EU MEDICAL DEVICE REGULATION 2017/745

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UNIVERSITÀ DI PISA

WHAT THEY HAVE IN COMMON?




European Medical Device Legislation

Directive 90/385/EEC on Active Implantable Medical Devices
Directive 93/42/EEC on Medical Devices

Regulation on medical devices: **Regulation (EU) 2017/745**
http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0745&from=EN

Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Regulation on in vitro diagnostic medical devices: **Regulation (EU) 2017/746**
http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0746&from=EN

The Medical Device Regulation is a law that regulates the marketing of Medical Devices in the EU

What is a Medical Device?

MDR 2017/745 – Article 2 (1)

"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:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

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.

EU Regulation 2017/745

- 101 Whereas…= WHY
- 10 Chapters of 123 Articles = WHAT
- XVII Annexes = HOW

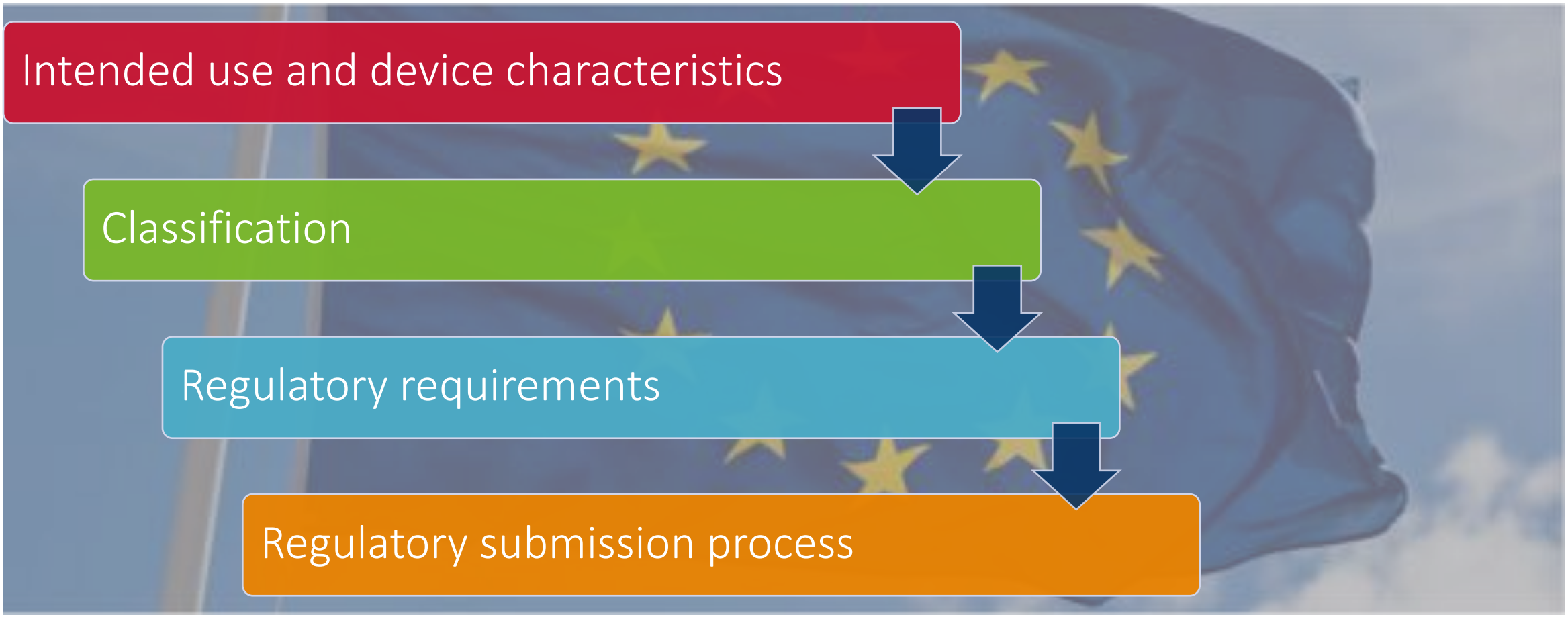
- Chapter I – Scope and Definitions
- Chapter II – CE Marking, Economic Operators, Reprocessing
- Chapter III – Identification and Traceability of Devices
- Chapter IV – Notified Bodies
- Chapter V – Classification and Conformity Assessment
- Chapter VI – Clinical Evaluation and Investigation
- Chapter VII – Vigilance and Market Surveillance
- Chapter VIII – Cooperation between Member States
- Chapter IX – Confidentiality, Data Protection, Funding, Penalties
- Chapter X – Final Provisions

EU Regulation 2017/745

- 101 Whereas…= WHY
- 10 Chapters of 123 Articles = WHAT
- XVII Annexes = HOW

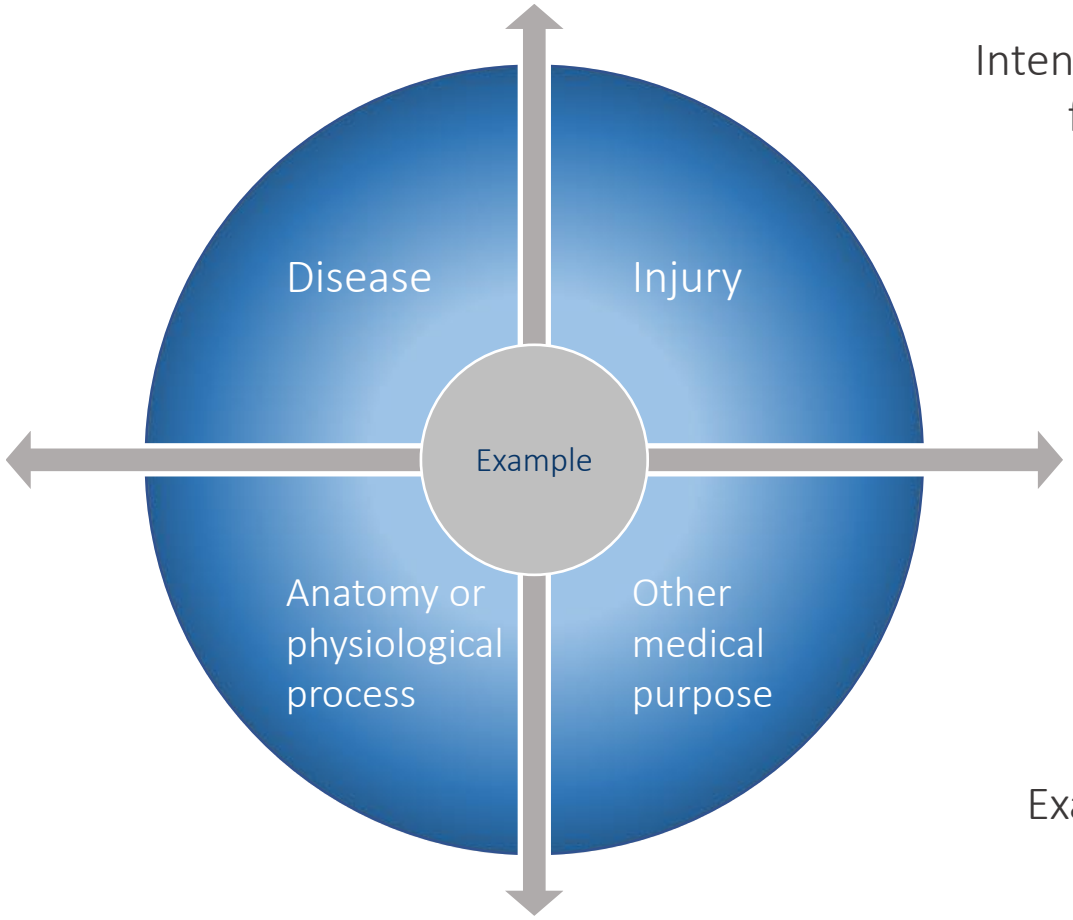
- Annex I – General safety and performance requirements
- Annex II – Technical Documentation
- Annex III – Technical Documentation on PMS
- Annex IV – EU Declaration of Conformity
- Annex V – CE Marking of Conformity
- Annex VI – European UDI System
- Annex VII – Requirements to be met by Notified Bodies
- Annex VIII – Classification Criteria
- Annex IX – Conformity Assessment – QMS and Technical Documentation
- Annex X – Conformity Assessment – Type Examination
- Annex XI – Conformity Assessment – Product Conformity Verification
- Annex XII – Procedure for Custom-made Devices
- Annex XIII – Certificates issued by a Notified Body
- Annex XIV – Clinical Evaluation and Post-market clinical follow-up
- Annex XV – Clinical Investigations
- Annex XVI – Products without an intended medical purpose
- Annex XVII – Correlation Table 90/385, 93/42 and Regulation

Overview of Regulatory Framework

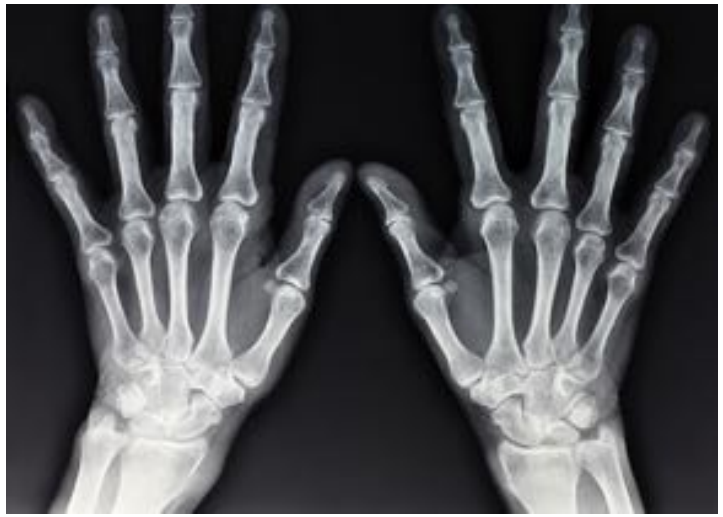


MDR 2017/745
INTENDED USE

MDR 2017/745 – INTENDED USE



Intended use The general purpose of the medical device or its function (what you "claim" the medical device does)



Example: …. is a diagnostic x-ray system for generation of x-rays for examination of various anatomical regions

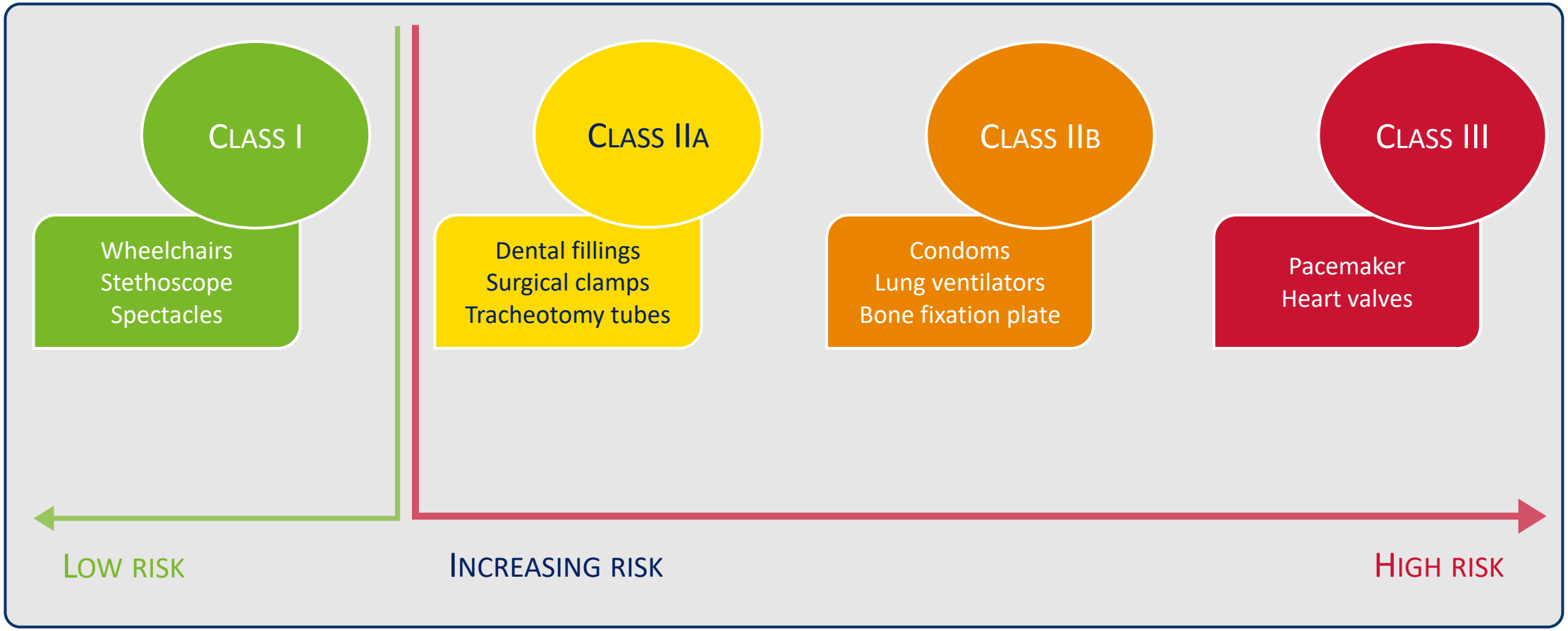
MDR 2017/745
CLASSIFICATION

MDR 2017/745 - CLASSIFICATION

- 1- 4 – Non-Invasive MD
- 5 –Invasive MD
- 9-13 – Active MD
- 14-22 – Special Rules

ANNEX VIII
22 CLASSIFICATION RULES

MDR 2017/745 – CLASS RISK



ANNEX VIII - CLASSIFICATION

Some new rules, new definitions, some clarifications, some upclassifications…

- ✓**Rule 3**: Upclassification of IVF media/solutions for organ storage to Class III
- ✓**Rule 8**: Upclassification of surgical meshes and spinal devices to Class III .
- ✓**Rule 9**: Active devices intended for controlling, monitoring or directly influencing the performance of active implantable devices are Class III.
- ✓**Rule 11**: Upclassification of some softwares (decision making SW, monitoring of physiological parameters) from Class I to IIa.

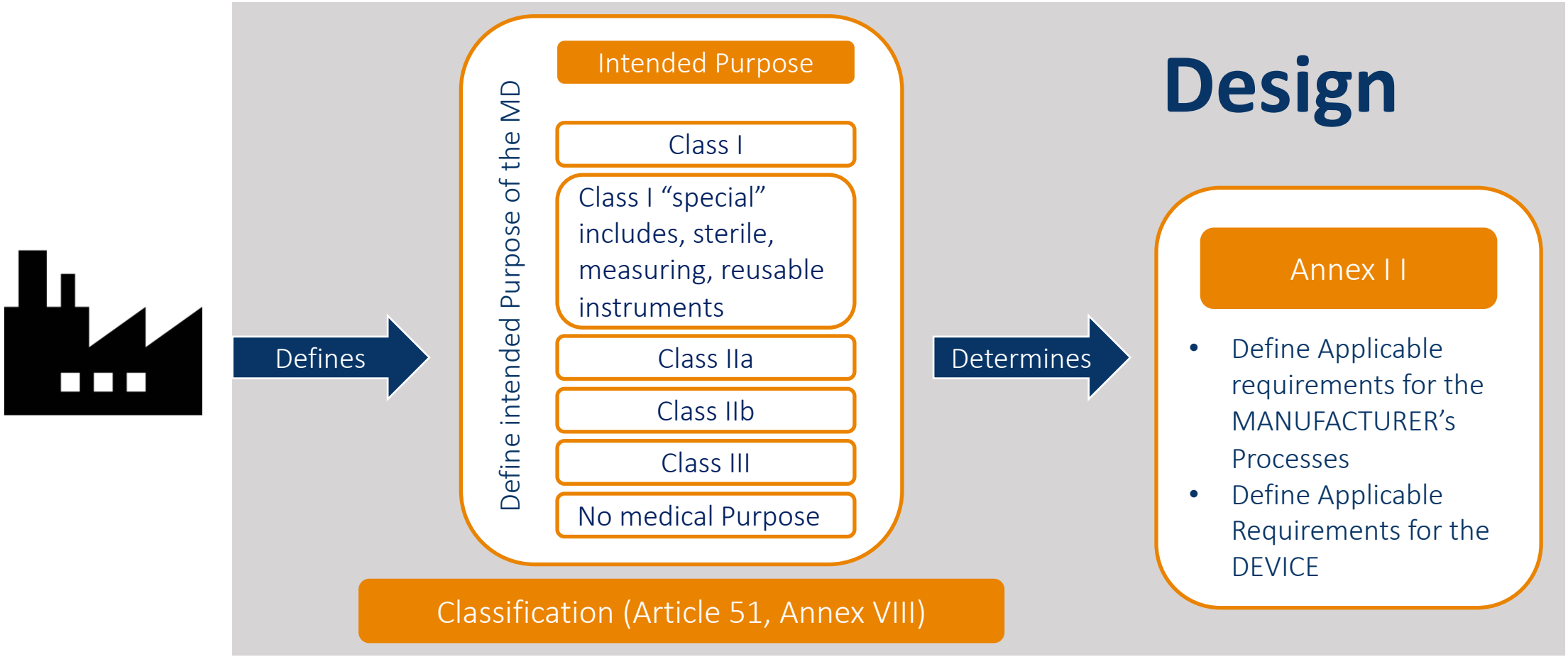
ANNEX VIII – NEW RULES

- ✓ **Rule 19**: Nanomaterials – Class IIa/IIb/III
- ✓ **Rule 20**: Invasive devices with respect to body orifices, […] intended to administer medicinal products by inhalation are classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as Class Iib

- ✓ **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 – Class IIa/IIb/III.

- ✓ **Rule 22**: Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as Class III - Upclassification from Class IIb to Class III

Design Requirements



REGULATORY REQUIREMENTS –CONFORMITY ASSESSMENT PROCEDURE–

BASED ON THE CLASSIFICATION, WE CAN DETERMINE THE APPROPRIATE CONFORMITY ASSESSMENT PROCEDURE...

What requirements need to be met for a conformity assessment?

1. General Safety and Performance Requirements (Annex I MDR):
   - ✓Benefits must outweigh risks and achieve claimed performance supported by clinical evidence and investigation
   - ✓Chemical, physical and biological properties for medical devices disclosed [Performance characteristics for ivds disclosed]
   - ✓Information supplied by manufacturer with the device; e.g. IFU and correct device labelling
2. Technical documentation (Annex II MDR)
3. Harmonized standards / common specifications (Articles 8 and 9 MDR) See Annex IX, X and XI of MDR for details

PRODUCT ON EUROPEAN MARKET

Many products require CE marking before they can be sold in the EEA. CE marking proves that your product has been assessed and meets EU safety, health and environmental protection requirements. It is valid for products manufactured both inside and outside the EEA, that are then marketed inside the EEA.

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

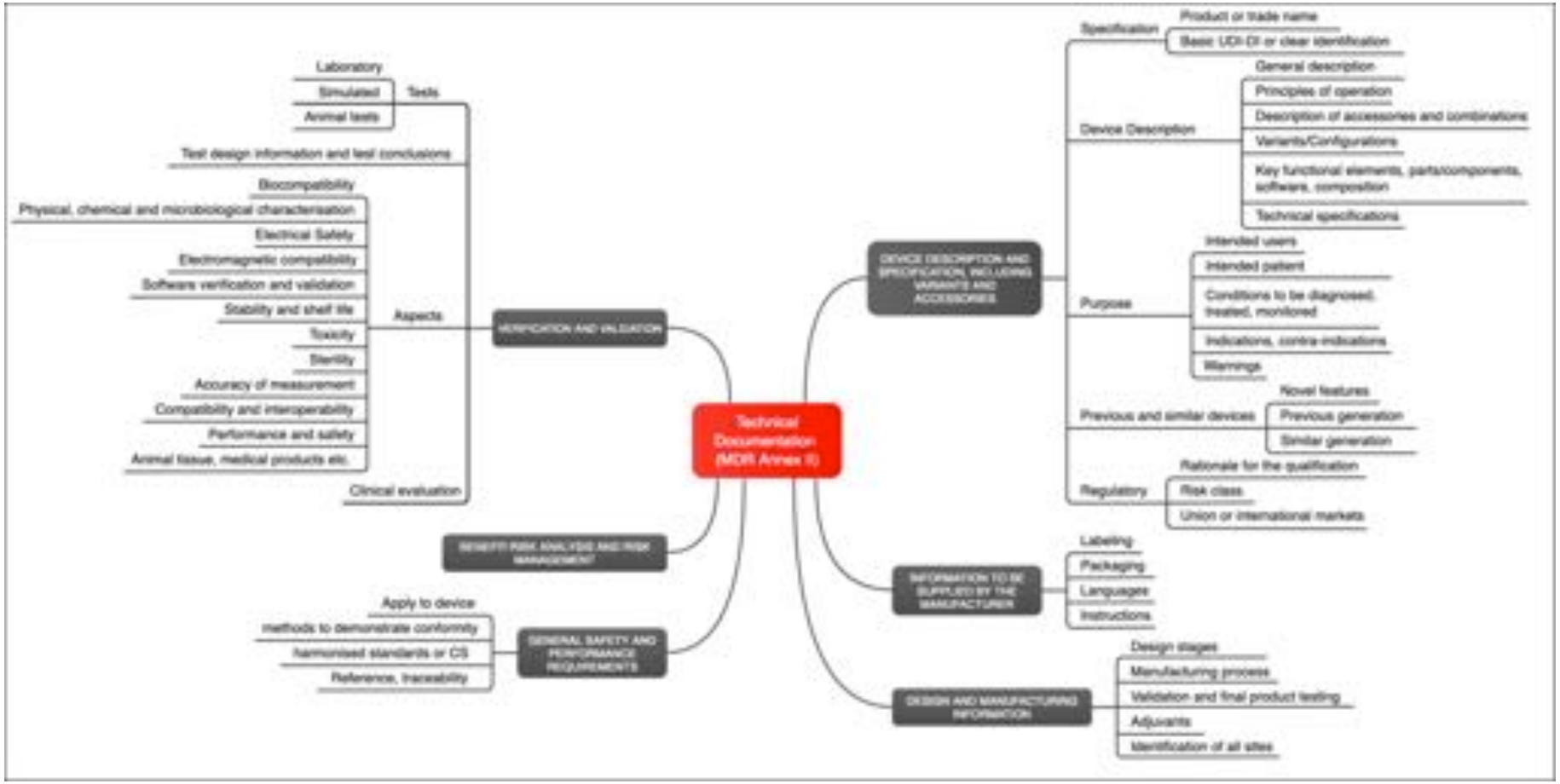
MDR 2017/745, Annex I

- General Requirements
  - Manufacturers shall establish, implement, document and maintain a risk management system
- Requirements regarding design and manufacture
  - E.g. chemical, physical and biological properties
- Requirements regarding the information supplied with the device
  - E.g. label and instruction use

CE

23 REQUIREMENTS

TECHNICAL DECUMENTATION



HARMONISED STANDARDS

Article 8 – MDR 2017/745

*"Devices that are in conformity with the relevant **harmonised standards**, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof." (1)*

International Standards Organization

ISO International Organization for Standardization

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

European Standards Organization

CEN CENELEC

WHAT IS AN HARMONISED STANDARD?

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

Presumption of Conformity

MDR 2017/745, Article 8

Some Key Standards

- ✓ EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes

  specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements

- ✓ EN ISO 14971:2016 –Medical devices – Application of risk management to medical devices

  specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

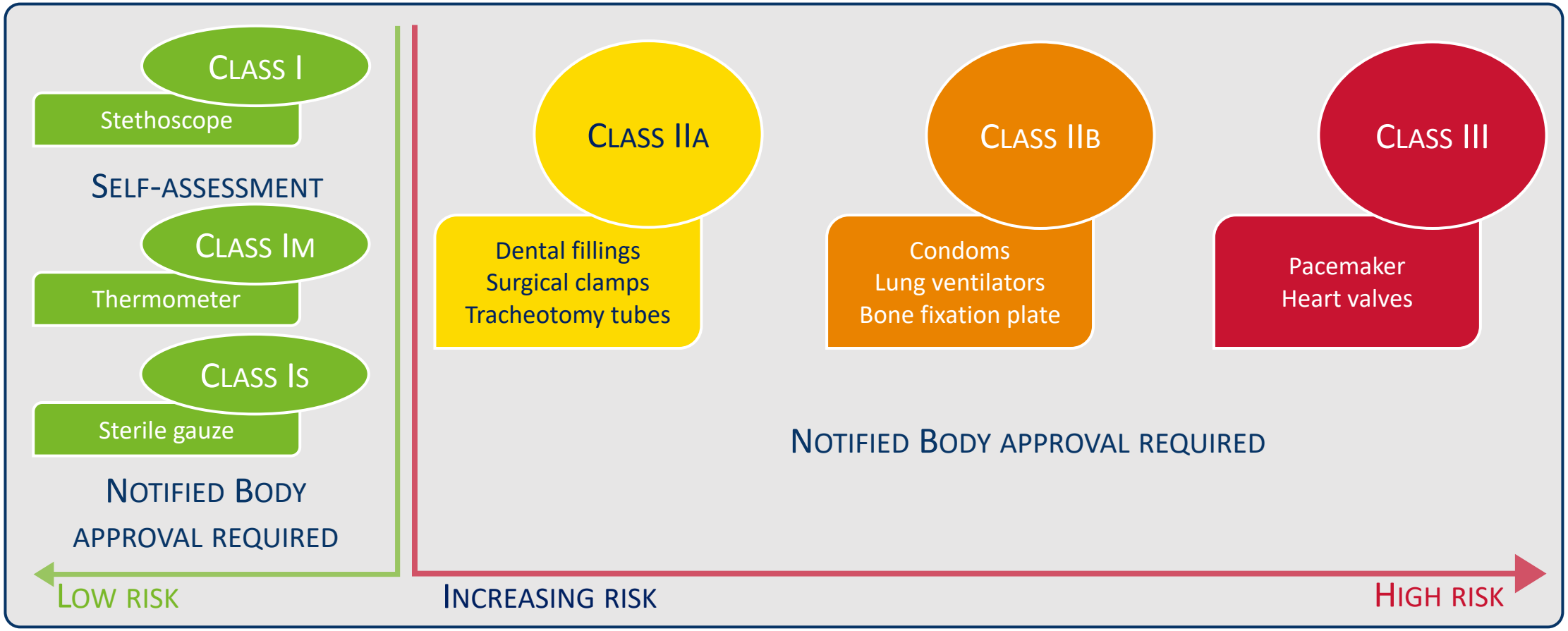
- ✓ EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

  identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document.

- ✓ IEC 60601-1:2018 Medical Electrical Equipment -- Part 1: General requirements for basic safety and essential performance

  contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment.

MDR 2017/745 – CLASS RISK



MDR CONFORMITY ASSESSMENT

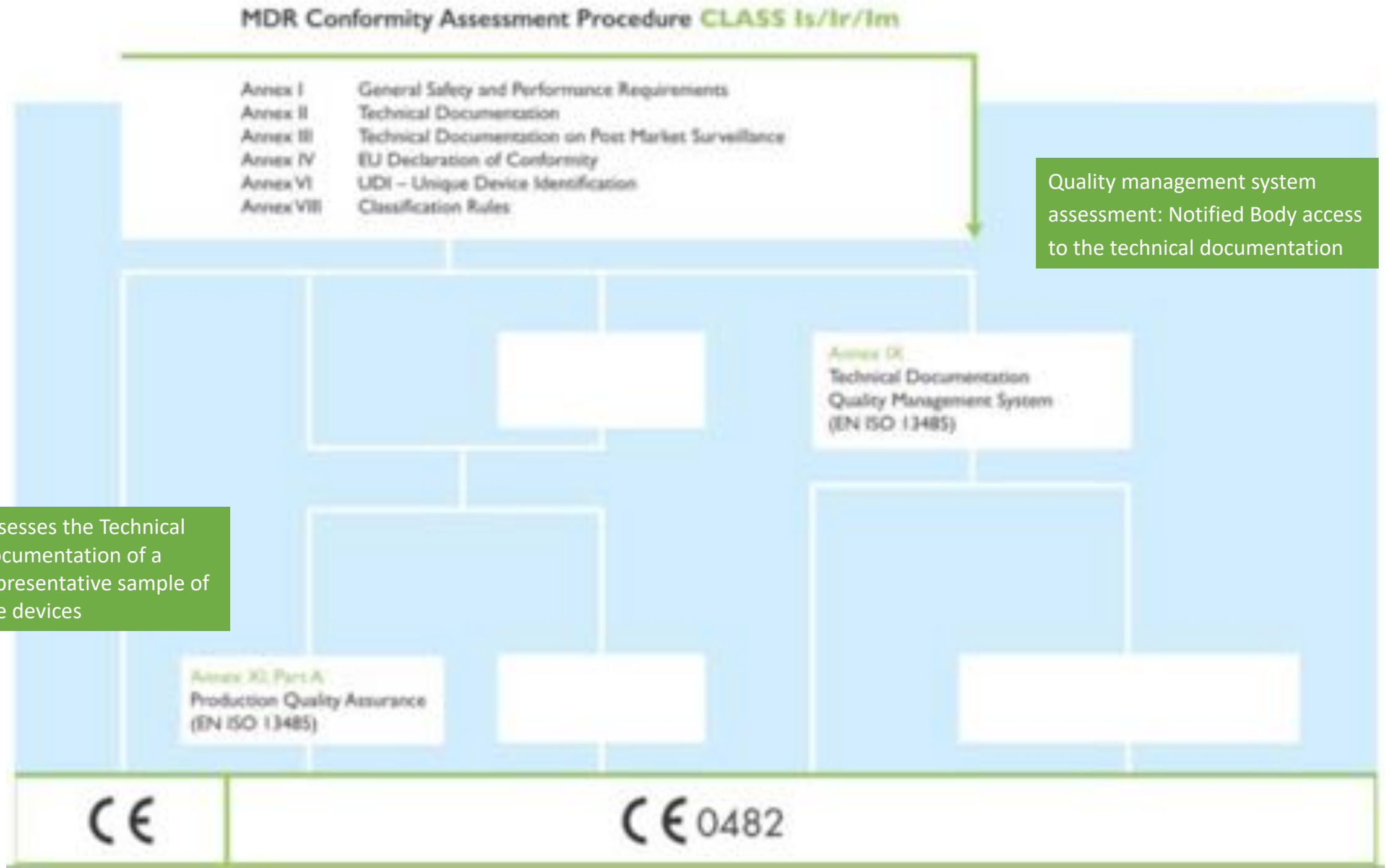
- ✓ Approval is requires for Class IIA, IIB and III medical devices.
- ✓ Some Class I devices will require notified body approval for parts of the manufacturing process that relates to sterility or metrology, if the medical device includes sterile products or a measuring functions.
- ✓ Manufactures can certify their products with any notified body within the EU

Conformity assessment is the method by which a manufacturer demonstrates that their devices comply with the requirements of MDR 2017/745. The classification of the medical device will have an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking on the medical device.

MDR Conformity Assessment Procedure CLASS I

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI – Unique Device Identification
Annex VIII	Classification Rules

CE


MDR Conformity Assessment Procedure CLASS Is/Ir/Im
Annex I General Safety and Performance Requirements
Annex II Technical Documentation
Annex III Technical Documentation on Post Market Surveillance
Annex IV EU Declaration of Conformity
Annex VI UDI – Unique Device Identification
Annex VIII Classification Rules
Quality management system assessment: Notified Body access to the technical documentation
Annex IX
Technical Documentation
Quality Management System
(EN ISO 13485)
Assesses the Technical Documentation of a representative sample of the devices
Annex XI Part A
Production Quality Assurance
(EN ISO 13485)
CE
CE 0482

CLASS I DEVICES

- ✓Similar to the current MDD Annex VII “EC declaration of conformity”.
- ✓New EU Declaration of Conformity (new Article 19) prepared by manufacturer,
- ✓Fulfill general obligations of all manufacturers (new Article 10),
- ✓Involvement of a Notified Body is limited for Class I devices, and only required for
  - ✓sterile devices,
  - ✓reusable surgical instruments or
  - ✓devices with a measuring function.

MDR Conformity Assessment Procedure CLASS IIa

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI – Unique Device Identification
Annex VIII	Classification Rules

Annex IX
Technical Documentation
Quality Management System
(EN ISO 13485)

NB carries out tests to confirm the conformity of the devices

Annex XI, Part A
Production Quality Assurance
(EN ISO 13485)

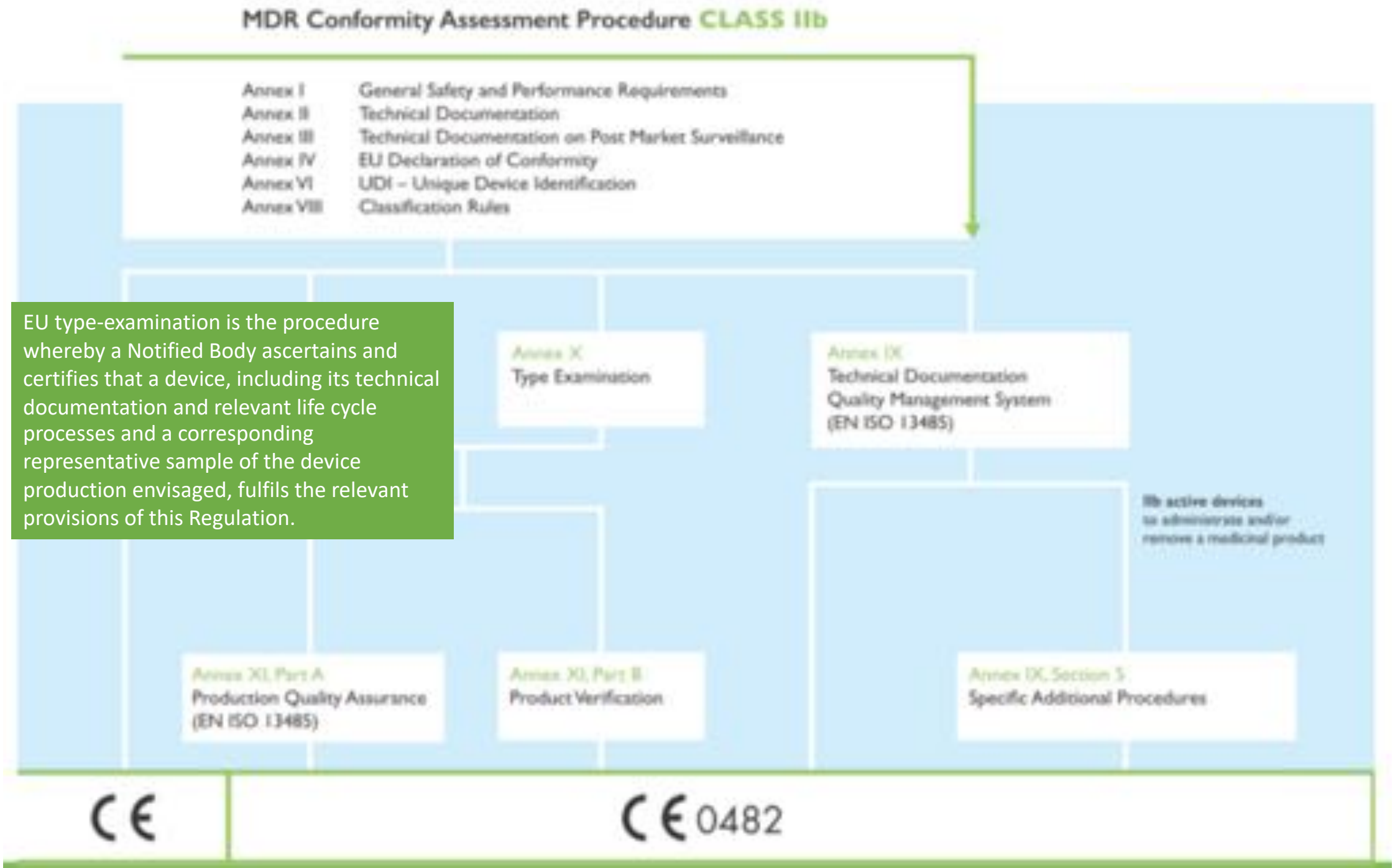
Annex XI, Part B
Product Verification

CE

CE 0482

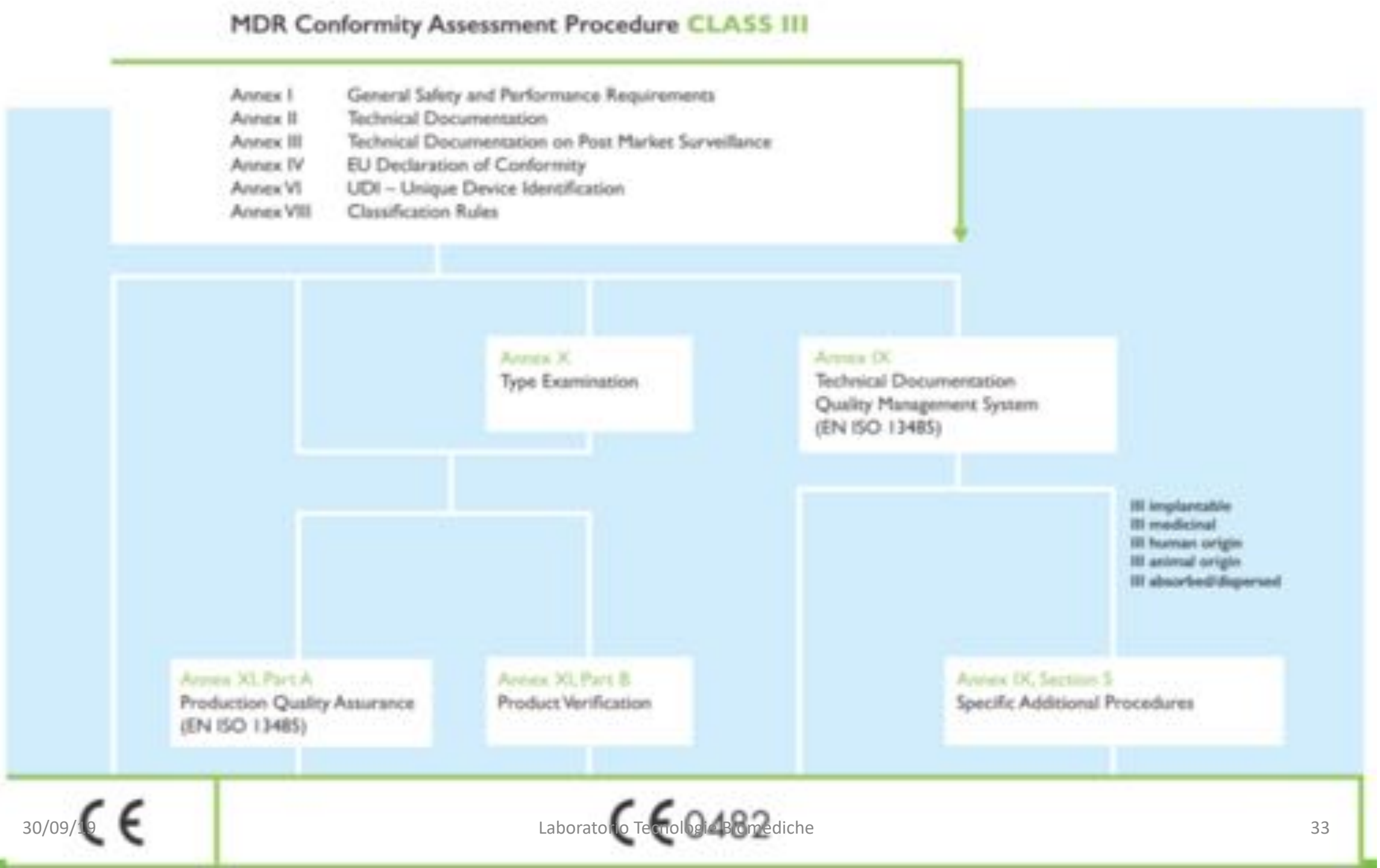
CLASS IIA DEVICES

- ✓ Similar to the current MDD, manufacturers of Class IIa devices have the option of following the same conformity assessment route as for Class IIb devices, the new EU MDR's Annex IX, **with the Notified Body only assessing representative technical documentation.**
- ✓ Manufacturers may choose not to follow the full quality management system approach essentially similar to the current MDD's Annex VII "EC declaration of Conformity" combined with either Annex IV or Annex V:
  - ✓ Compile the new technical documentation (new Annex II)
  - ✓ Manufacturer prepares the new "EU declaration of conformity" (new Article 19)
  - ✓ and then the Notified Body either:
    - ✓ (a) assesses the Technical Documentation of a representative sample of the devices (Annex XI, Part A, Section 10),
    - ✓ or (b) carries out tests to confirm the conformity of the devices (Annex XI, Part B, Section 18).


MDR Conformity Assessment Procedure CLASS IIb
Annex I General Safety and Performance Requirements
Annex II Technical Documentation
Annex III Technical Documentation on Post Market Surveillance
Annex IV EU Declaration of Conformity
Annex VI UDI – Unique Device Identification
Annex VIII Classification Rules
EU type-examination is the procedure whereby a Notified Body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.
Annex X
Type Examination
Annex IX
Technical Documentation
Quality Management System
(EN ISO 13485)
IIb active devices
Annex XI, Part A
Production Quality Assurance
(EN ISO 13485)
Annex XI, Part B
Product Verification
Annex IX, Section 5
Specific Additional Procedures
CE
CE 0482

CLASS IIB DEVICES

- ✓ Similar to the current MDD, manufacturers of Class IIb devices have the option of following the same conformity assessment route as for Class III devices, the new EU MDR's Annex IX with the difference that the **Notified Body is only required to assess the technical documentation of at least one representative device of each generic device group produced by the manufacturer.**
- ✓ As with the current MDD, there are alternative routes for manufacturers of Class IIb devices who chose not to follow the full quality management system approach. These are the same as those for Class III devices with one fewer alternative available to manufacturers of Class IIb devices compared to the MDD: there is no equivalent to the MDD's Annex VI "product quality assurance". Manufacturers currently following this route will have to choose an option from the new Annex XI. Either Part A, "Production Quality Assurance", or Part B, "Product Verification".

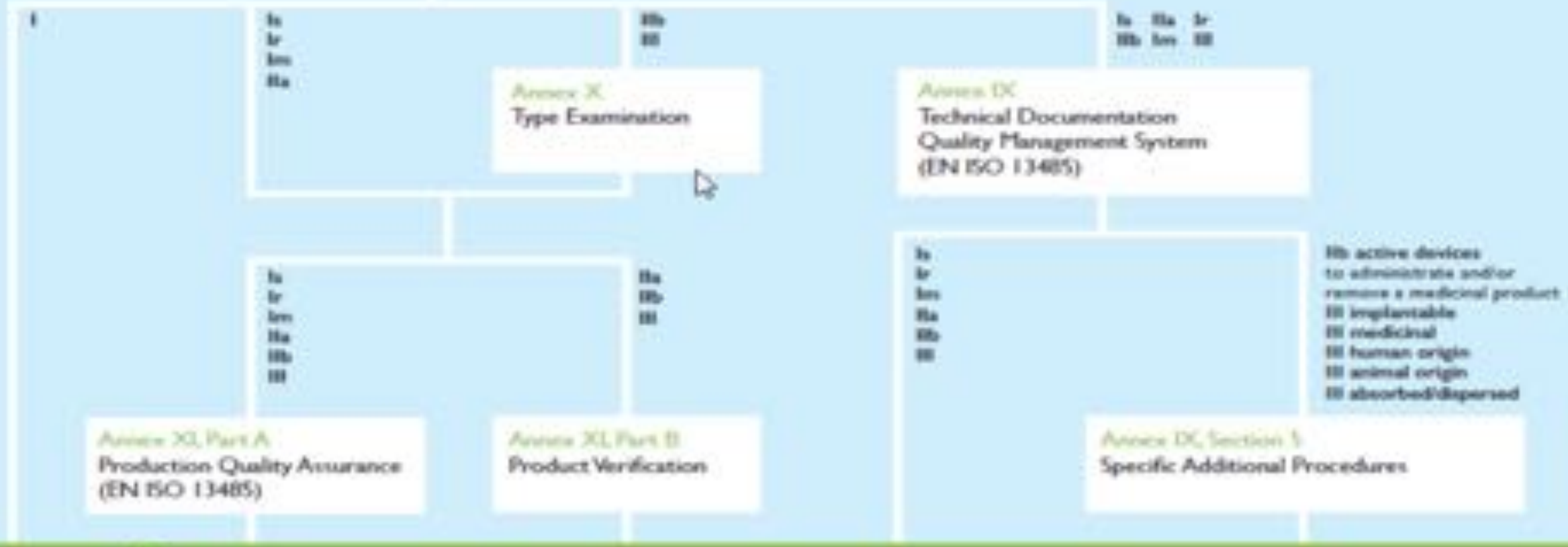

MDR Conformity Assessment Procedure CLASS III
Annex I General Safety and Performance Requirements
Annex II Technical Documentation
Annex III Technical Documentation on Post Market Surveillance
Annex IV EU Declaration of Conformity
Annex VI UDI – Unique Device Identification
Annex VIII Classification Rules
Annex X
Type Examination
Annex IX
Technical Documentation
Quality Management System
(EN ISO 13485)
III implantable
III medicinal
III human origin
III animal origin
III absorbed/dispersed
Annex XI, Part A
Production Quality Assurance
(EN ISO 13485)
Annex XI, Part B
Product Verification
Annex IX, Section 5
Specific Additional Procedures
CE
CE 0482

CLASS III DEVICES

- ✓ The current MDD's Annex II "full quality assurance" route will be replaced by the new EU MDR's Annex IX "conformity assessment based on quality management system assurance and assessment of the technical documentation".
- ✓ There are alternatives for those manufacturers who chose not to follow the full quality management system approach: the current MDD alternative for Class III devices of Annex III "EC type-examination", combined with either Annex IV "EC verification" or Annex V "production quality assurance" will be replaced by the new EU MDR's Annex X "conformity assessment based on type examination" combined with new Annex XI "conformity assessment based on product conformity verification".
- ✓ This is essentially identical to those of the current MDD. The new EU MDR's Annex XI "conformity assessment based on product conformity verification" includes both the MDD's current options; Part A being the new "Production Quality Assurance" route, replacing the current MDD's Annex V "production quality assurance". Part B being the new "Product Verification" route, replacing the current MDD's Annex IV "EC verification".

MDR Conformity Assessment Procedure OVERVIEW

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI – Unique Device Identification
Annex VIII	Classification Rules



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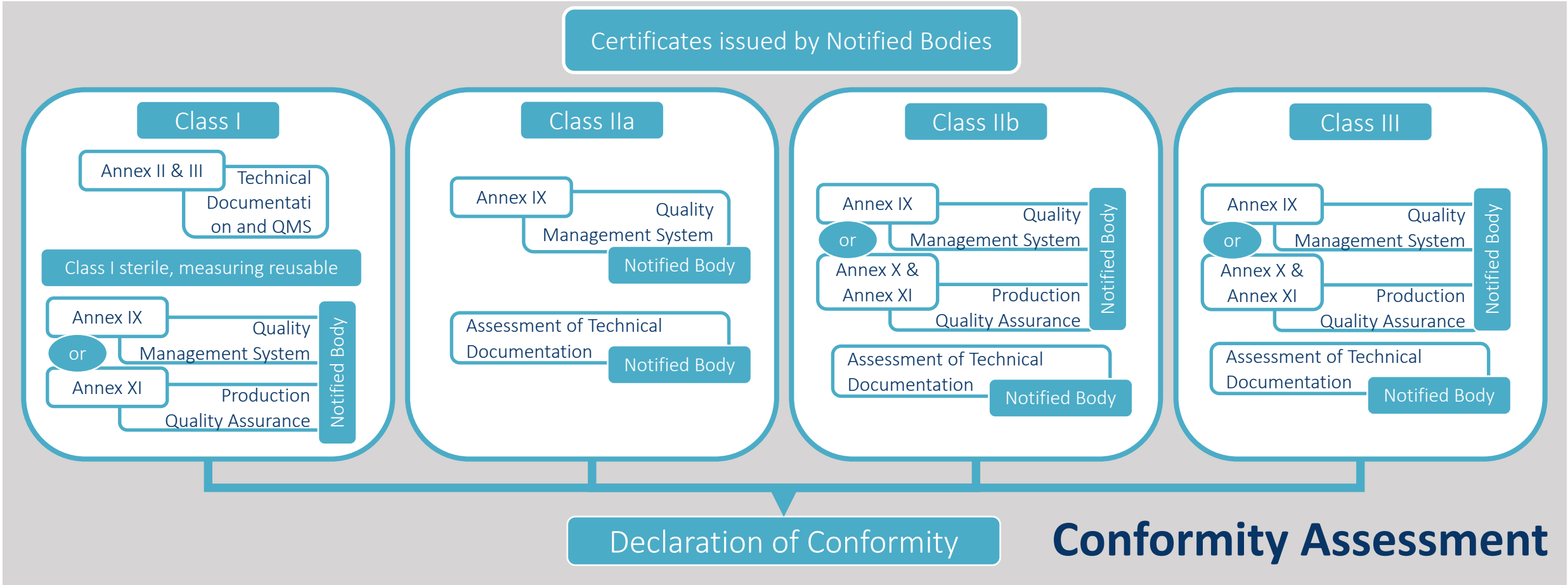
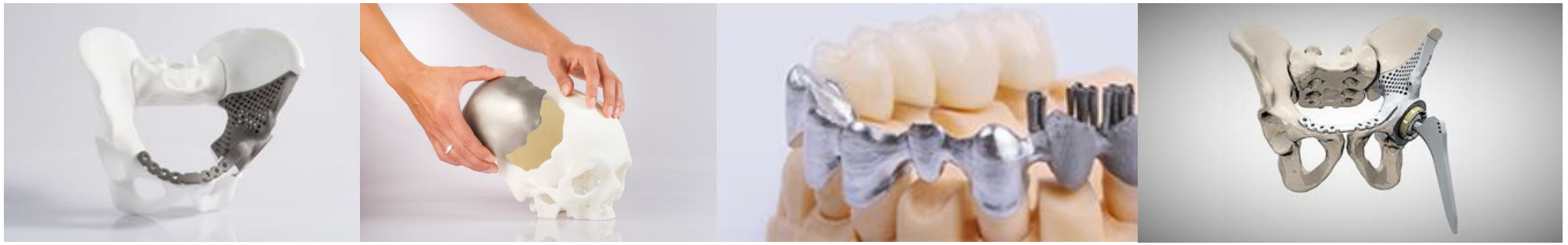
CONFORMITY ASSESSMENT PROCEDURE



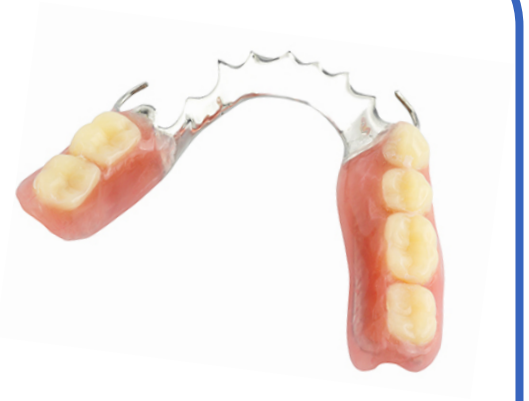
MDR 2017/745 – CUSTOM-MADE MD

"custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs." MDR 2017/745 Article 2 (3)

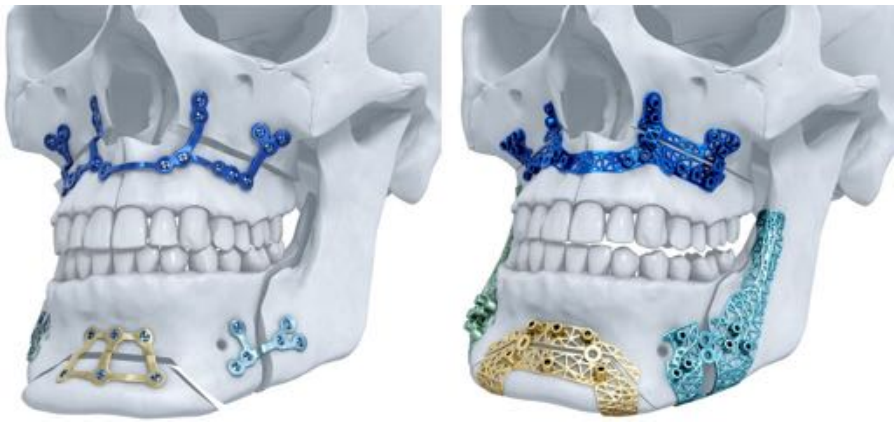


Mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices.

Example of Custom-Made MDs



Dentures



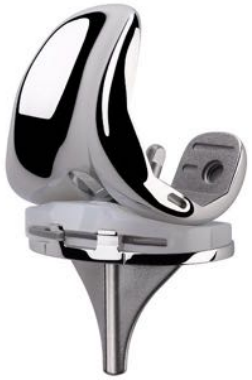
Maxillofacial implants

Custom insole

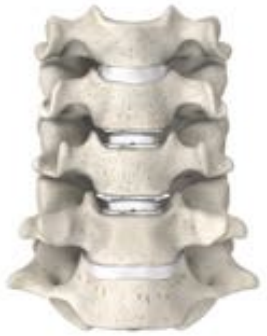
CUSTOM-MADE VS CUSTOMIZED

"CUSTOMIZED" DOES NOT EQUAL A CUSTOM-MADE MEDICAL DEVICE

An existing medical device that is adapted, altered, fashioned, modified or 'customised' to fit a patient is NOT a custom-made medical device (e.g. contact lenses, orthodontic braces)



KNEE REPLACEMENT



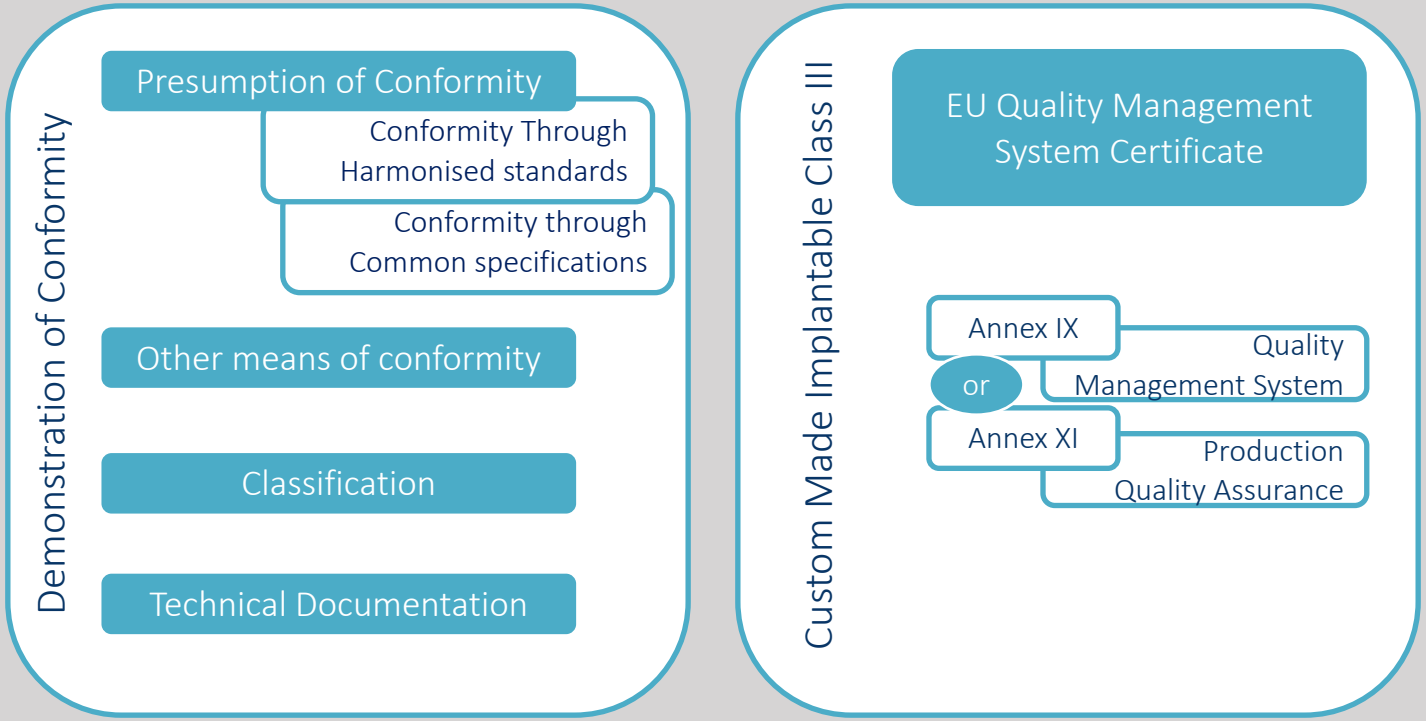
LUMBAR INTERBODY CAGES

PROSTHETIC LEGS

CUSTOM MADE MEDICAL DEVICE

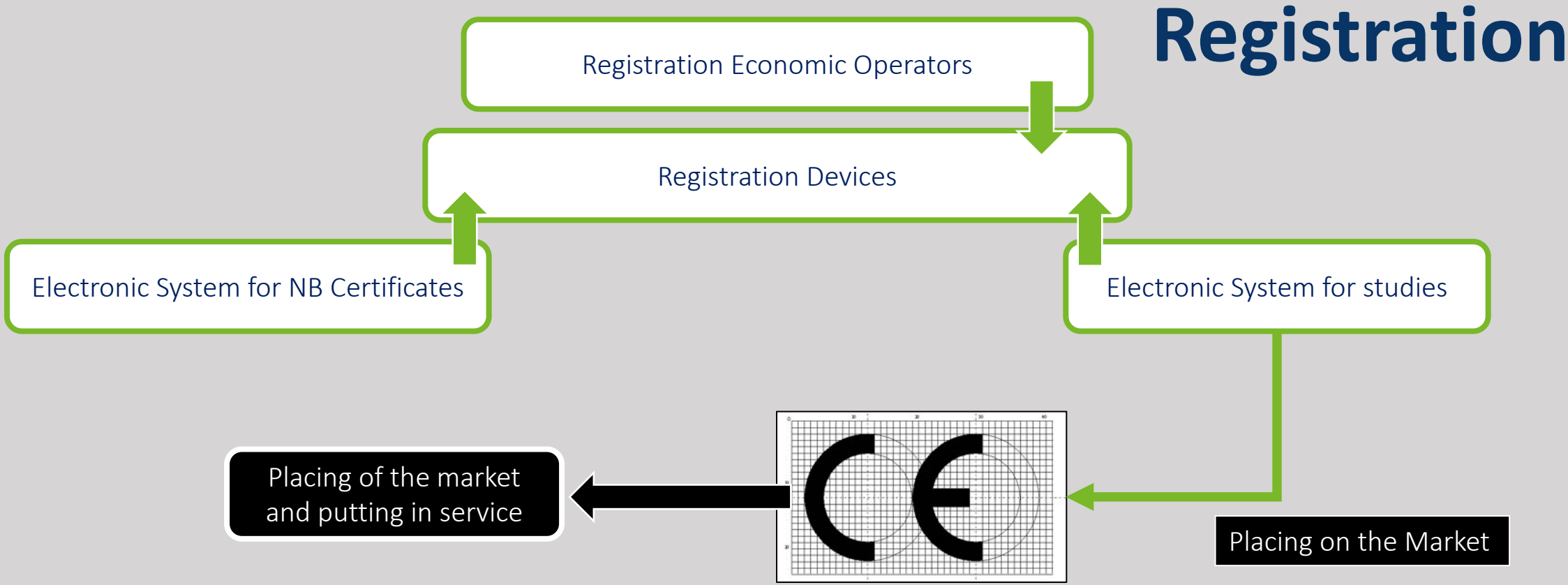
- ✓Unlike the current MDD where the requirements for custom made devices are part of the current MDD Annex VIII **the new EU MDR has a dedicated Annex, Annex XIII "procedure for custom made devices**". However, the requirements to draw up a statement about the device and keep records etc. are fundamentally the same as in the current MDD.
- ✓The exception being **class III custom made devices**, where **a quality system assessment by a Notified Body is required**; either the "quality management system assessment" of the new Annex IX, Chapter 1 or the "Production Quality Assurance" of the new Annex XI, Part A.

CONFORMITY ASSESSMENT PROCEDURE



Conformity Assessment

REGISTRATION



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