European Medical Device Regulations (MDR): *What To Expect*

MDQC
March 2016

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Sources for MDR Update

Commission

- Proposal for a Regulation of the European parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
- http://ec.europa.eu/growth/sectors/medical-devices

Parliament

- 2012/0266(COD) - 02/04/2014 Text adopted by Parliament, 1st reading/single reading
- EP adopted by 547 votes to 19, 63 abstentions
- http://www.europarl.europa.eu reference=2012/0266 COD

Council

- Consolidated draft for EPSCO 19 June 2015 - 400 pages with many alterations and additions
- Sept 2015 - Council's full 'General Approach'
- http://data.consilium.europa.eu/doc/document/ST-12040-2015-REV-1/en/pdf
- http://data.consilium.europa.eu/doc/document/ST-12040-2015-ADD-1/en/pdf

Foreseeable outcome – best guess of today

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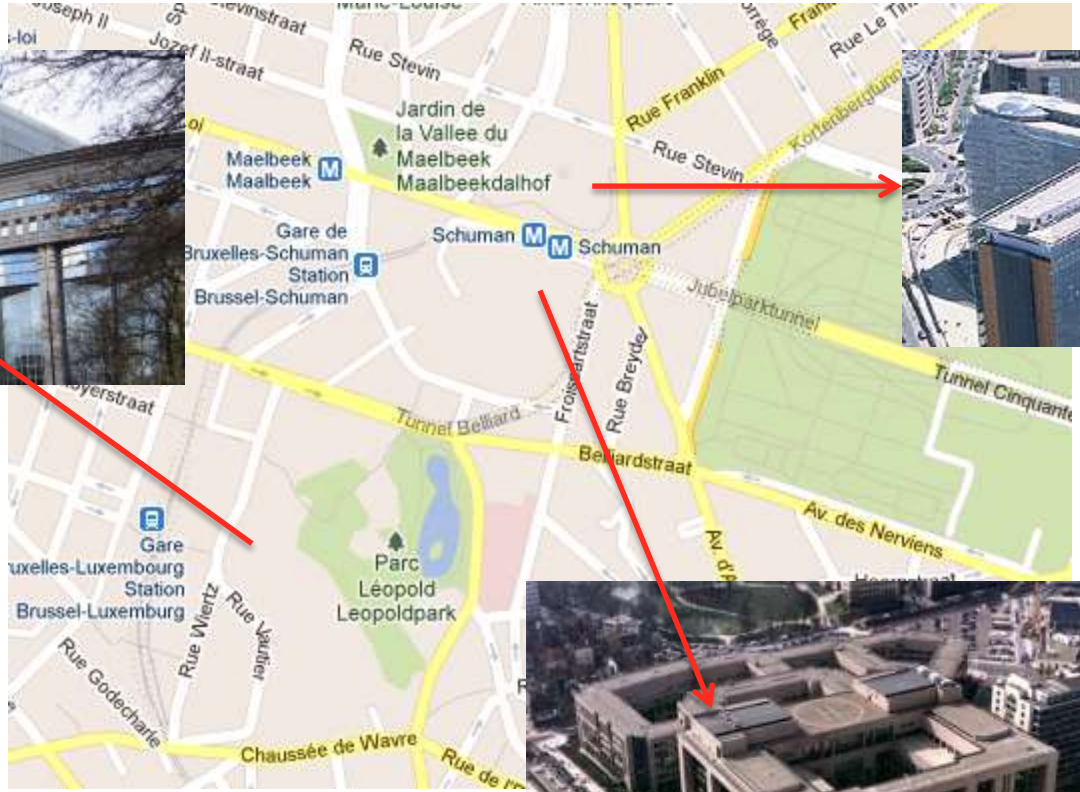
Trialogue Discussions – behind closed doors

EU Parliament



EU Commission

EU Council of Ministers

MDR Timeline – Realistic Expectations:

2016 Q1/Q2

- Trilogue concludes
- Agreement on MDR & IVDR

2016 Q3/Q4

- EC Administration
- Translation into all EU languages

2016 Q4
2017 Q1

- EU MDR & IVDR Enter into force
- 3 year transition for MDR and 5 year transition for IVDR

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How to read 400 pages …

Regulation No ?/2016/EU

1. Check Definition of **Medical Device** (Article 2)
2. Determine "**Device Class**" (Article 41, Annex VII)
3. Select "**Conformity Assessment Procedure**" (Article 42)
4. Identify Applicable "**Essential Requirements**" (Article 4, Annex I)
5. Assemble "**Technical Documentation"** (Annex II)
6. Apply Conformity Assessment Procedure (Annexes VIII, IX, X, XI)
7. Complete "**Declaration of Conformity**" (Article 17, Annex III)
8. Affix "**CE Mark**" (Article 18, Annex IV)

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Proposed MDR Chapter I
Scope and Definitions

Headlines – Proposed MDR Chapter I
Scope and Definitions

- Expansion of regulations to cover:
  - Clinical investigations in Europe
  - Adverse incident/vigilance requirements
  - Cosmetic products - after Common Speciation (CS) published – Annex XV
  - Remanufacture of devices – single use devices
- Many new definitions
- Intended alignment with GHTF/IMDRF

Article 2 – Medical Device

'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 specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for injury or disability,
- investigation, replacement or modification of 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

Article 1 excludes *IVD* devices from this Regulation

Article 2 – Medical Device

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.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.

Article 1 – Scope – Annex XV – No Medical Purpose

- Contact lenses or other articles intended to be introduced into or onto the eye;
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings;
- Substances, combinations of substances, or articles intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;
- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

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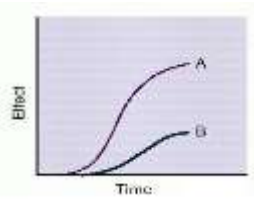
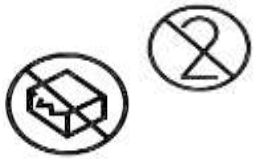
Safety & Performance Requirements Annex I

Annex I – Safety & Performance Requirements



1. Safe, Perform as Intended, State of the Art
2. Risk Reduction, Risk Management, Risk Control
3. Lifetime
4. Packaging



5. Evaluated Benefits of achieved performance > Known and Foreseeable Undesirable Side Effects

6. Devices with no medical purpose – "shall not present any risk or only the maximum acceptable risks"

6a. Machinery Directive – 2006/42/EC

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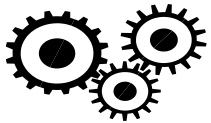
Annex I – Safety & Performance Requirements



7. Chemical, Physical & Biological Properties

8. Infection & Microbial Contamination

9. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body

10. Devices incorporating materials of biological origin

11. Construction and environmental properties

12. Devices with a diagnostic or measuring function

13. Protection against radiation

Annex I – Safety & Performance Requirements

14. Electronic programmable systems

15. Active devices and devices connected to them

16. Protection against mechanical and thermal risks

17. Protection against the risks posed to the patient or user by supplied energy or substances

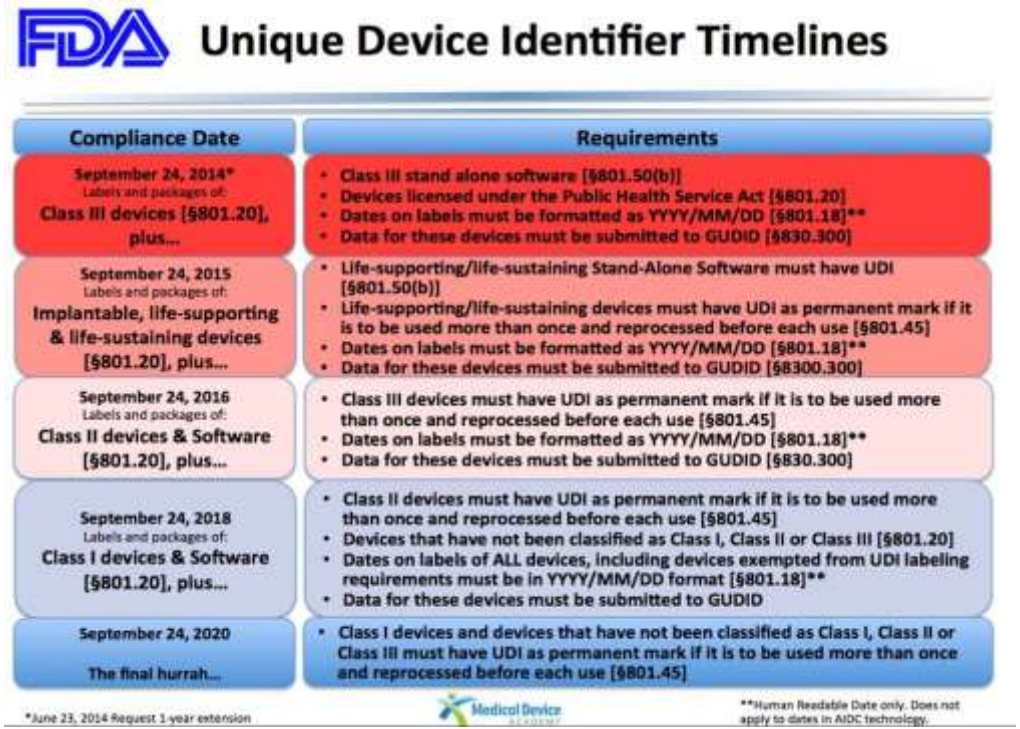
18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

19. Information Supplied by the Manufacturer + Implant Card (Article 16) + Promotional Material CE Marked (Article 18) + UDI (Article 24)

Unique Device Identification – Article 24

- COMMISSION RECOMMENDATION – 2013/172/EU on a common framework for a unique device identification system of medical devices in the Union.
- Work toward GHTF / IMDRF UDI
- FDA have completed specifications

- EN ISO 15223 – date format – YYYY/MM/DD



*EU will probably allow GS1 & HIBCC

*GS1 & HIBCC accepted by Turkey, Japan, India, USA

+ Argentina, China, Canada, Brazil, Korea, Saudi Arabia

Safety & Performance Requirements Check List

Safety & Performance Requirement #1

Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Applicable	Demonstration of Compliance	Location of Evidence

A/NA	Standards	CS	Test Reports	Location

A/NA	Applicable Harmonised Standards & Common Specifications	Technical File Record	Location

Fulfilled	Standards & CS Considered	Reports/ Justification

Harmonised Standards – Article 6
Common Specifications – Article 7

Proposed MDR Chapter II Economic Operators, Reprocessing, CE Marking, Free Movement

Headlines – Proposed MDR Chapter II
Economic Operators, Reprocessing, CE Marking, Free Movement

- Solution to keep healthcare institution in-house devices out of CE Marking
- Harmonized Standards and Common Specifications provide PoC
- Explicit requirements for manufacturers:
  - Risk management system
  - Post market clinical follow-up
  - Comply with UDI requirements
  - Quality management system
  - Authorized representative – permanent access to technical documentation
- Importer and distributor requirements
- Person responsible for regulatory compliance
- **Single-use devices and re-processing**
- Information to supplied with implantable devices

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Industry Concerns*: Single-use Devices and Re-processing

- Reprocessing potentially permitted inconsistently by EU Member States
- Where permitted the framework is identified in MDR
  - re-processor is re-manufacturer
  - Fully responsible as manufacturer under CE Marking
- Hospitals can deviate from requirements for in-house reprocessing

**"Industry Concerns" – not necessarily representative of BSI concerns/opinions*

MDR Chapter III
Identification, Traceability, Clinical Summary, EUDAMED

Headlines – Proposed MDR Chapter III
Identification, Traceability, Clinical Summary, EUDAMED

- Traceability of devices between economic operators and healthcare institutions
- Medical device nomenclature – free of charge
- UDI system
- Registration of economic operators
- Single Registration Number (SRN) process
- Summary of safety and clinical performance (class III and implantable) – report validated by NB uploaded Eudamed
- European databank
- Transparency of system

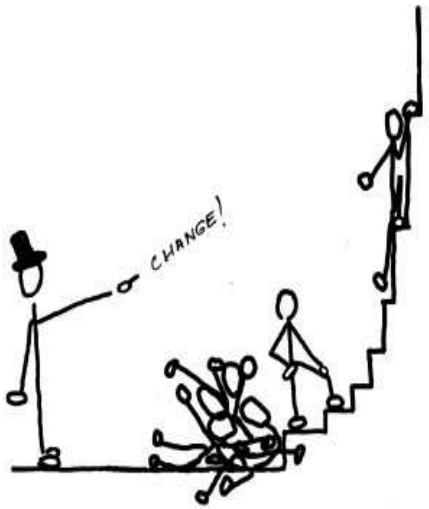
Proposed MDR Chapter IV
Notified Bodies

Headlines – Proposed MDR Chapter IV Notified Bodies

- Prescriptive rewrite – stricter requirements
  - Conflict of interest
  - Competence
  - Procedures
  - Language
  - Designation process

Joint Audits Under 920/2013 EC

- Voluntary assessments continuing; mandatory assessments increasing in number
- Requirements still stepping up
- Notified Bodies
  - merging
  - stopping
  - Suspended, de-designated
  - scope reductions
  - sales stop, specific regions stop, ….



Proposed MDR Chapter V Classification and Conformity Assessment

Headlines – Proposed MDR Chapter V Classification and Conformity Assessment

- Reclassifications –
  - Class III: spinal, joints, AIMD, nano, some others
  - Class IIa: reusable surgical instruments
- Scrutiny of clinical data for implantable class III devices
  - Submission of NB and manufacturer evaluation (and PMCF) to EC expert panel (15 days/60 days)
    - Exceptions permitted:
      - For extensions to cleared CE marked devices and NB is satisfied no adverse impact on benefit/risk ration

      or

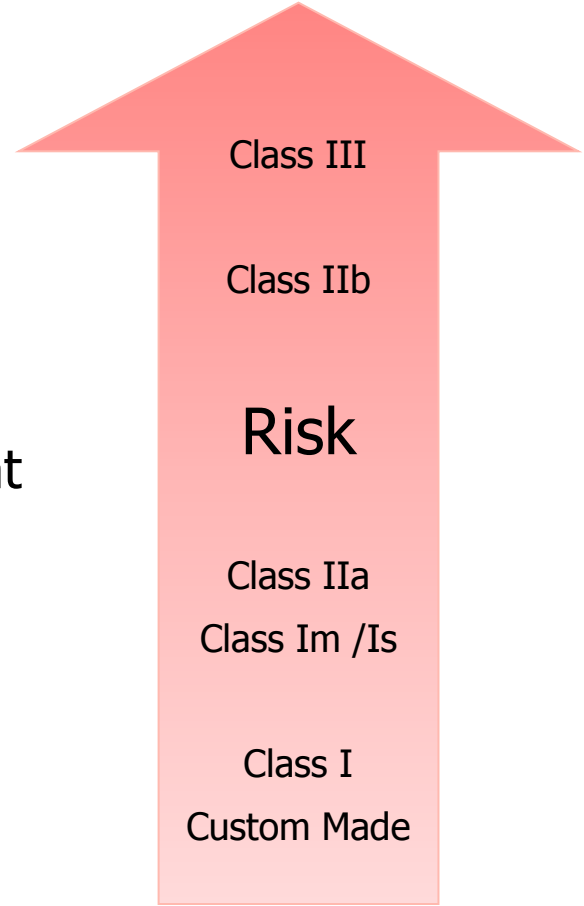
      - Where an common specification exists addressing clinical evaluation for type of device

Classification & Conformity Assessment – MDD

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification



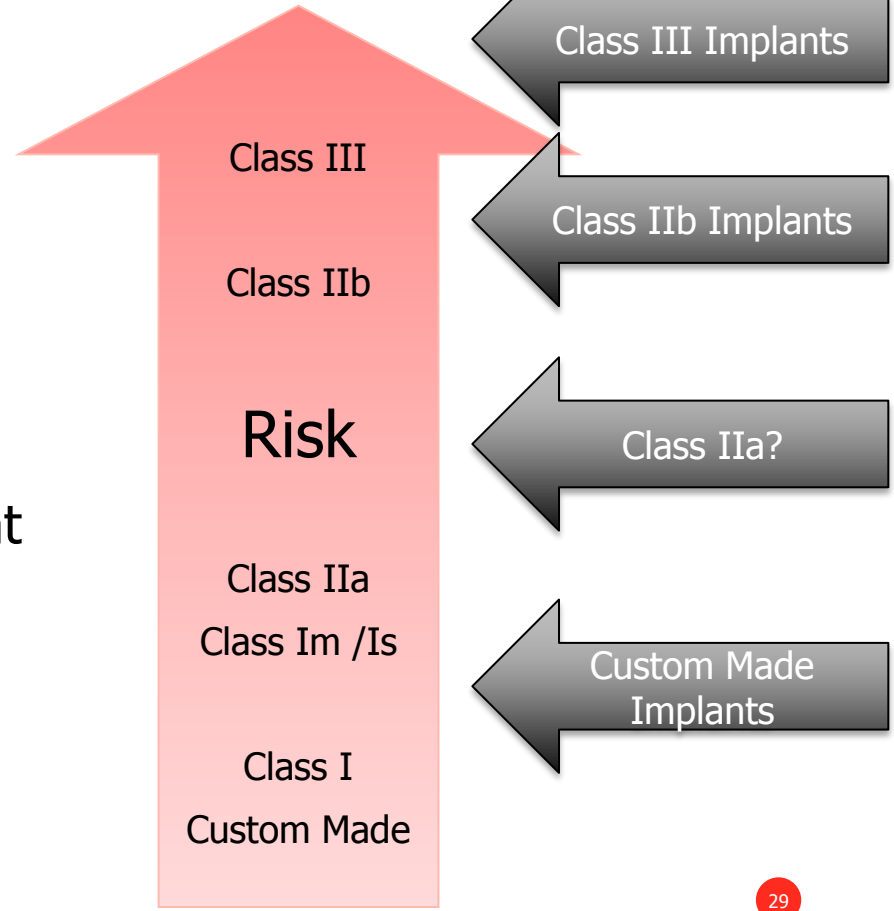
Classification & Conformity Assessment – MDR

Commission Assessment

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification



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Changes to Rules:

Rule 2

- All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class IIa:
  - if they may be connected to an active medical device in class IIa or a higher class,
  - if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags, which are in class IIb.
- In all other cases they are in class I.

Changes to Rules:

Rule 3

- All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa.

- All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body are in class III.

Changes to Rules:

Rule 5

- All invasive devices with respect to body orifices, other than surgically invasive devices which are not intended for connection to an active medical device or which are intended for connection to a class I active medical device:
  - are in class I if they are intended for transient use,
  - are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the a nasal cavity, in which case they are in class I,
  - are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa.
- All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.

Changes to Rules:

Rule 6

- All surgically invasive devices intended for transient use are in class IIa unless they:
  - are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,
  - ~~are reusable surgical instruments, in which case they are in class I,~~
  - are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are in class III,
  - are intended to supply energy in the form of ionising radiation in which case they are in class IIb,
  - have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,
  - are intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in class IIb.

Changes to Rules:

Rule 8

- All implantable devices and long-term surgically invasive devices are in class IIb unless they:

  - are intended to be placed in the teeth, in which case they are in class IIa,
  - are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,
  - have a biological effect or are wholly or mainly absorbed, in which case they are in class III,
  - are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicinal products, in which case they are in class III,
  - are active implantable devices or their accessories, in which case they are in class III,
  - are breast implants, in which case they are in class III,
  - are total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
  - are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III with the exception of components such as screws, wedges, plates and instruments.

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Changes to Rules:

Rule 9

- All active therapeutic devices intended to administer or exchange energy are in class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in class IIb.
- All active devices intended to control or monitor the performance of active therapeutic devices in class IIb, or intended directly to influence the performance of such devices are in class IIb.
- All active devices intended to emit ionizing radiation for therapeutic purposes including devices which control or monitor such devices, or which directly influence their performance are in class IIb.
- All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are in class III.

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Changes to Rules:

Rule 17

- All devices manufactured *incorporating or consisting of tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only.

New Rule #19:

- All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

Article 2

- 'nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;
- Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials;
- + 'particle' 'agglomerate' 'aggregate'

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New Rule #21:

- Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, or applied on skin and that are absorbed by or locally dispersed in the human body are:
  - in class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,
  - in class III if they are intended to be introduced into the gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body,
  - in class IIb in all other cases, except if they are applied on skin, in which case they are in class IIa.

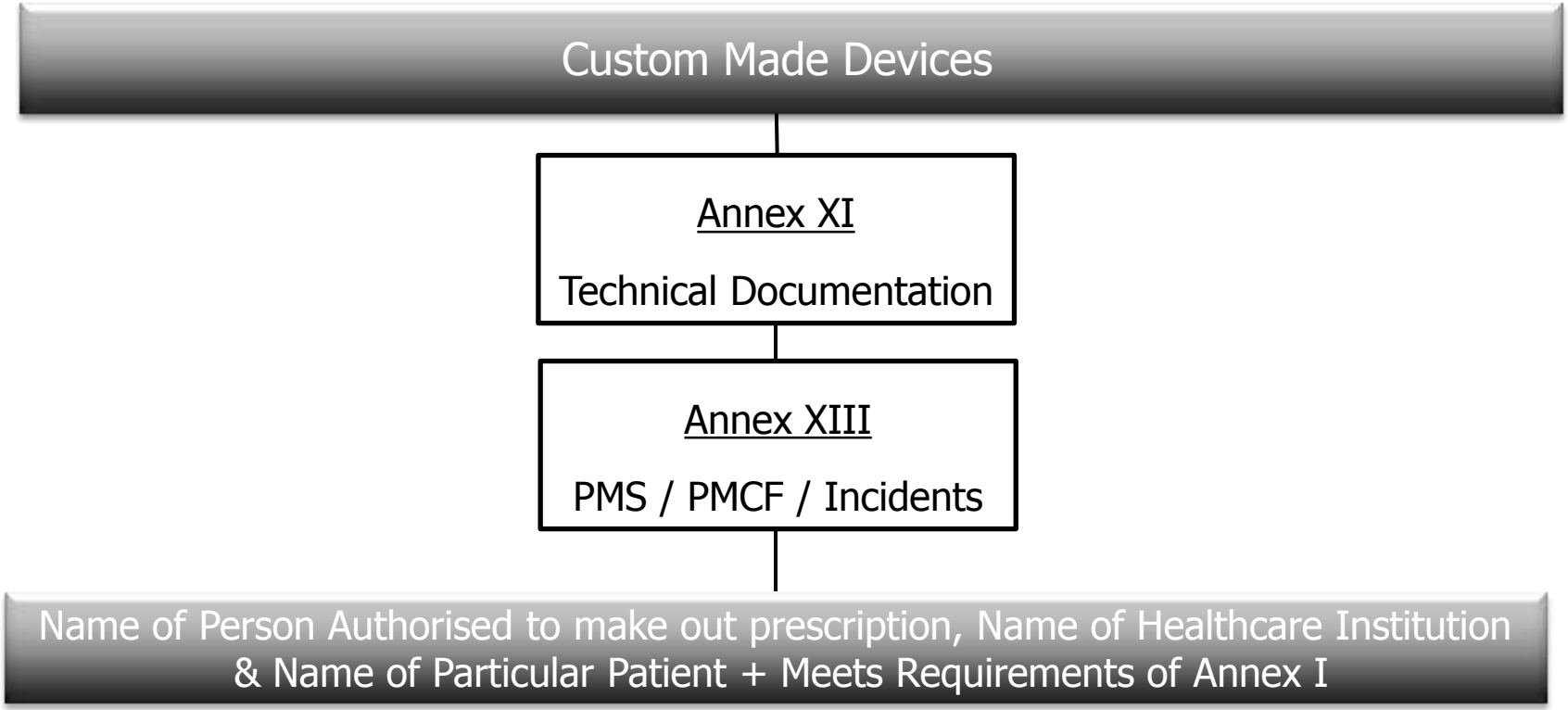
New Rule #22:

- All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are in class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product and those that are intended to treat life threatening conditions, in which case they are in class IIb.

New Rule #23:

- Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.

Conformity Assessment Article 42



Class III Implantable – Custom Made Devices

Annex XI

Technical Documentation

Annex VIII

QMS

Annex X – Part A

Production Quality Assurance

Name of Person Authorised to make out prescription, Name of Healthcare Institution & Name of Particular Patient + Meets Requirements of Annex I

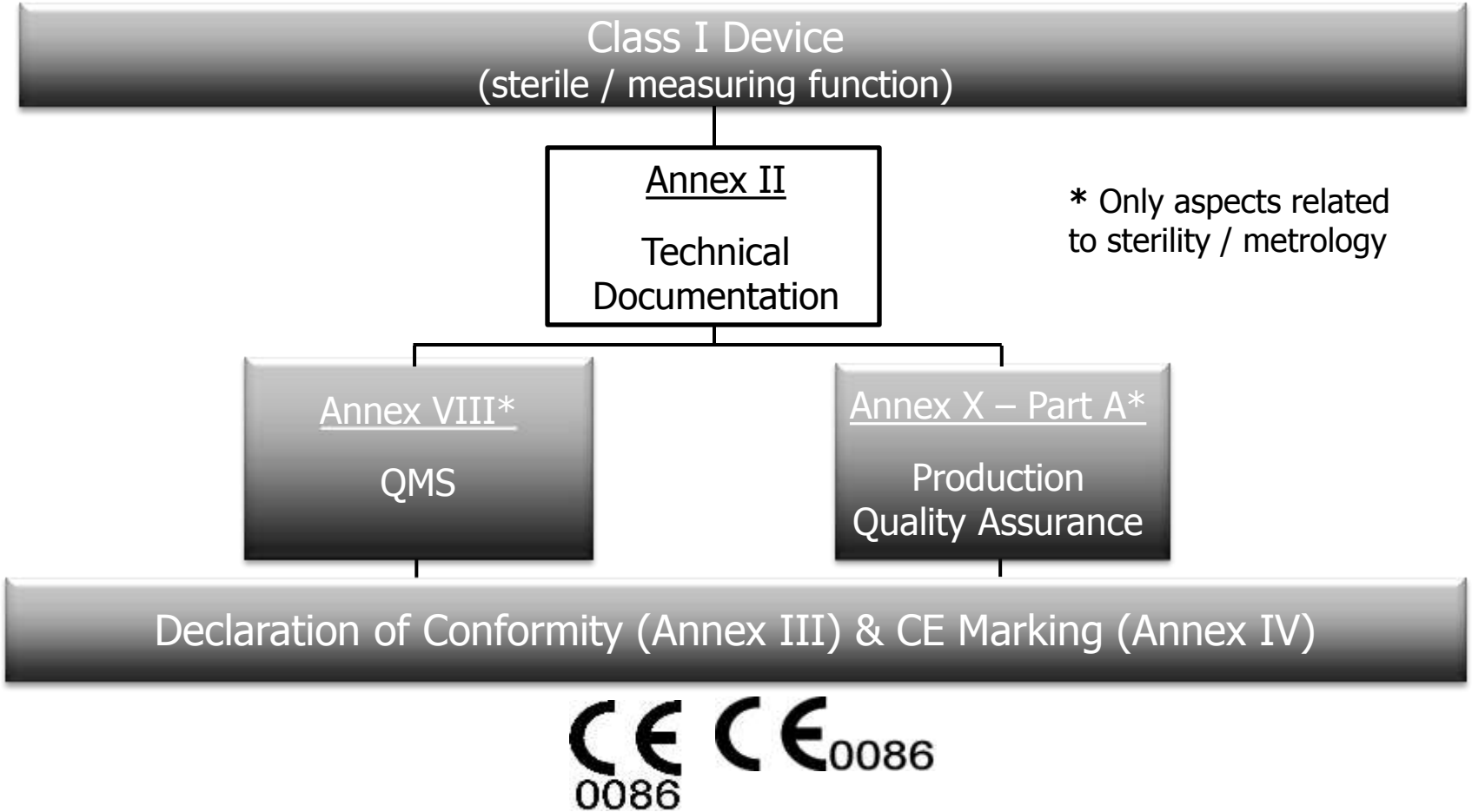
CE 0086 CE 0086

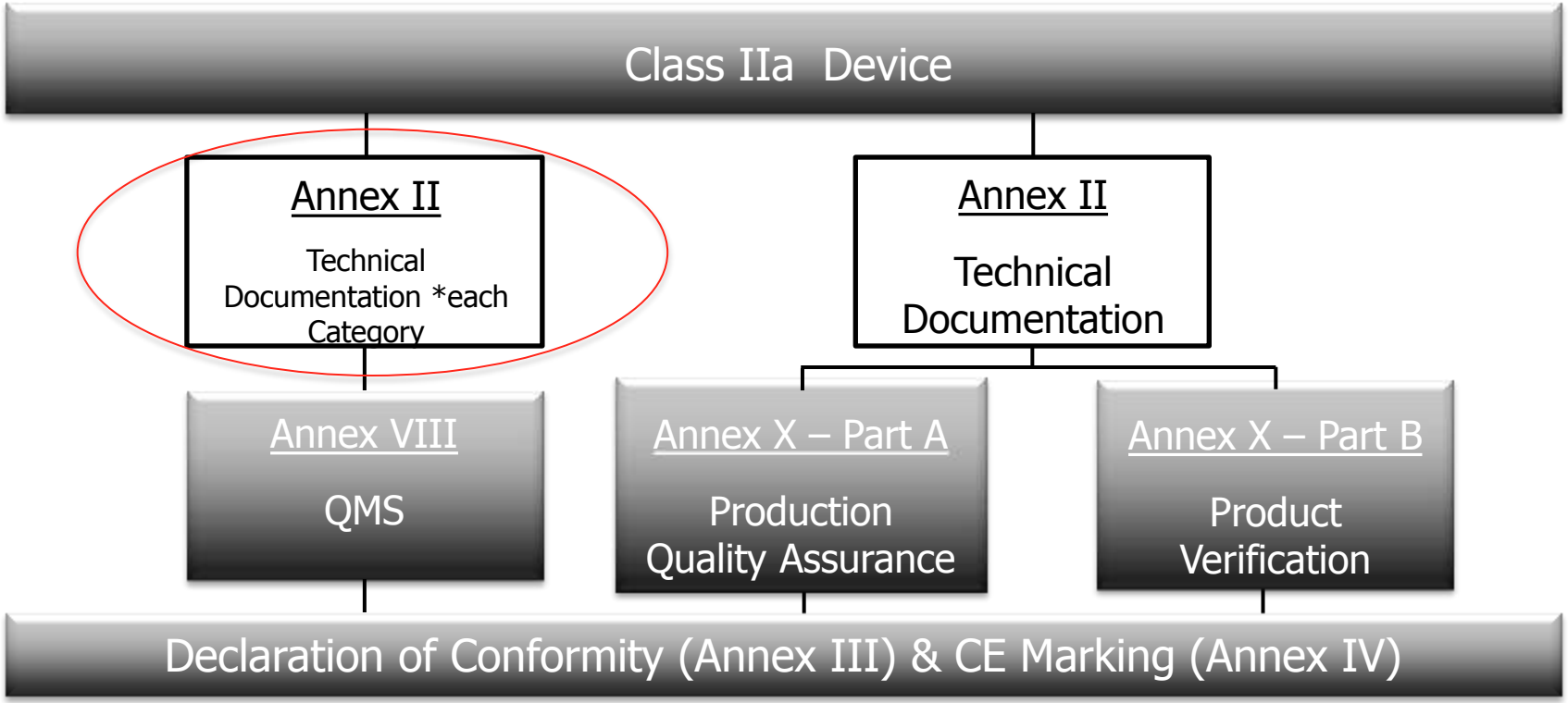
Class I Device
(non-sterile / no measuring function)

Annex II

Technical Documentation

Declaration of Conformity (Annex III) & CE Marking (Annex IV)





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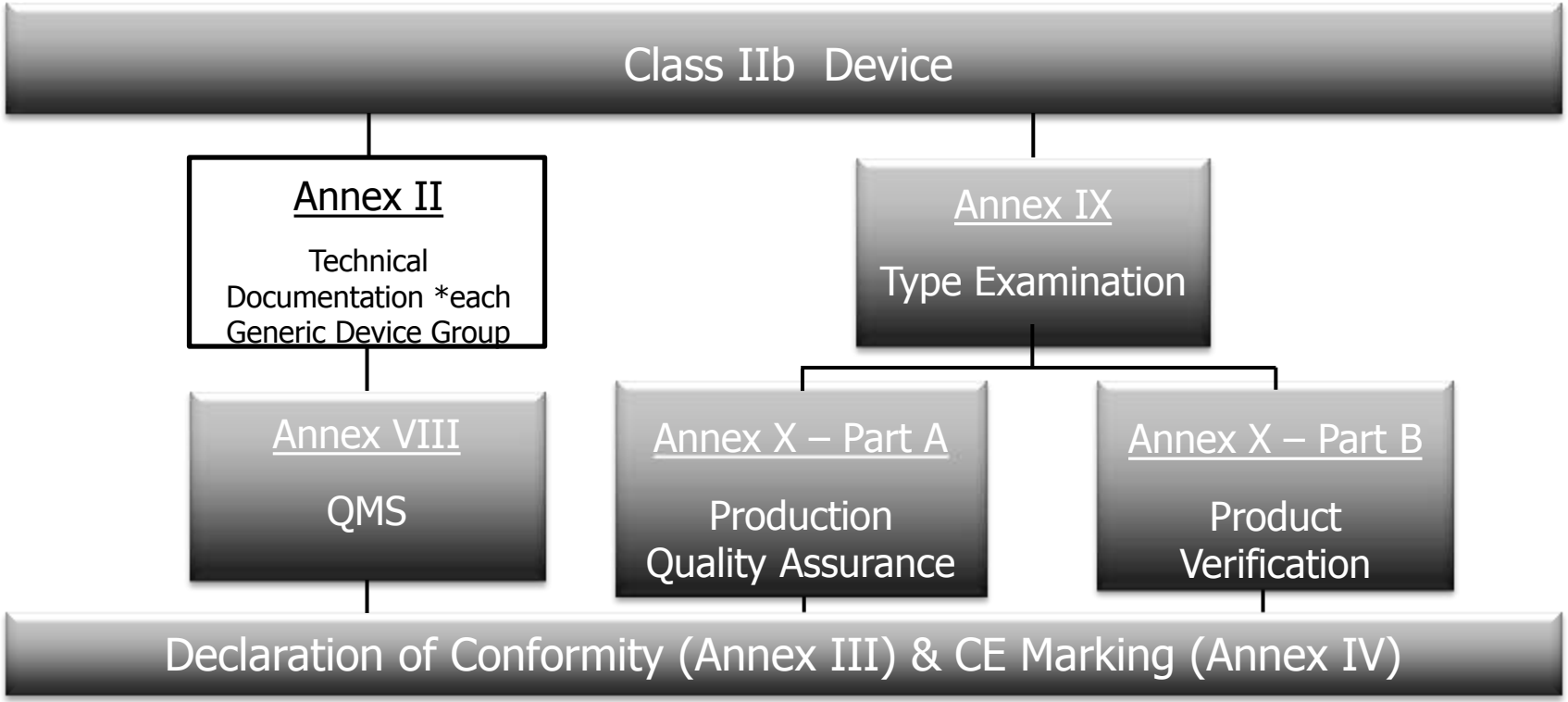

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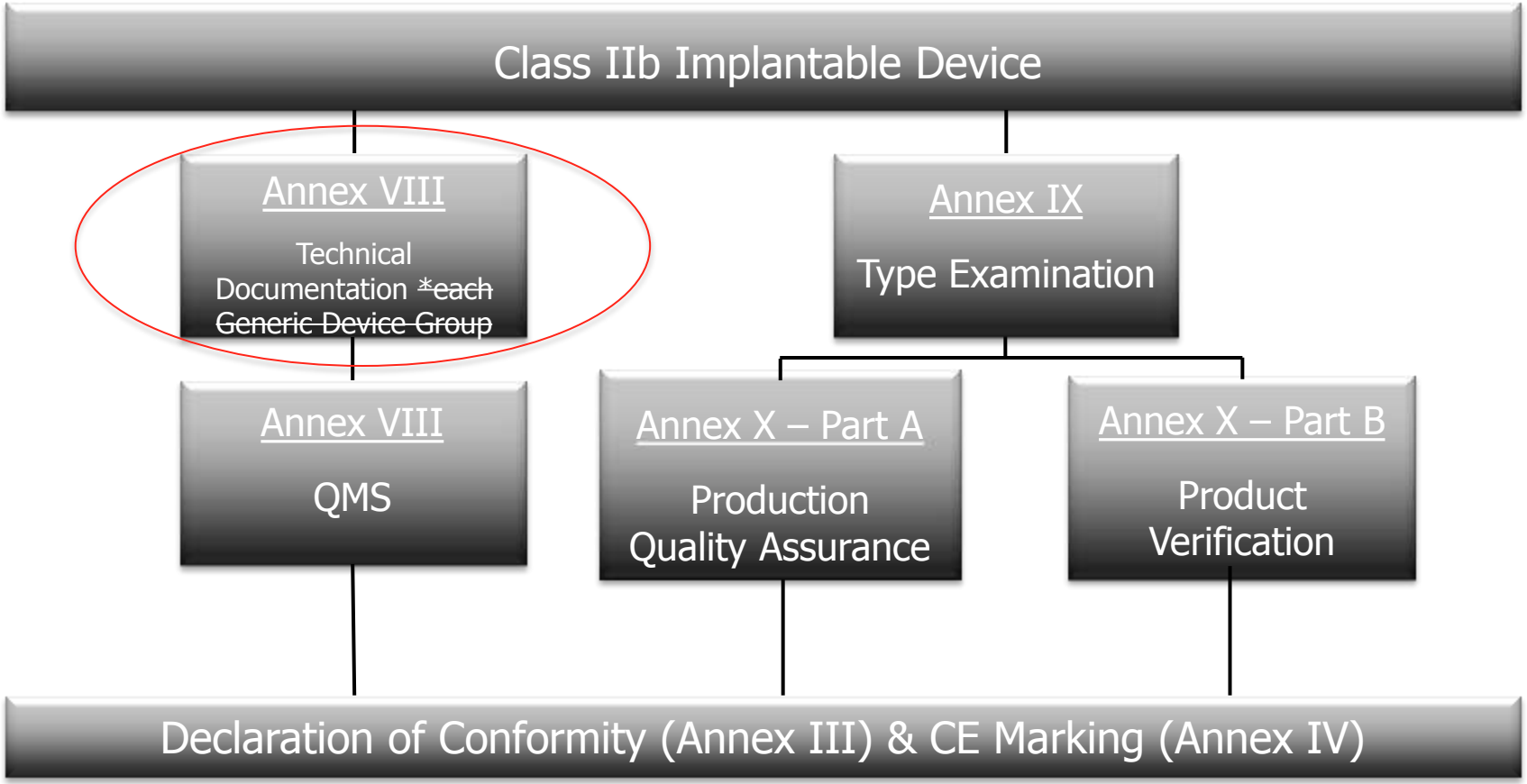

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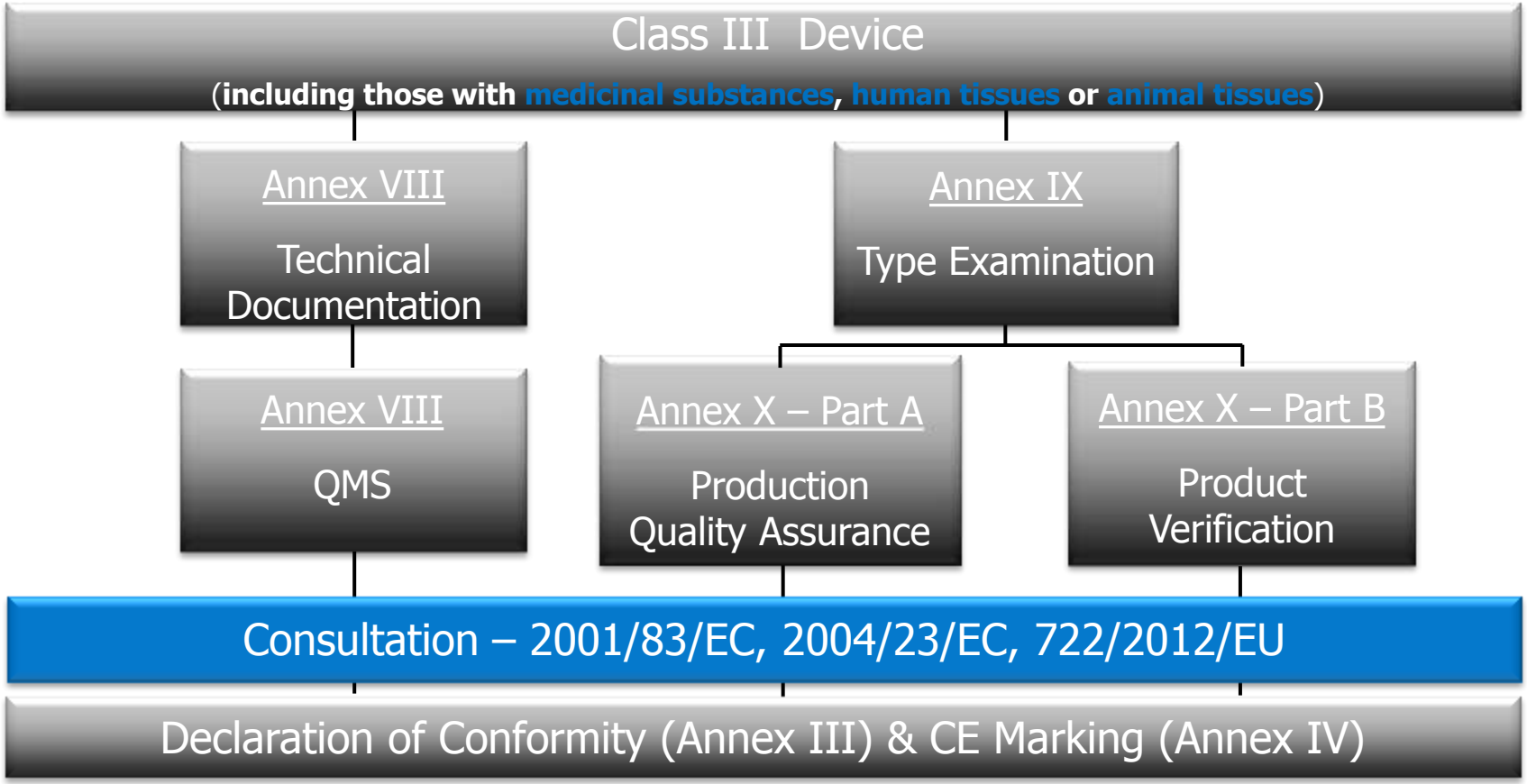

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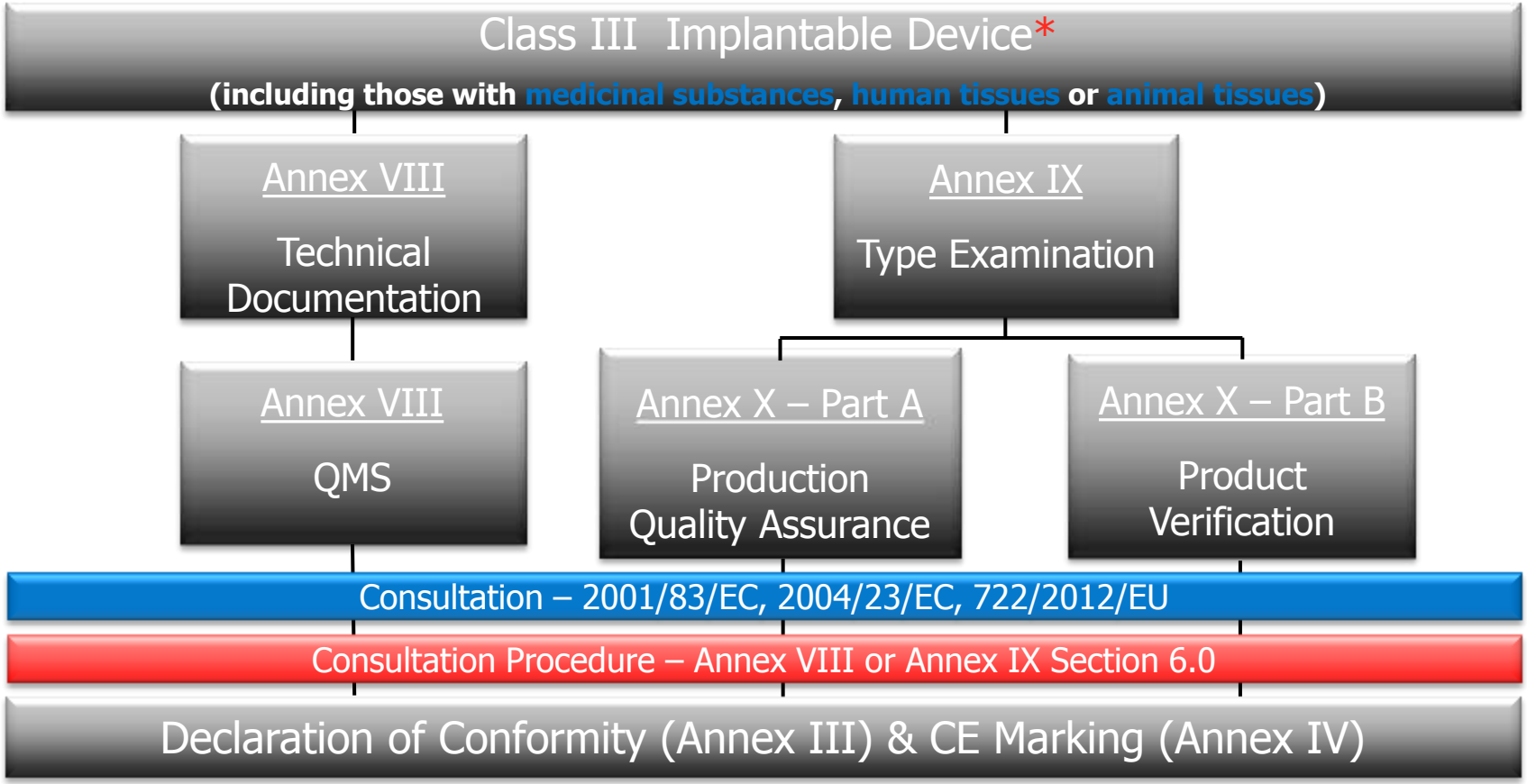


CE 0086 CE 0086

Industry Concerns*: Scrutiny of clinical data for implantable class III devices

- Potential delays, less predictable clearance of class III implantable devices
- No criteria for expert panel selection
- Duplicative assessment following Notified Body assessment
- Delays innovation and patient benefit

**"Industry Concerns" – not necessarily representative of BSI concerns/opinions*

Industry Concerns*: NB review of implantable class IIb devices

- Lead to significant review by NB's of class IIb devices similar to class III's
- Could be an oversight by Council
- If specific implantable devices need further NB scrutiny then up-classified to class III as justified
- May overwhelm the NB system and be additional burden for SME's

*"*Industry Concerns" – not necessarily representative of BSI concerns/opinions*

Headlines – Proposed MDR Chapter VI
Clinical Evaluation, Clinical Investigation

- Manufacturer may request clinical strategy review from EC expert panel
- Clinical data only from published peer reviewed data
- Class III normally require clinical investigation
- Clinical evaluation – class III and implantable devices can rely on equivalency data only:
  - Manufacturers own proven equivalent devices

  or
  - Devices where manufacturer has contractual access to all data of equivalent devices
- PCMF required – class III and implantable devices updated at least annually summary report
- Clinical investigation documentation detailed precisely
- EUDAMED
- Consistent EU processes

Industry Concerns*: Clinical Evidence

- Clinical data excludes some sources of valid data – valid but unpublished: e.g. registries, patient feedback
- New equivalence approach may lead to unnecessary clinical investigations – expensive, unethical, not valid regulatory science perspective
- Clinician's may be unenthusiastic to conduct studies where data outcome is commonly anticipated/expected

**"Industry Concerns" – not necessarily representative of BSI concerns/opinions*

Headlines – Proposed MDR Chapter VII
Vigilance and Market Surveillance

- PMS suitable to analyze data on quality, performance and safety
  - Update risk/benefit determination, clinical evaluation, summary of safety & clinical performance
- PMS plan required
- Periodic safety update report defined, including volume of sales, population of users, and frequency of use – Class III and implantable updated annually and submitted to NB
- Vigilance in line with new MEDDEV
- Annual surveillance plans from authorities, including announced and unannounced facility visits

Technical Documentation
Annex II

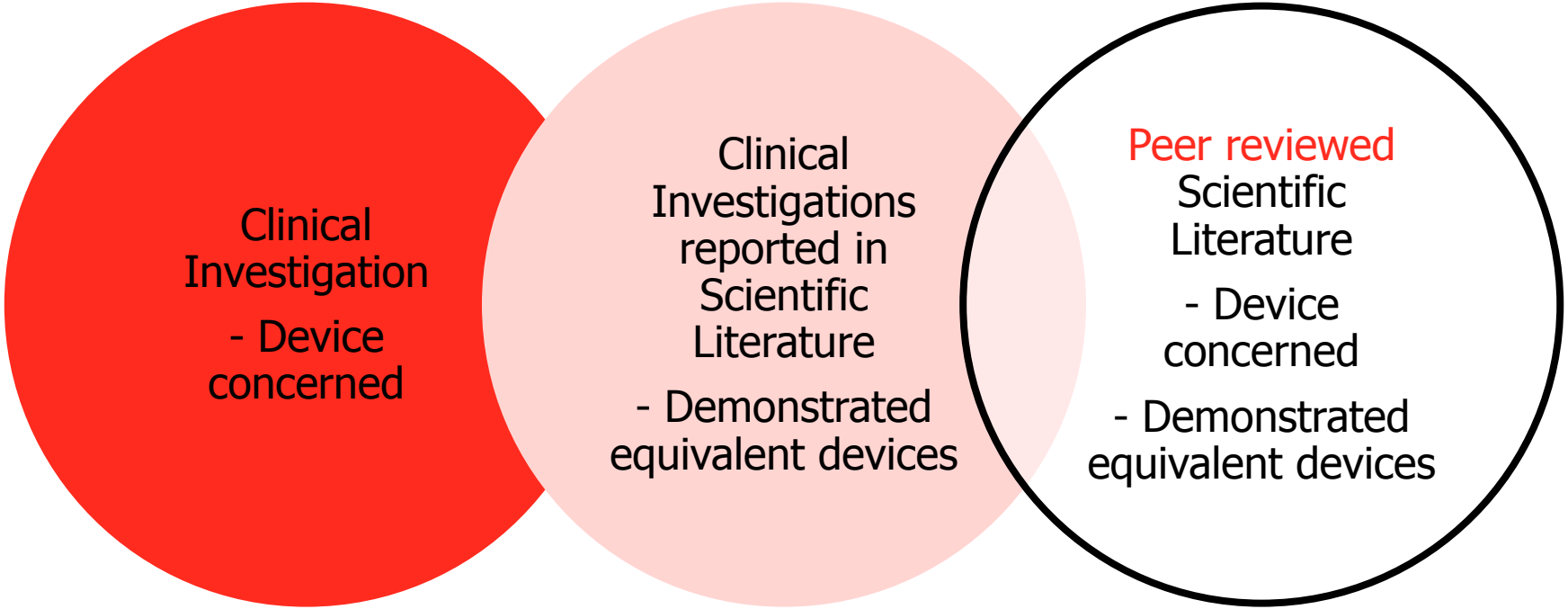
Technical Documentation – Annex II

- The technical documentation and, if applicable, the (STED) to be drawn up by the manufacturer shall include:

1. DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES
   - Device description and specification
   - Reference to previous / similar generations of the device
2. INFORMATION SUPPLIED BY THE MANUFACTURER
3. DESIGN AND MANUFACTURING INFORMATION
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION
   - Pre-clinical and clinical data
   - Additional information in specific cases

Clinical Evidence

Information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:



+ Generated and verified from the manufacturer's post-market surveillance system (PMCF).

*Article 49 has some other words that only allow publications from the SAME manufacturer

QMS

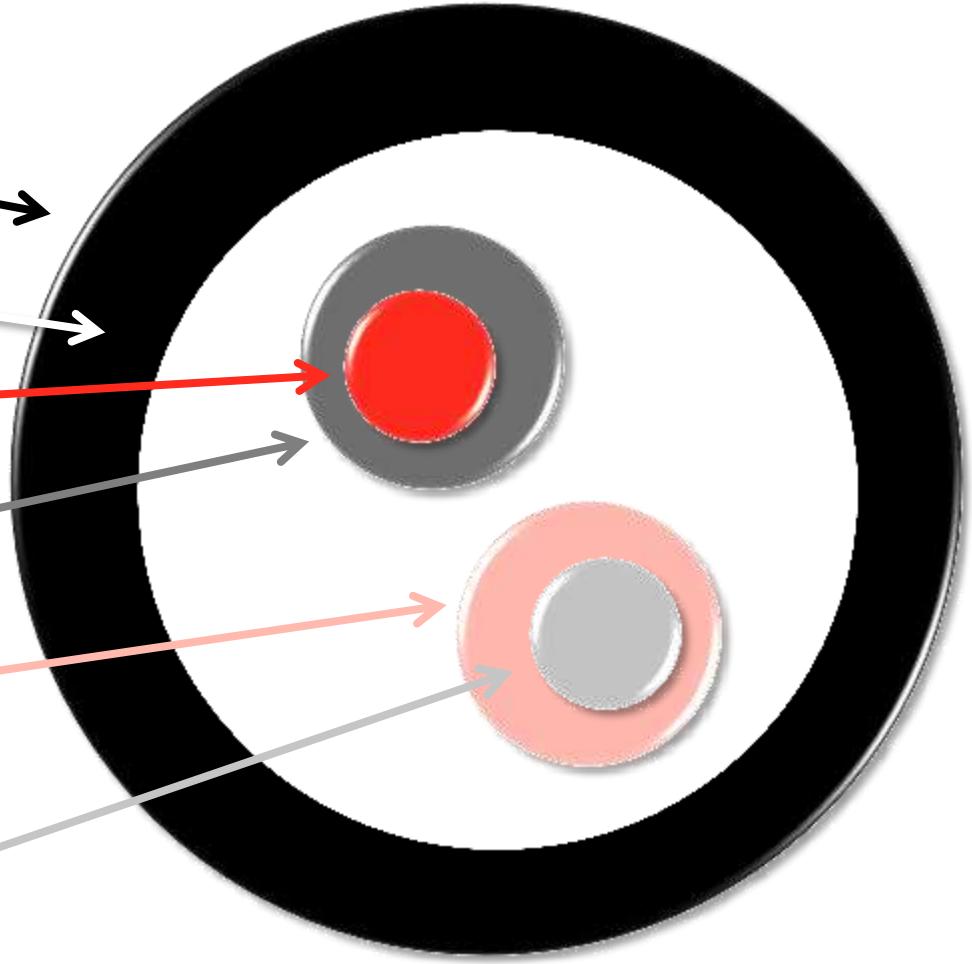
PMS
Article 60a

Vigilance
Article 61-66

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up
Annex XIII



Applies to every class of device under every route of conformity.

Declaration of Conformity Annex III

Declaration of Conformity – Annex III

Declaration of Conformity

Manufacturer: Name, registered trade name or registered trade mark

Address: Address of their registered place of business
Where they can be contacted and their location be established

EU Authorised Representative: Name and Address

Devices:

- Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered (it may include a photograph, where appropriate)
- UDI device identifier
- Risk class of the device in accordance with Annex VII

References to the relevant harmonised standards / common technical specifications

Where applicable, additional information

Notified Body: Where applicable, name and identification number
Description of the conformity assessment procedure performed
Identification of the certificate(s) issued

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

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

Name and function of the person who signs

Signature _____ Indication for and on behalf of whom he/she signs _____

Date ___ Place and date of issue _____

- Name, Single Registration Number and address of the manufacturer;
- If applicable, name and address of the authorised representative;
- A statement that the declaration of conformity is issued under the responsibility of the manufacturer;
- UDI – Article 24;
- Product and trade name, product code, catalogue number or other unambiguous reference, including intended purpose;
- Risk class of the device in accordance with Annex VII;
- A statement that the device is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
- References to the relevant harmonised standards / common specifications used in relation to which conformity is declared;
- Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;
- Where applicable, additional information;
- Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.

Certificates & CE Mark
Annex XII & Annex IV

Certificates Issued by a Notified Body – Annex XII:

- name, address and identification number of the notified body;
- name and address of ONE manufacturer and, if applicable, of the authorised representative;
- unique number identifying the certificate;
- single registration number of the manufacturer
- date of issue;
- date of expiry;
- data needed for the unambiguous identification of the device(s)
  - Product Specific – clear identification (name, model, type) of device, intended purpose (same as in IFU), risk classification and UDI
  - Quality System – identification of device or groups of devices, risk classification and for Class IIb the intended purpose
- if applicable, reference to a replaced previous certificate;
- reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
- examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);
- if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
- if applicable, information about the surveillance by the notified body;
- conclusions of the notified body's conformity assessment with regard to the relevant Annex;
- conditions for or limitations to the validity of the certificate;
- legally binding signature of the notified body according to the applicable national law.

Headlines – Proposed MDR Chapter VIII, IX, X

- Chapter VIII
  - Cooperation, MDCG, Expert Panels
- Chapter IX
  - Confidentiality, Data Protection, Funding, Penalties
- Chapter X
  - Final Provisions
    - Implementation timetable for UDI
    - Transition arrangements

Industry Concerns*: Legacy – Established Technology

- Transitioning to compliance with MDR
- First assessment against MDR
- Longstanding safe III devices with no original clinical studies
- Clinical data derived from post-market
- Lack of planned PMCF
- Disconnect between definitions of clinical data under MDD and MDR
- Potential to overwhelm the system

**"Industry Concerns" – not necessarily representative of BSI concerns/opinions*

Other Considerations

- Manufacturers update technical documentation, systems and processes
  - General Safety and Performance Requirements
    - Including labelling requirements e.g. SRN, UDI, CMR substances etc.
    - Technical Documentation and Technical Documentation on PMS
- Notified Bodies conduct conformity assessment & assessment of technical documentation
  - Assessing legacy devices – gaps to be addressed – new requirements and PMS
  - CE Certificates issued against MDR
- Aligning expectations with new realities
  - Pre-market scrutiny / clinical expectations
  - Resources to achieve and maintain compliance

How BSI is responding

- Providing input of practical concerns to decision makers / influencers
- Recruiting product experts
- Preparing for additional Notified Body reviews
  - Reviewing up-classified devices
  - Thoroughly understanding expectations of new clinical scrutiny process for class III implantable devices
  - Resources to review
    - Class IIb implantable technical documentation
    - Clinical and safety summary reports
    - Annual safety update reports
  - Upgrade conformity assessment of all existing QMS
- Staying closely involved and sharing information with stakeholders

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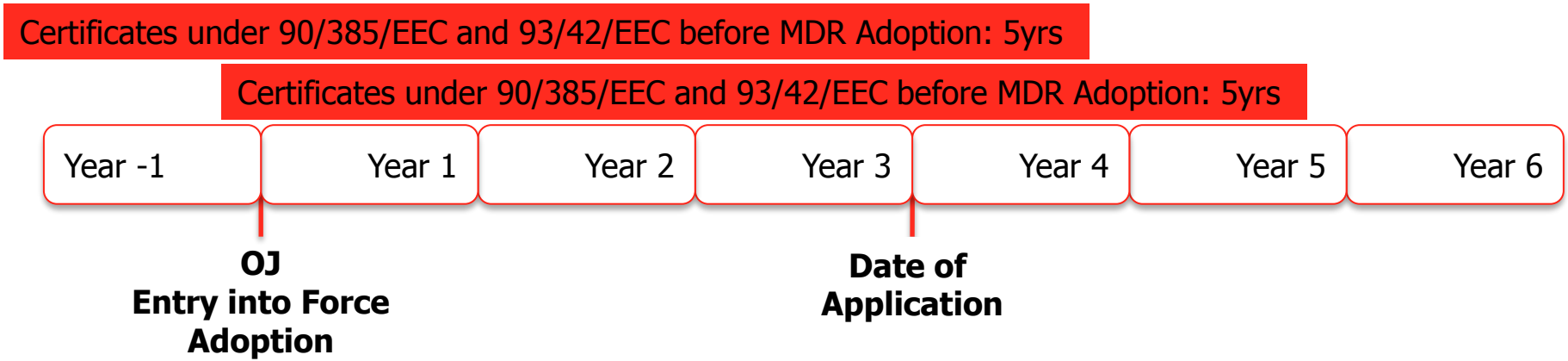
Article 94

Transition 93/42/EEC & 90/385/EEC ⇨ Medical Devices Regulation

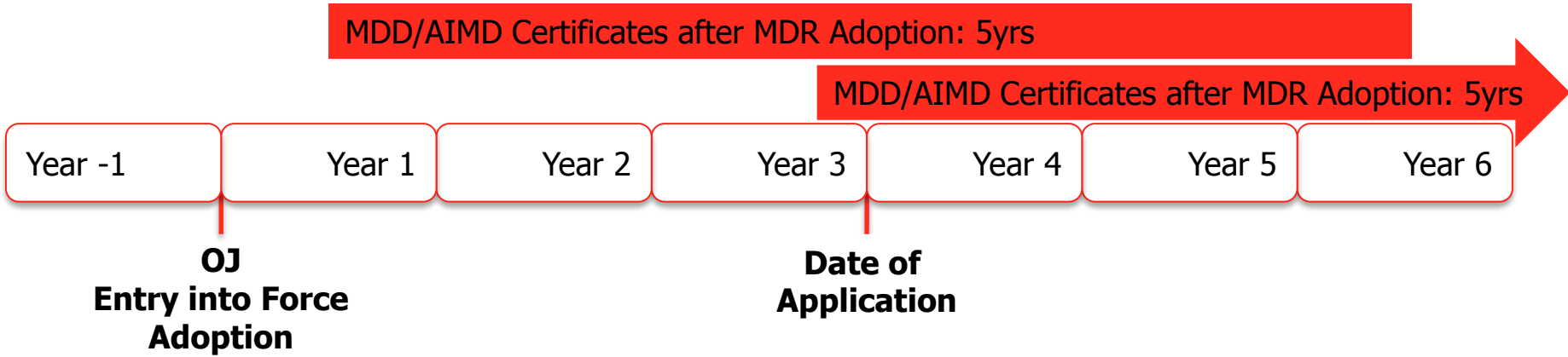
Article 94 – Transitional provisions Point 2 - 1

- Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its delivery. They shall however become void at the latest two five years after the date of application of this Regulation.



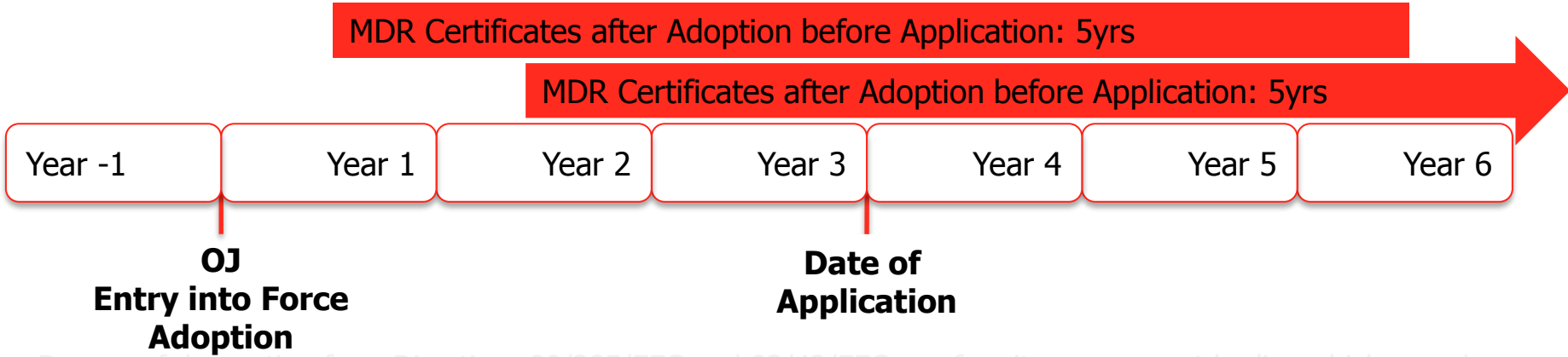
Article 94 – Transitional provisions Point 2 - 3

- Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its delivery. They shall however become void at the latest five years after the date of application of this Regulation.



Article 94 – Transitional provisions Points 3 and 4

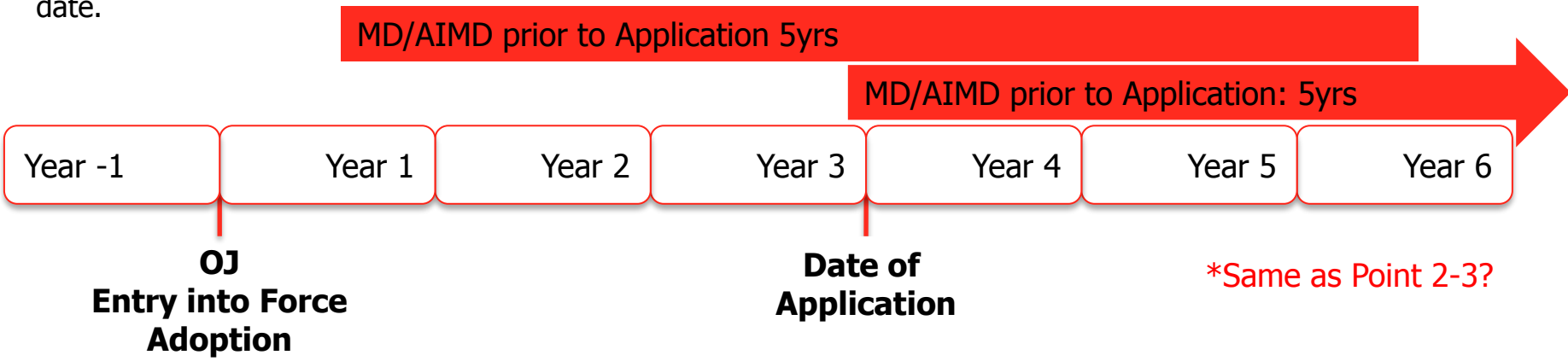
- By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.
- Devices which were lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to the date referred to in Article 97(2) may continue to be made available until 5 years after that date.



- By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

Article 94 – Transitional provisions Points 3 and 4

- By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.
- Devices which were lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to the date referred to in Article 97(2) *date of application may continue to be made available until 5 years after that date.



- By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.