products!

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Amend and maintain QMS

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
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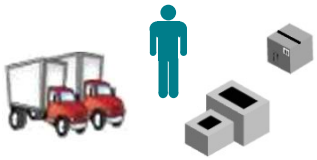
All manufacturers need for conformity

Quality and Risk Management System	Technical File	Post-market: Vigilance, Follow-up
§10 (2) & (9) ➢ Annex I (3) *In case also* ➢ Annex IX *or* ➢ Annex XI, A	§10 (4)* ➢ Annex II ➢ Annex III *for custom made: §10(5) ➢ Annex XIII (2)	§10 (10) & (13) ➢ §83 (PMS) ➢ §87, §88 (reporting) ➢ §61, Annex XIV (PMCF) *for custom made: ➢ Annex XIII (5)

Includes External resources !



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QMS Audits

Regular visits

- Announced
- Scheduled
- E.g. annually

Additional visits

- Announced
- On application
- E.g. extensions, significant changes

Unannounced audit visits

- Unannounced
- At random
- To verify device conforms to Tech. Doc.

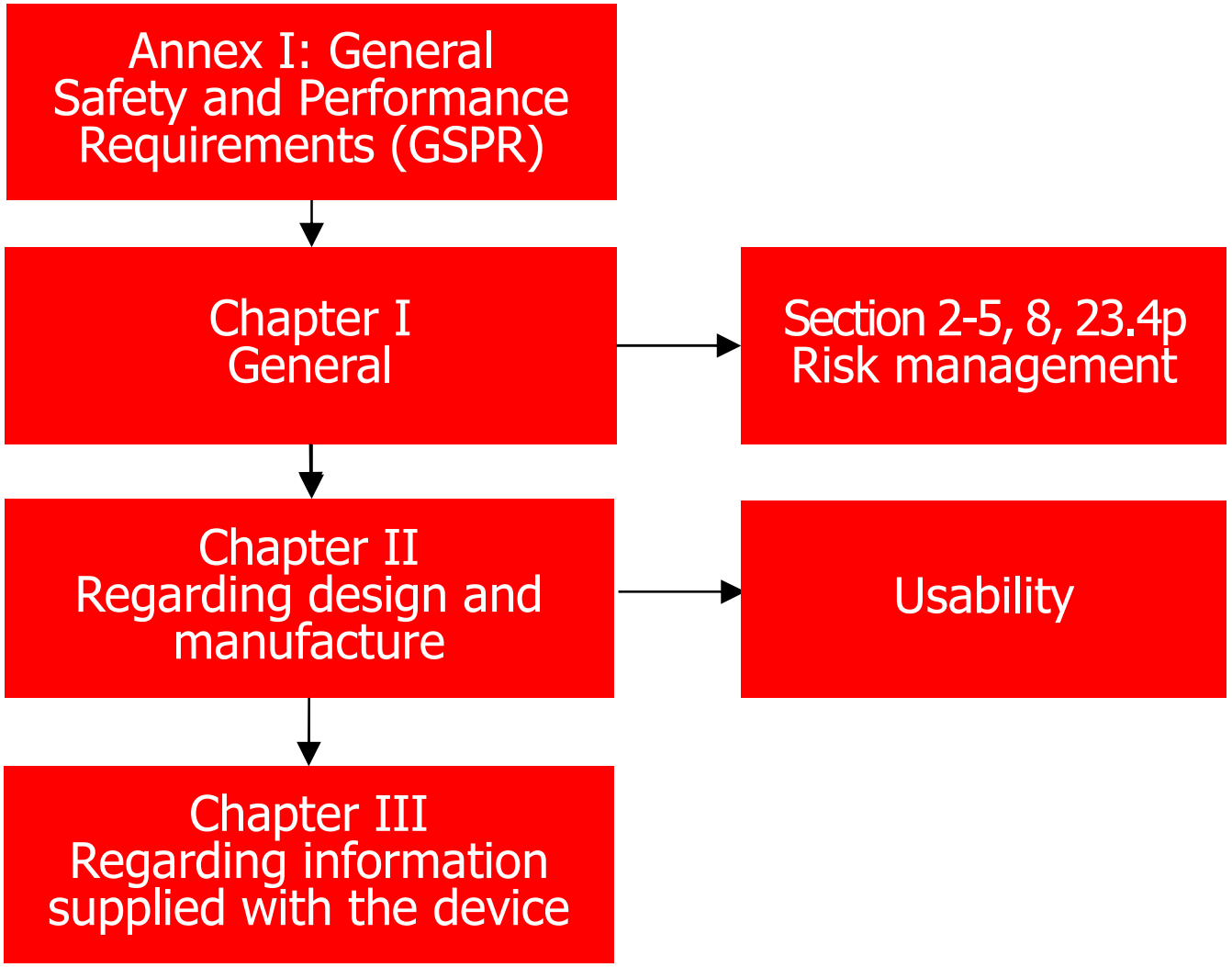
By default at the premise of manufacturer or external partner

Identify applicable safety and performance requirements

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
2	Determine risk class of device and applicable MDR codes	(Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
3	Select conformity assessment procedure	(Chapter V, §52)
4	Maintain QMS	(Chapter II, §10)
5	**Identify applicable safety and performance requirements**	**(Chapter II, §5, Annex I)**
6	Assemble Technical Documentation	(Annex I, Annex II, Annex XIV)
7	Apply conformity assessment procedure	(Annexes IX, X, XI A or XI B)
8	Assign Unique Identifications	(Chapter III, §27-34, Annex VI)
9	Complete Declaration of Conformity and affix CE mark	(Chapter II, §19 =>Annex IV) (Chapter II, §20, =>Annex V)
10	Post-market surveillance and updates	(Chapter VII, §83 to 86, Annex XIV => Annex III)

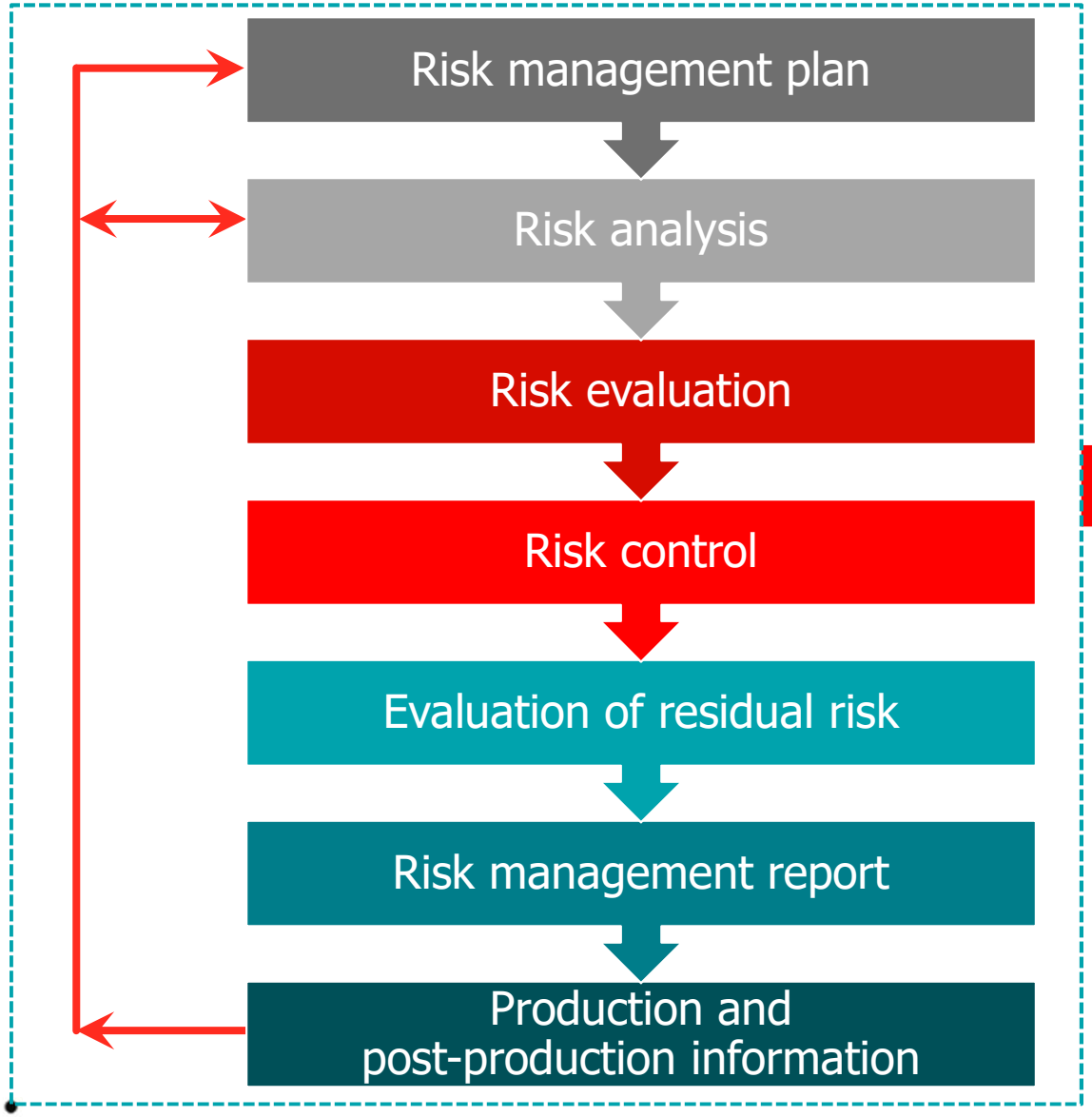
bsi.

All medical devices must fulfil…



…if requirements are applicable

Risk management process



Output

Adapted from
ISO 14971
Clause 4.1

Information supplied with the device

For the user

- Technical knowledge
- Experience
- Education, training
- Language proficiency
- Particular device and intended purpose
- Situation and objective
- Environment

Types of information supplied with the device

Labels

- On device
- Exempt possible: If not possible/ appropriate, shift to package

Packaging

- On sterile packaging

STERILE

Instruction for use

- Together with device
- Exempt possible: Class I/IIa
- Exempt for eIFU (207/2012)

Implant card

- Together with device
- See §18, not annex I
- Some items must be on card, others delivered with device
- Website obligatory

Certain information must be on manufacturer's website, if any

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Assemble Technical Documentation

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
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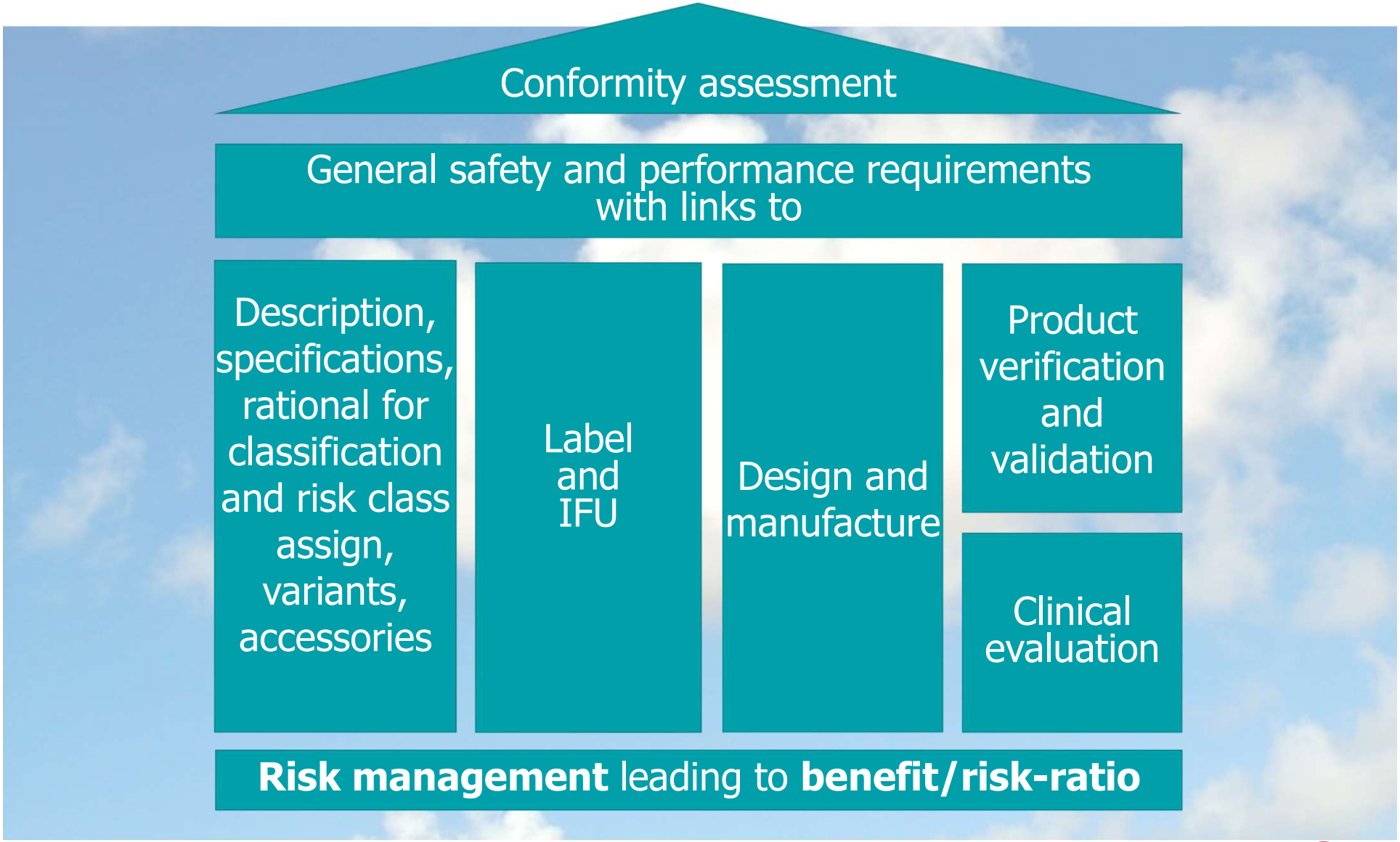
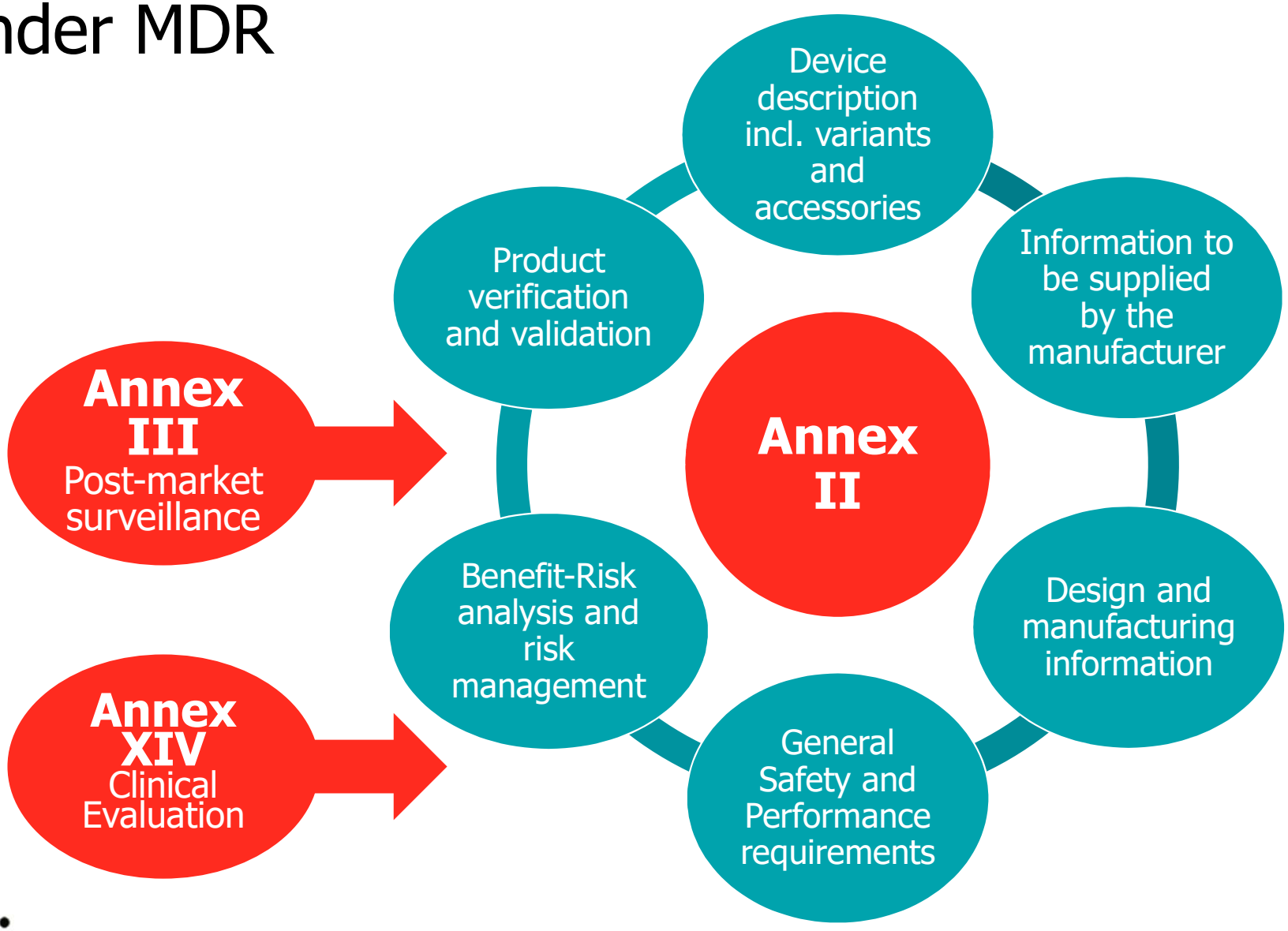
Pillars of the Technical Documentation



Content of a Technical Documentation under MDR



bsi.

Apply conformity assessment procedure

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
2	Determine risk class of device and applicable MDR codes	(Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
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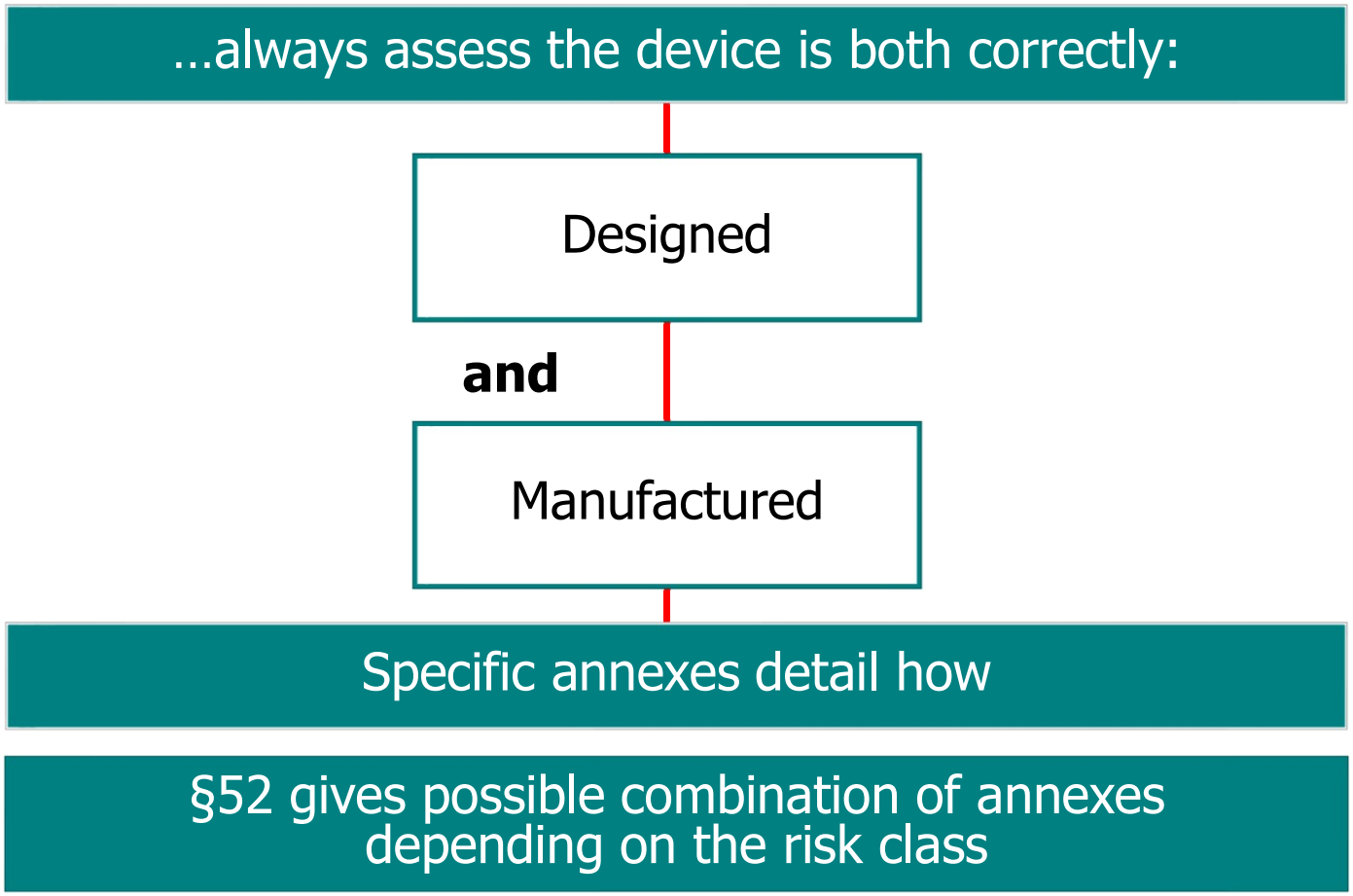
Conformity assessment procedures…



Sampling Class IIa and Class IIb devices for the assessment of the technical documentation

- MDCG Guidance published 11 December 2019
  - MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation
- https://ec.europa.eu/docsroom/documents/38669

- Category of devices (IIa)
  - the relevant MDA/MDN codes (MDR) according to Regulation (EU) 2017/2185 on the codes for the designation of notified bodies

- Generic device group (IIb non-implantable)
  - the 4th level of the European Nomenclature on Medical Devices (EMDN) (i.e. combination of one letter plus 6 digits)

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Sampling Regimes for Conformity Assessment of Class IIa and Class IIb Devices

- Class IIa Devices: at Least one device from each device category reviewed prior to QMS certificate issue
- Class IIb Devices: at Least one device from each generic device group reviewed prior to QMS certificate issue

- After issuing the certificate, the notified body will continue to assess technical documentation in line with the sampling plan
- Surveillance assessment must include an assessment of the technical documentation which means that at least one technical documentation must be reviewed each year
- Entire device range must be covered during the period of validity of the certificates.
  - Sample and assess technical documentation between the issue of a certificate and its expiry date of
    - At least one device per category for Class IIa
    - At least one device per generic device group for Class IIb

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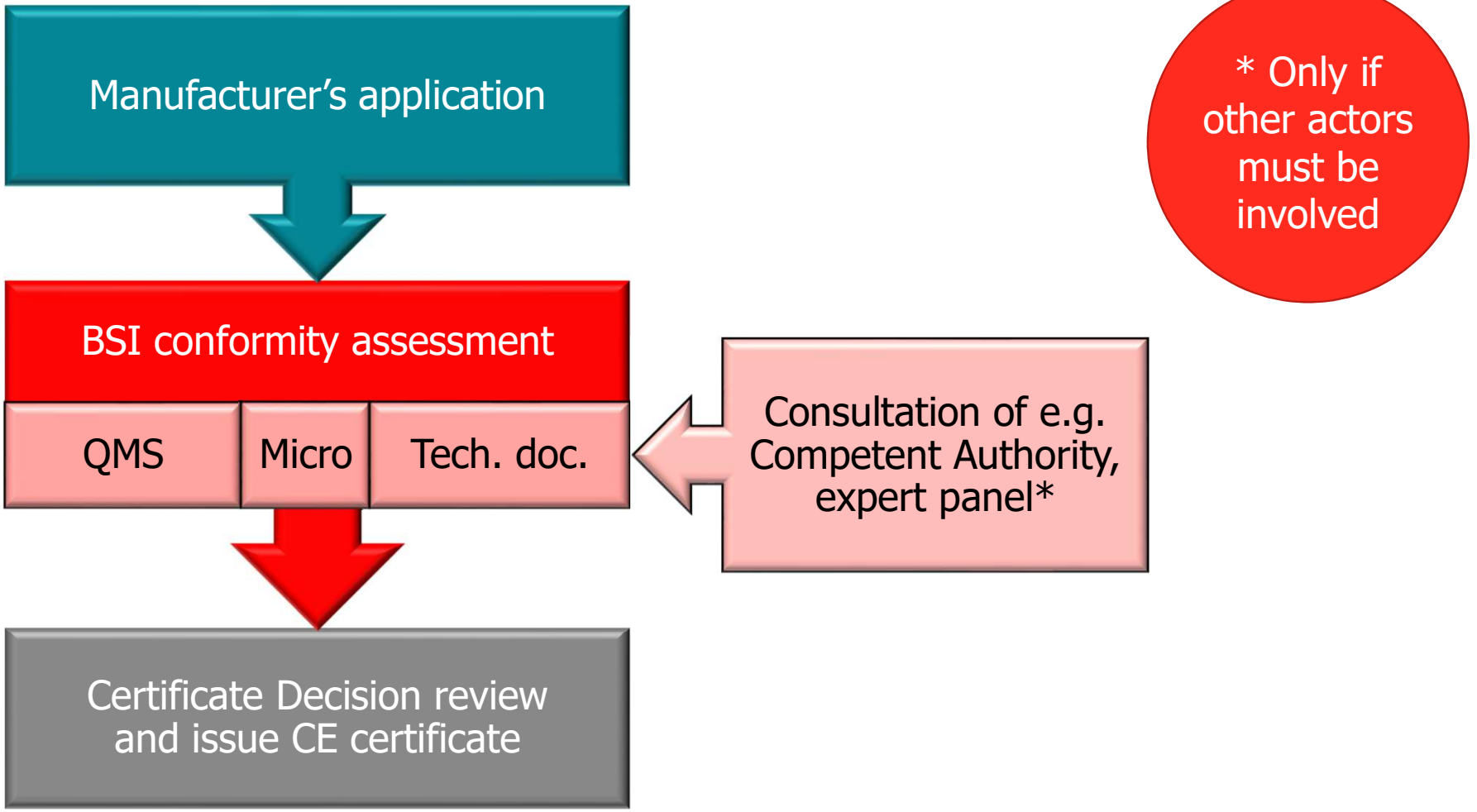
Notified Body Annex IX conformity assessment process of BSI as an example



Surveillance of Technical Documentation

Sampling

- Announced
- Scheduled
- E.g. annually

Initial and Changes

- Announced
- On application
- E.g. initial, extensions, significant changes

Unannounced audit visits

- Unannounced
- At random
- To verify device conforms to Tech. Doc.

By default at the premise of manufacture or external partner

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Will the technical file work?

Manually?

Easy play?

Memory?

Unambiguous

Up-to-date

Readily searchable

Clear

Organized

Assign unique identifications

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
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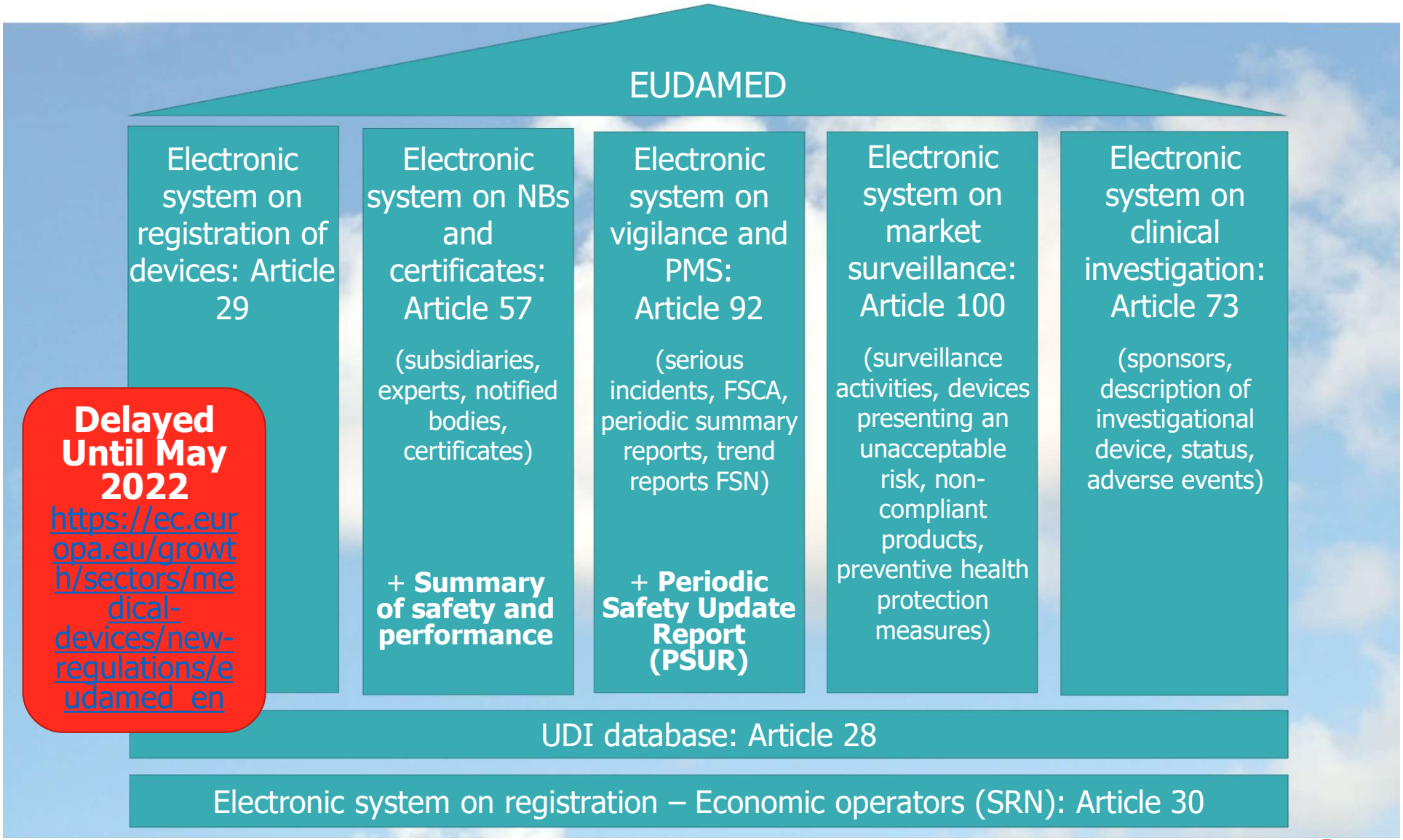
European database on medical devices: §33



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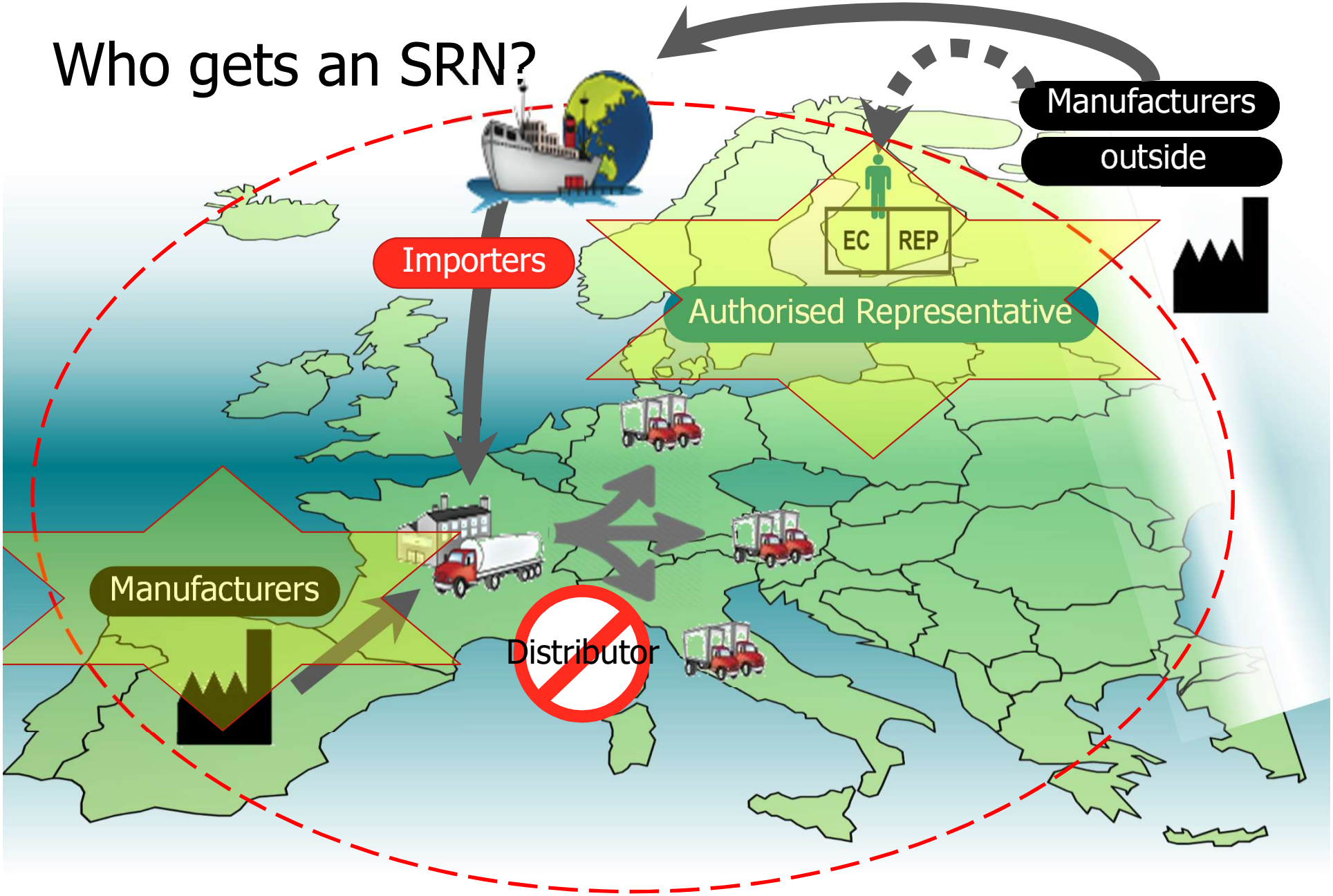
Who gets an SRN?



UDI for devices

UDI – DI
'Device Identifier'

Specific to a model

UDI – PI
'Production Identifier

Specific for LOT/batch/series

Shipping container

UDI 'Unique Device Identifier'

- Device, label, package
- Implant card
- FSCA and vigilance reports
- Record of re-labelling re-packing
- List of all UDI assigned
- Supply List

Difference in meaning

Basic UDI-DI identifies Device (group)

≠

UDI-DI ensures identification and traceability of a device

Connects devices with same:
- Intended purpose
- Risk class, and
- Essential manufacturing and design characteristics

- On device/label/packaging
- New one, if different name, trade name, device version, models, etc.

Each UDI-DI has exactly one Basic UDI-DI

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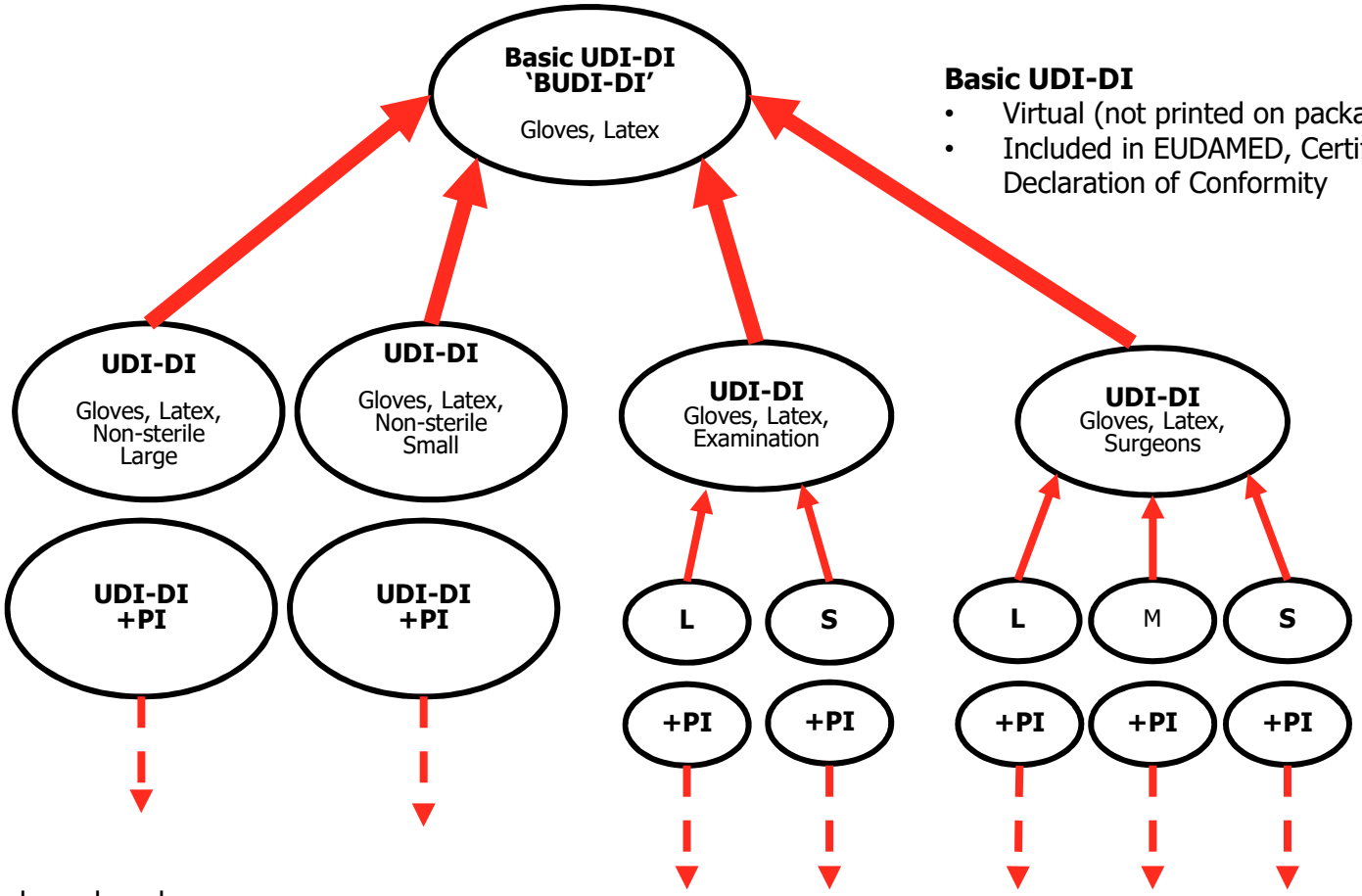
Basic UDI-DI versus UDI DI



Basic UDI-DI

- Virtual (not printed on packaging)
- Included in EUDAMED, Certificate, Declaration of Conformity

Basic UDI-PI

- Printed on single pack and tertiary packaging levels
- Included in EUDAMED

Complete Declaration of Conformity (DoC) and affix CE Mark

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
2	Determine risk class of device and applicable MDR codes	(Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
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10	Post-market surveillance and updates	(Chapter VII, §83 to 86, Annex XIV => Annex III)

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Declaration of Conformity: Annex IV

CE Declaration of Conformity

Manufacturer: Name, registered trade name/mark, registered place of business, SRN

Device: With product and tradename, risk class, basic UDI-DI

Assessment: CS and procedure used, IDs of NB & certificates

.............For other necessary information see Annex IV.............

A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer.

A statement that the device is in conformity with this regulation, and if applicable, with the other relevant union legislation that makes provision for the issuing of a declaration of conformity.

26. May 2020

John Doe

John Doe,
CEO for
Manufacturer Ltd.

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CE mark

Do not change proportions!
Add number of NB, if involved!

Where does the CE mark appear?

Device itself

Packaging
(if not on device)

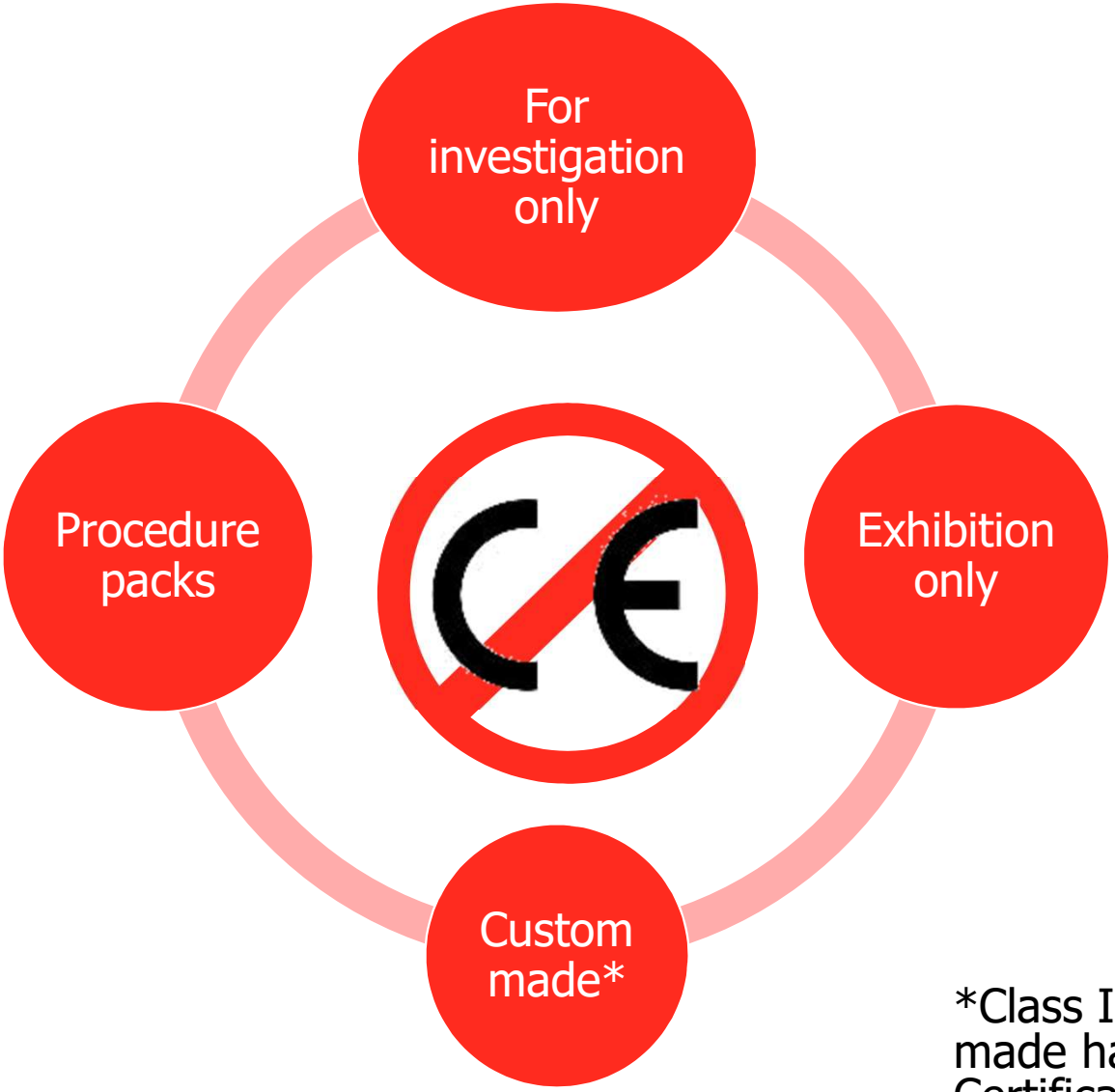
Sales packaging

Sterile
Packaging

Instruction for
Use

Promotional
Material
(if mentioning
conformity)

CE mark is prohibited for



*Class III custom made has NB Certificate but no CE Mark

Post-market Surveillance (PMS)

1	Check device is within scope of MDR	(Chapter I, §1, §2, Annex XVI)
2	Determine risk class of device and applicable MDR codes	(Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
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10	**Post-market surveillance and updates**	**(Chapter VII, §83 to 86, Annex XIV => Annex III)**

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§2 definitions: PMS

Definition (§2 MDR)

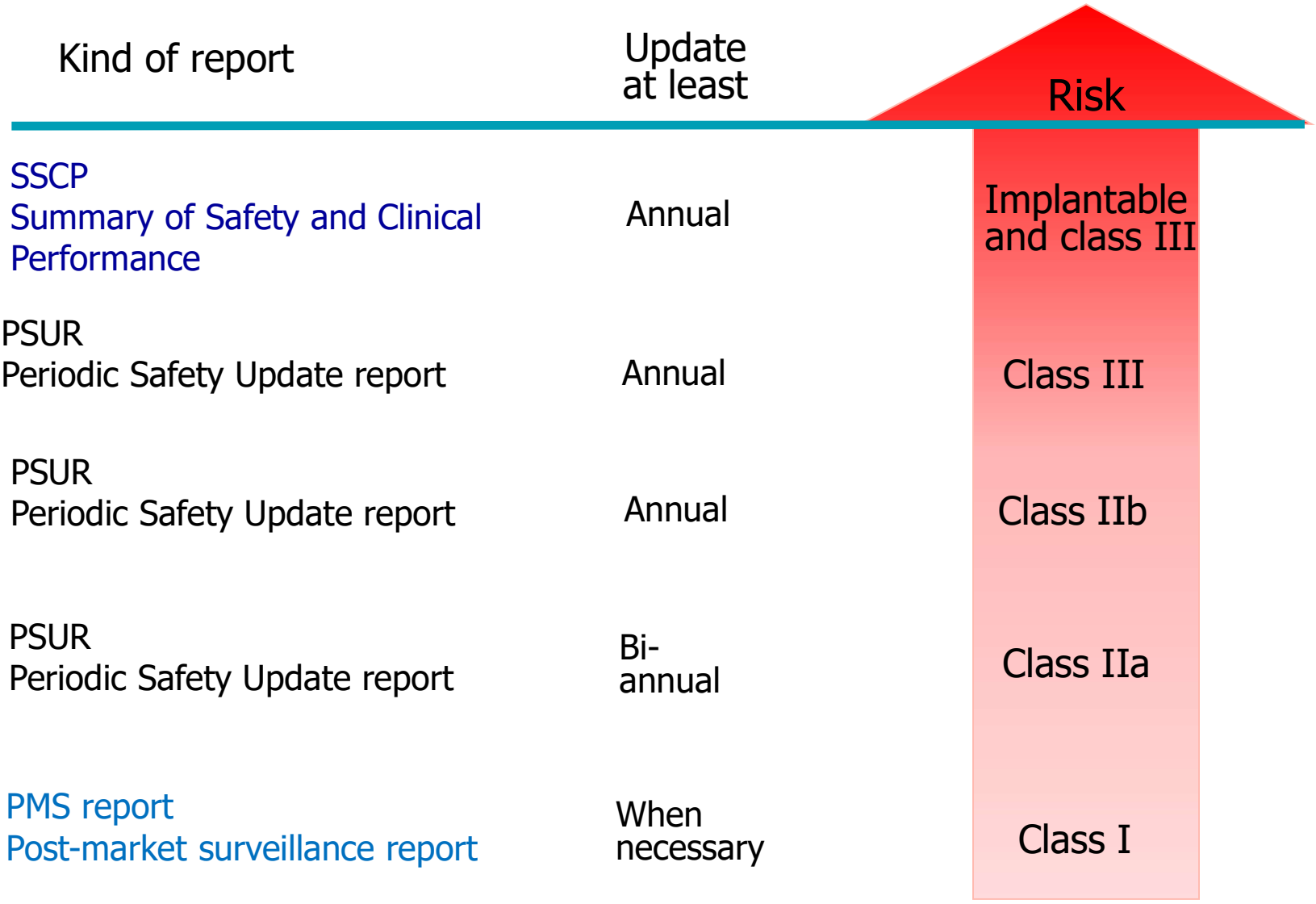
- All activities carried out:
- By the manufacturers in cooperation with other economic operators
- To institute and keep up to date a systematic procedure
- To proactively collect and review experience gained from their devices
- Placed on the market, made available on the market or put into service
- For the purpose of identifying any need to immediately apply any necessary corrective or preventive actions

Issues to consider:

- Be comprehensive
- Involve your distributors
- EN ISO 13485: Documented procedure
- Sit and wait is not enough
- Know your devices
- Be ready to act

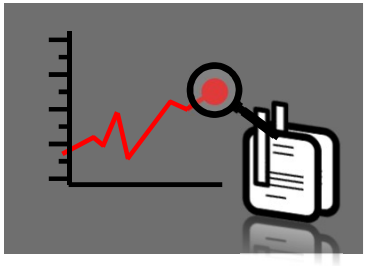
Also for devices CE marked under the Directive

Post-market reports



Contents of Periodic Safety Update Report (PSUR)

- Throughout lifetime
- Considering PMS Plan (and other plans)
- Available Information:

PMS	**Summary of data/conclusions**
	**Population, use frequency**
	**Benefit/risk conclusion**
PMCF	**Main findings of Post-market Clinical Follow-up**

€ **Sales Data, Sales Volume**

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Alarming issues

Complaint:

- Communication about:
- Related to deficiency of a device,
- Which is outside manufacturer's control

Adverse event:

- Untoward, unintended, abnormal
- Regardless of any relation to device

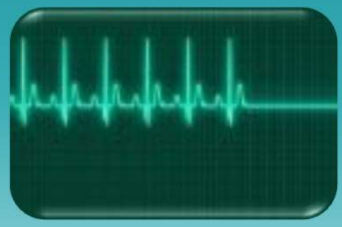
Incident:

- Malfunction, deterioration, inadequate information, undesirable side-effect
- of a device which is made available

When is an incident serious?

- **Directly or indirectly**
- **Led, might have led or might lead to any of the following:**

Serious deterioration of state of health



Death

Serious public health threat

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Reporting timelines for serious incidents

In doubt? Report!

In case of	*Manufacturer reports immediately after it*	*But at latest within*
Any serious incident	Established **casualty** or it is reasonably possible	**15** days after awareness of incident
Death	Established or suspected **casualty**	**10** days after awareness of incident
Unanticipated serious incident	Established or suspected **casualty**	**10** days after awareness of incident
Serious public health threat	Becomes **aware of threat**	**2** days after awareness of **threat**

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Recap and transition arrangements

MDR CE marking

1. Check device is within scope of MDR	1. (Chapter I, §1, §2, Annex XVI)
2. Determine risk class of device and applicable 'NBOG' codes	2. (Chapter V, §51 => Annex VIII) (Article 38, Regulation 2017/2185)
3. Select conformity assessment procedure	3. (Chapter V, §52)
4. Maintain QMS	4. (Chapter II, §10)
5. Identify applicable safety and performance requirements	5. (Chapter II, §5, Annex I)
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8. Assign Unique Identifications	8. (Chapter III, §27-34, Annex VI)
9. Complete declaration of conformity (DoC) and affix CE mark	9. (Chapter II, §19 => Annex IV) (Chapter II, §20, => Annex V)
10. Post-market surveillance and updates	10. (Chapter VII, §83 to 86, Annex XIV => Annex III)

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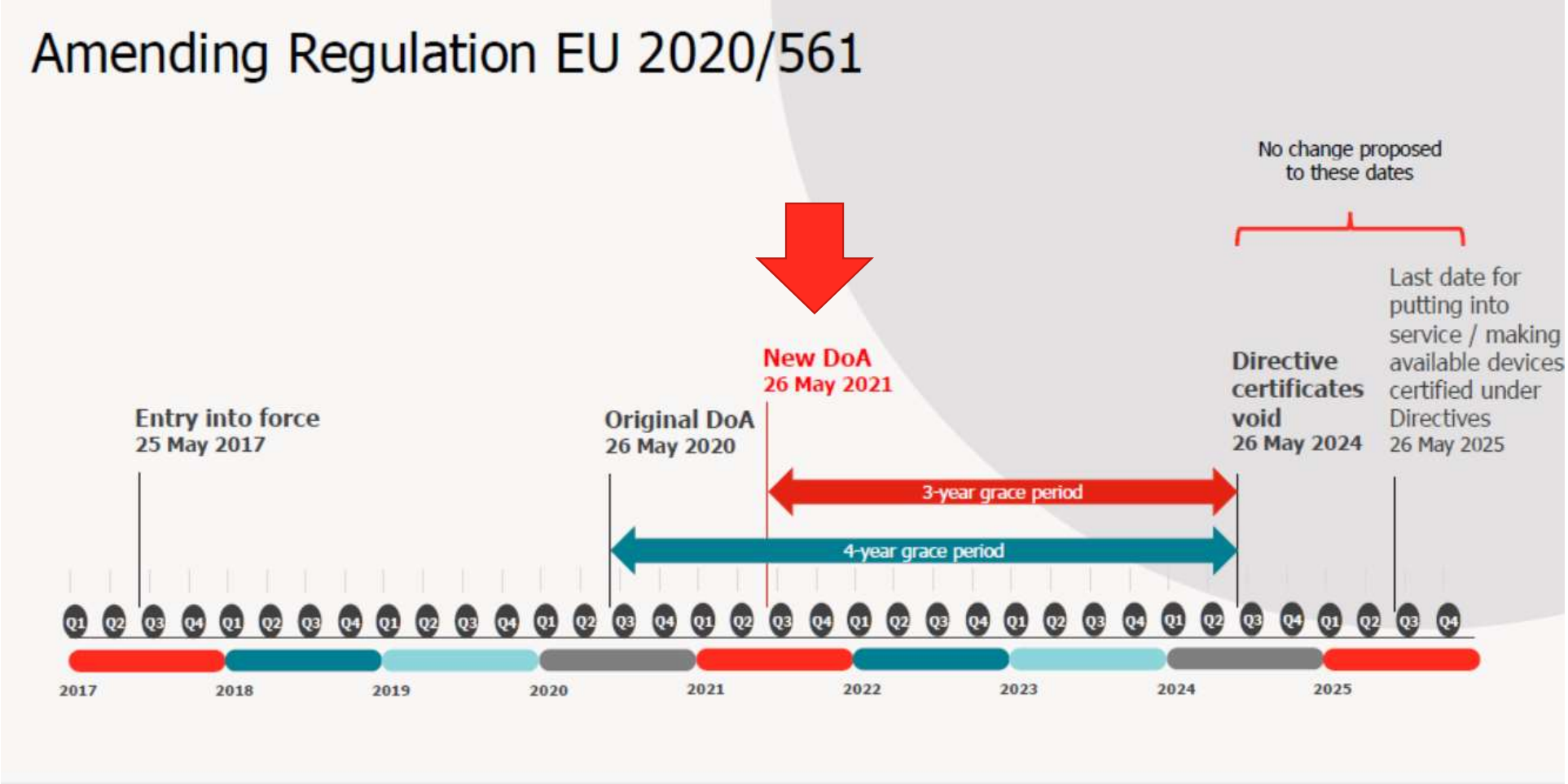
Transition timelines for the MDR



Amending Regulation EU 2020/561 → MDR Article 120 (3)

After 26 May 2021 (instead of 26 May 2020), devices with a NB certificate under MDD/AIMDD, Class I devices that are up-classified under MDR can only be placed on market if:

- They continue to comply with applicable Directives
- There are no significant changes in the design or intended purpose

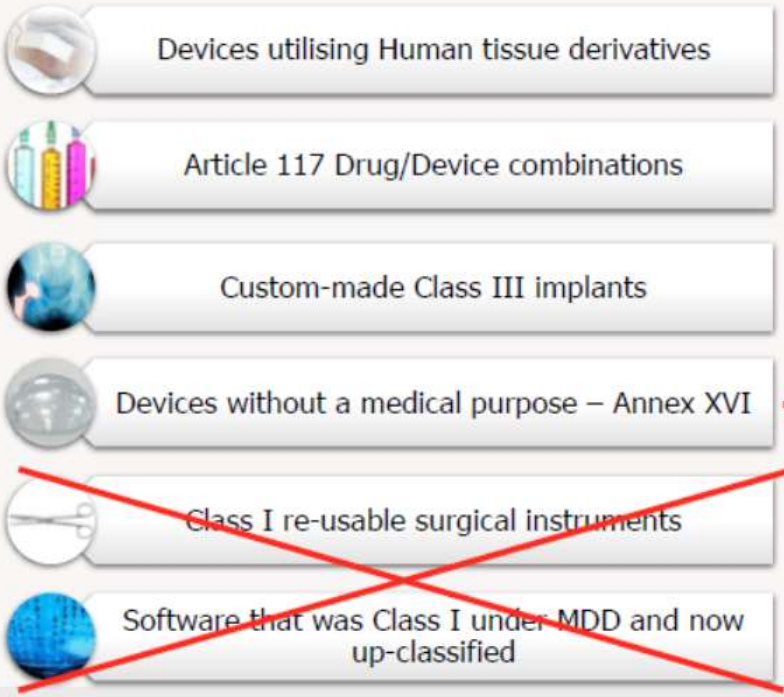
However, the following MDR requirements will apply from

26 May 2021

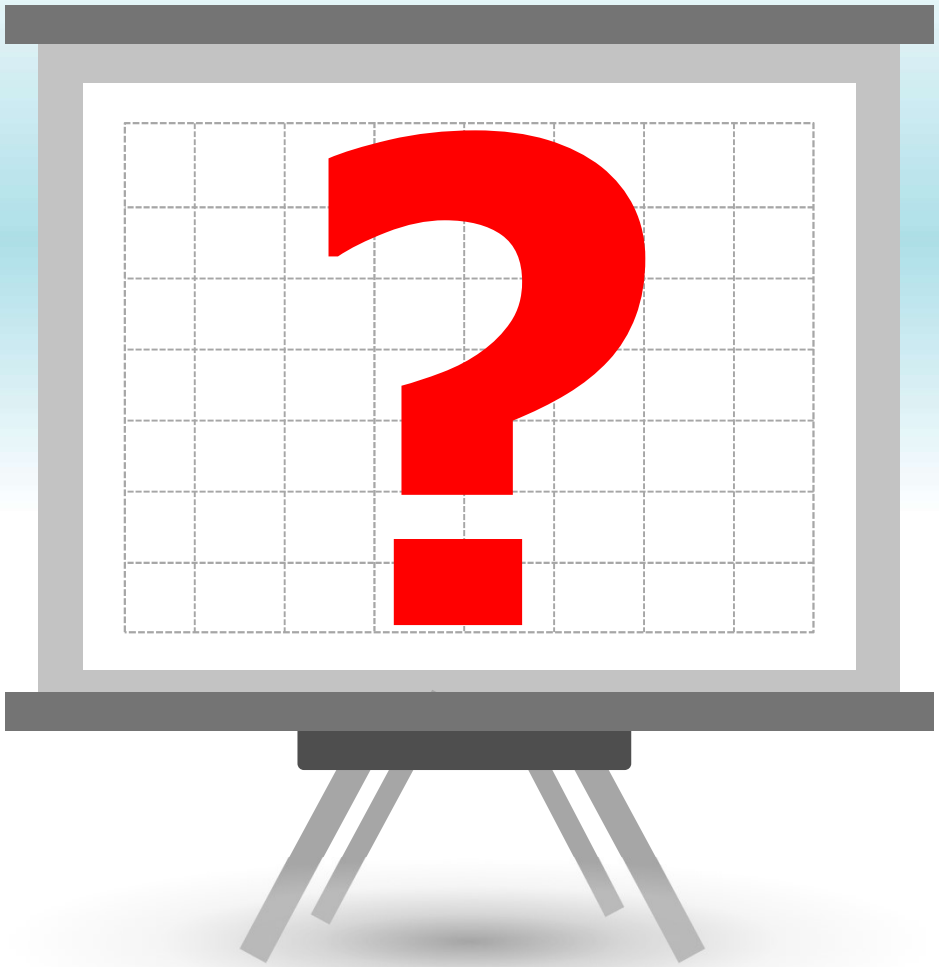
- post-market surveillance
- market surveillance
- vigilance
- registration of economic operators
- registration of devices

Impact on Priorities

The following devices/products need MDR certificates by 26 May 2021 (instead of 26 May 2020) for continued market viability:



Course review and final questions



...making excellence a habit.™