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America

AFDO - 2017
2017/745 - Medical Device Regulation (MDR)

Presented by Tamas Borsai
Division Manager TÜV SÜD
tborsai@tuvam.com
June 20, 2017

Overview

1 Overview of the MDR

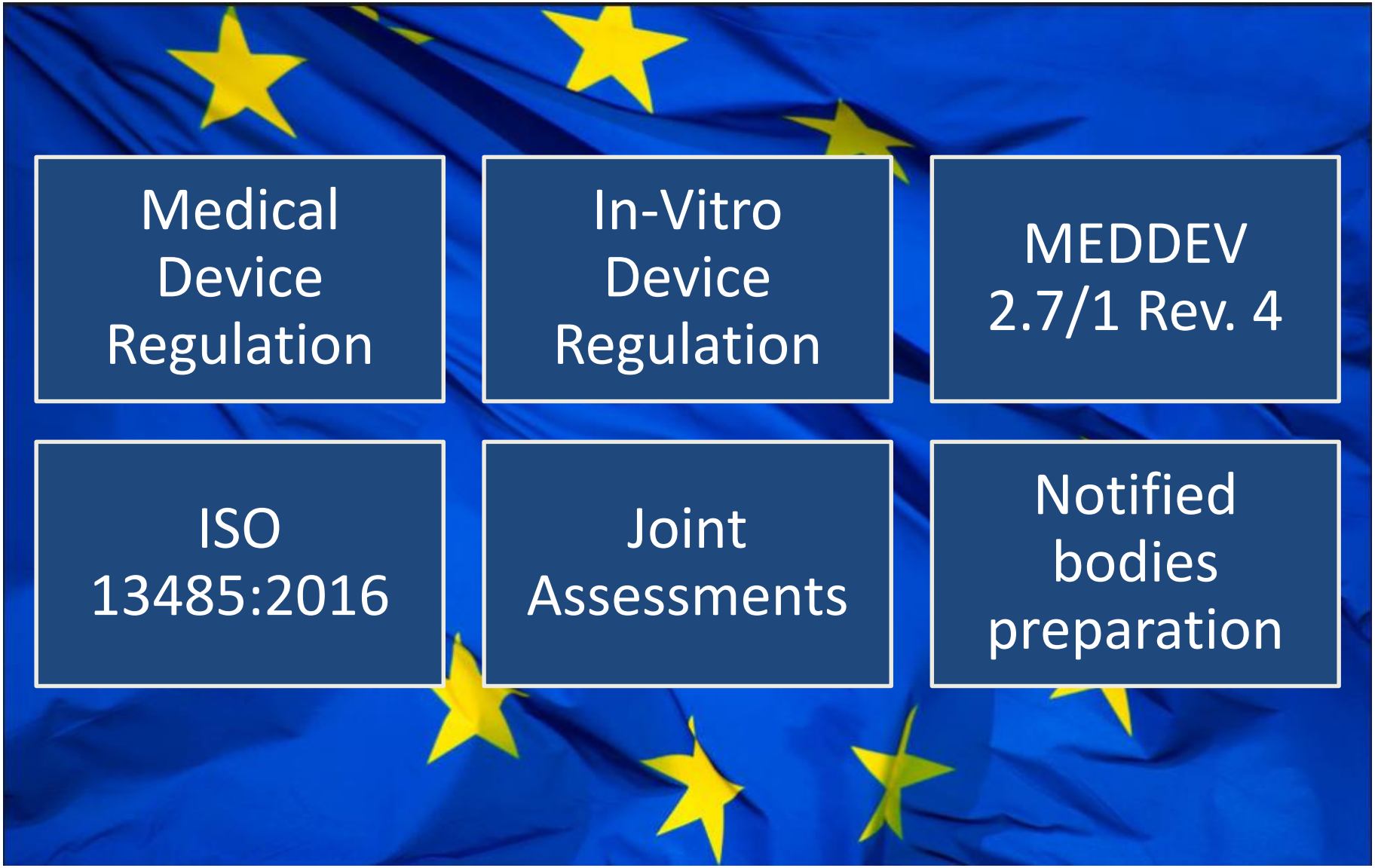
2 Changes in Classification

3 Changes in QMS

4 Changes in Clinical Requirements

5 Changes in Reporting

What is happening in Europe?



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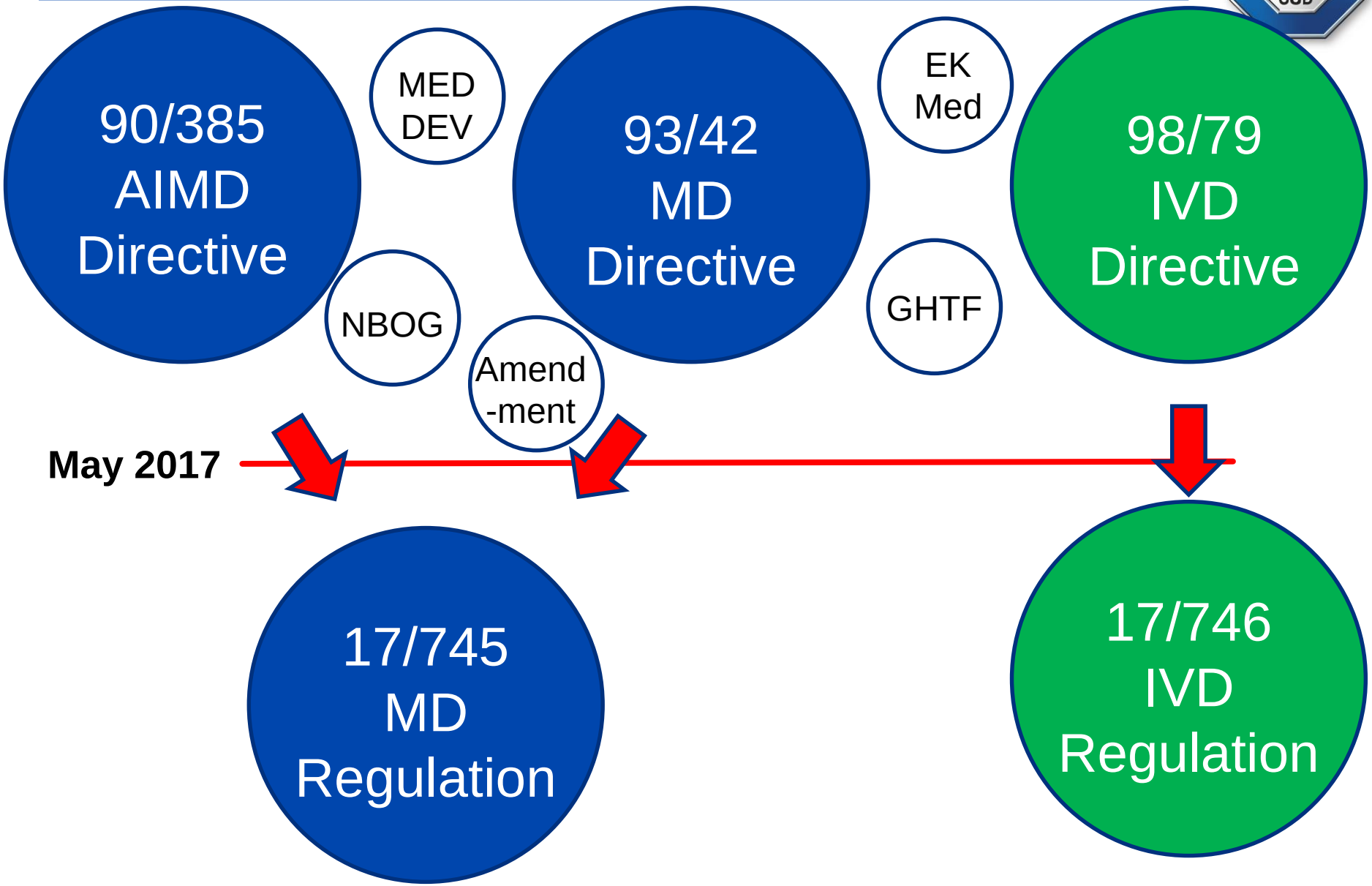
Contents

What is included?



Important Changes and Improvements

Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level

Reinforcement of the criteria for designation and processes for **oversight of notified bodies**

Inclusion of **certain aesthetic products** which present the same characteristics and risk profile as analogous medical devices

Introduction of a **new risk classification system** for diagnostic medical devices based on international guidance

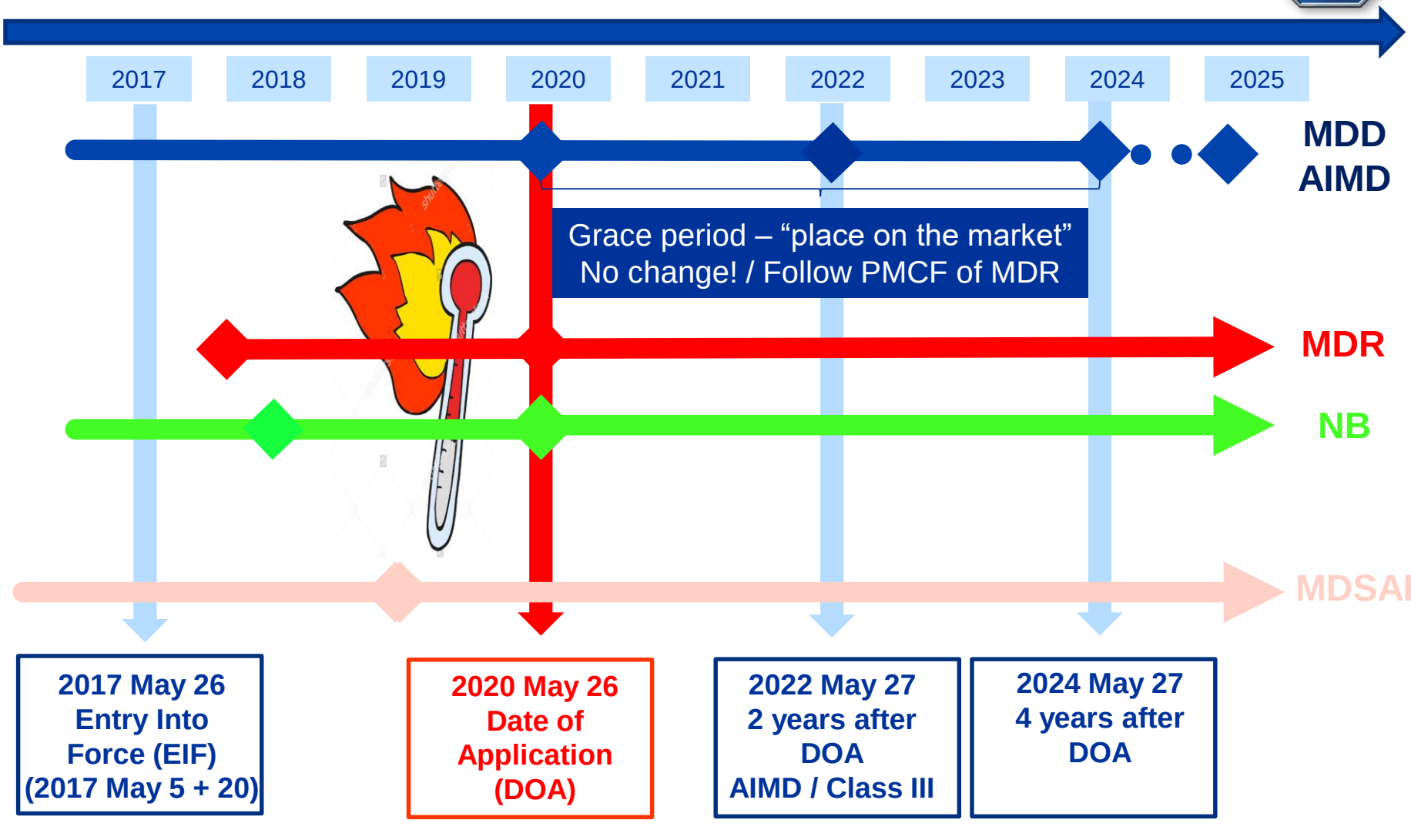
EUDAMED - EU database on medical devices and a device traceability system

EU-wide requirement for an **'implant card'** to be provided to patients

Reinforcement of the rules on clinical data, including an EU-wide coordinated procedure for the authorisation

Reinforced **requirement for manufacturers to collect data** about the real-life use of their devices

MDR – Transition – Article 120



Overview of Stucture: Chapters

Chapter I	Scope and definitions
Chapter II	Making available and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement
Chapter III	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices
Chapter IV	Notified bodies
Chapter V	Classification and conformity assessment
Chapter VI	Clinical evaluation and clinical investigations
Chapter VII	Post-market surveillance, vigilance and market surveillance
Chapter VIII	Cooperation between Member States, Medical Device Coordination Group, Expert laboratories, Expert panels and device registers
Chapter IX	Confidentiality, data protection, funding, penalties
Chapter X	Final provisions

Overview of Stucture: Chapters

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 V	• CE marking of conformity
Annex VII	• Information to be submitted with the registration of devices and economic operators, UDI
Annex VII	• Requirements to be met by Notified Bodies
Annex VIII	• Classification criteria
Annex IX	• Conformity assessment based on a quality management system and assessment of the TD
Annex X	• Conformity assessment based on type examination
Annex XI	• Conformity assessment based on 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	• List of groups of products without an intended medical purpose referred to in Article 1(1a)
Annex XVII	• Correlation table

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Classification

Annex VIII

Rule 1-4	• Non-Invasive Devices
Rule 5-8	• Invasive Devices
Rule 9-13	• Active Device
Rule 14-22	• Specific or additional Rules

- More rules, some existing rules reworded
- Changes in the classification rules of medical devices might lead to change in classification for particular medical devices.
- Manufacturers shall check if the applied classification rule is still right

Classification

Annex VIII

MDR Classification	Additional / Specific requirements	Scrutiny procedure after certification

• Class I
  • sterile
  • w/ measuring function
  • reusable surgical instruments
• Class IIa
• Class IIb
• Class III
	• implantable class IIb
	• Medicinal substance
	• Medicinal substance derived from human blood/plasma
	• Introduced thru body orifice
	• Absorbed thru skin
	• Tissues or cells:
	  • Animal origin
	  • Derivates of human origin
		• implantable class III
		• active devices delivering medicinal products

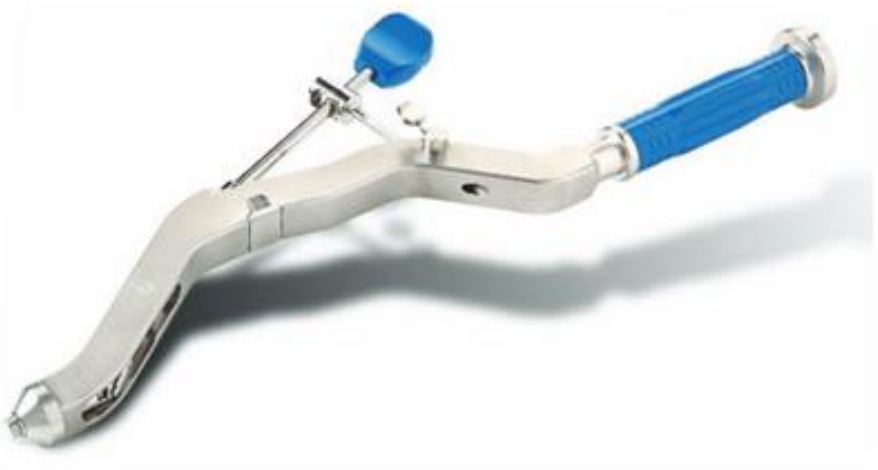
Classification

‘Reusable surgical instrument’ means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and **which is intended by the manufacturer to be reused** after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

Article 7

Reusable surgical instruments, involvement of the **notified body** is limited:

> “… to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.”



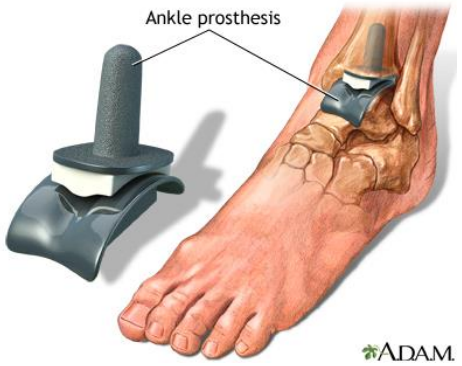
Rule 8 – Implantable devices

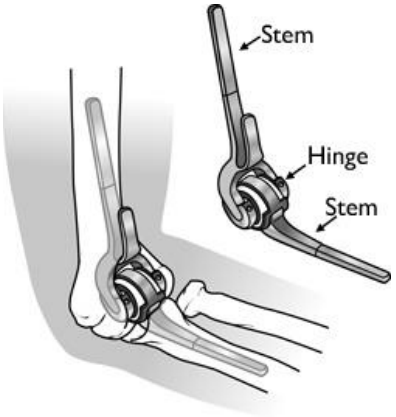
- **Total and partial joint replacements are class III**

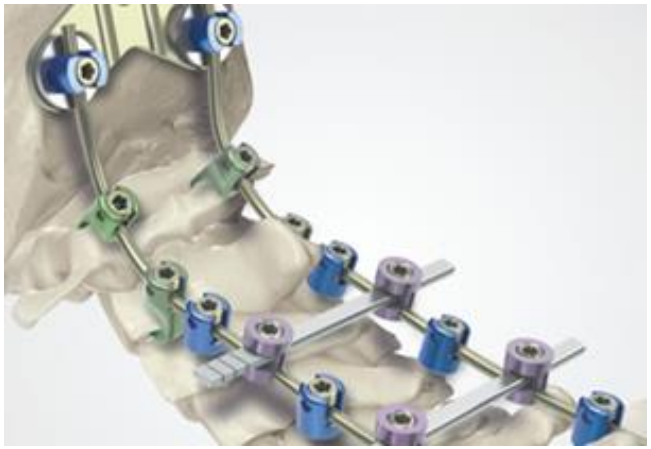
  with the exception of ancillary components such as screws, wedges, plates and instruments. (IIb implantable new category)

- **Spinal disc replacement implants and implantable devices that come into contact with the spinal column are class III**

  with the exception of components such as screws, wedges, plates and instruments. (IIb implantable new category)







Rule 11 - Software

with diagnostic or therapeutic purpose

Class IIa

Except if such a decision may cause

Death or an irreversible deterioration of health

Class III

Serious deterioration of health or surgical intervention

Class IIb

for monitoring physiological processes

Class IIa

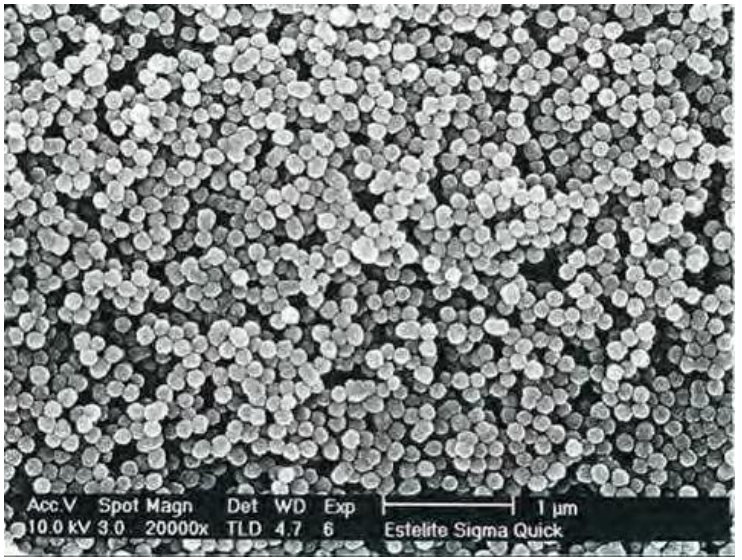
Unless immediate danger to the patient

Class IIb

Rule 19 – Nanomaterials

All devices incorporating or consisting of **nanomaterial** are:

- Class III if they present a high or medium potential for internal exposure.
- Class IIb if they present a low potential for internal exposure.
- Class IIa if they present a negligible potential for internal exposure.



Rule 20 – Inhalation devices

Devices for inhalation of medicinal products:

- are Class IIa;
- are Class IIb in case impact on the efficacy and safety of the administered medicinal product / intended for treating life-threatening condition;

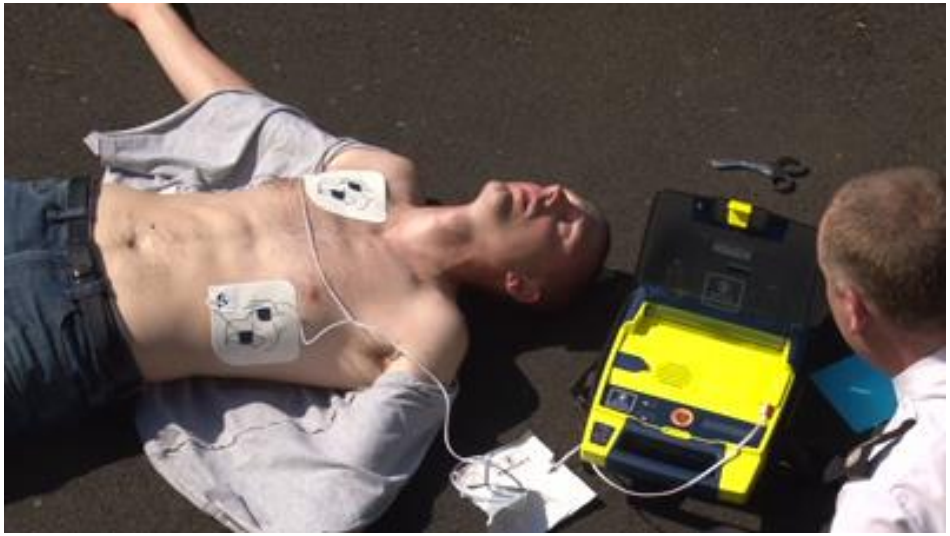
Rule 21 – Absorbable substances

Substances introduced into the human body or applied to the skin;

- are class III if introduced through body orifice;
- are class III if absored in the stomach or lower gastrointestinal;
- are class IIa if applied to the skin / nasal or oral cavity;
- are class IIb in all other cases;

Rule 22 – “Closed loop” systems

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**, **class III**



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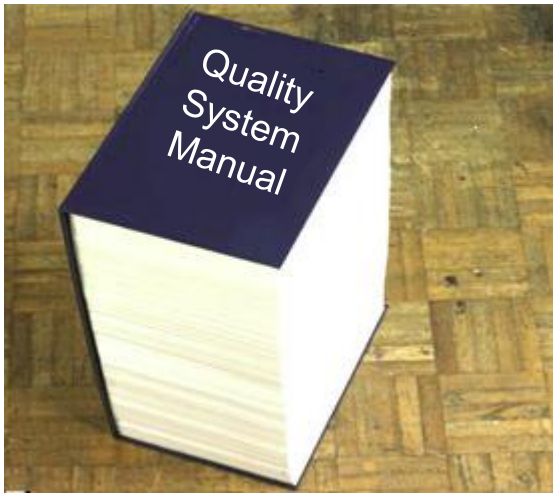
Changes in QMS - Obligations

Article 10 – General obligations of manufacturers

Follow EN ISO 13485:2016 (13485:2016)
Risk management EN ISO 14971:2012 (ISO 14971:2007)

Article 13 / 14 General obligations of importers / distributors

Verification of product registration
Keeping register of complaints
Copy of Declaration of Conformity



Changes in QMS - Obligations

Article 15 - Person responsible for regulatory compliance

Responsibilities

- Conformity of the device is appropriately checked
- TD / DoC up-to-date
- post-market surveillance
- vigilance reporting

Qualification

- Minimum university degree
- Four years of experience

Special rule for micro and small companies

Article 61 – Clinical evaluation

Shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan

Changes in QMS – Technical Documentation

Technical File

Design Dossier

→ Technical Documentation

Annex II Technical Documentation

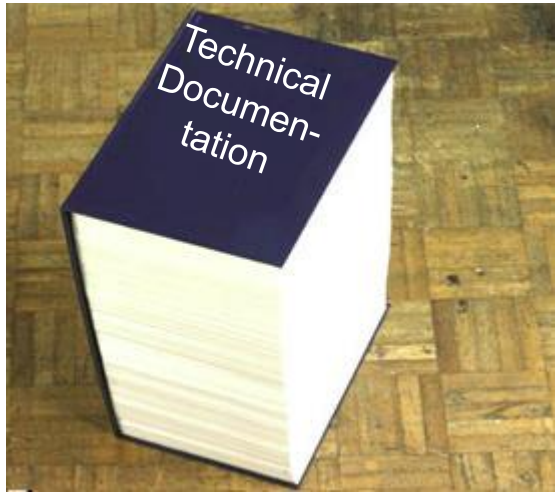
Annex III Technical Documentation on post-market surveillance

Article 11 EU Representative to keep available a copy of the TD

Article 45 NB needs a copy of the TD

OEM – PLM (Recommendation 2013/473/EU)

Notified bodies should note that manufacturers:
*a) have to fulfil their **obligations** themselves **regardless** of any **partial or total outsourcing** of the production via subcontractors or suppliers;*
*b) do not fulfil their obligation to have at their disposal the **full technical documentation** and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system;*



Article 27 – UDI – Unique Device Identification
Annex VI

UDI-DI – device identifier, specific to a manufacturer and a device

UDI-PI – specific to the unit produced

Article 33 - EUDAMED

Article 29(4) for registration of devices;

Article 28 for the UDI-database;

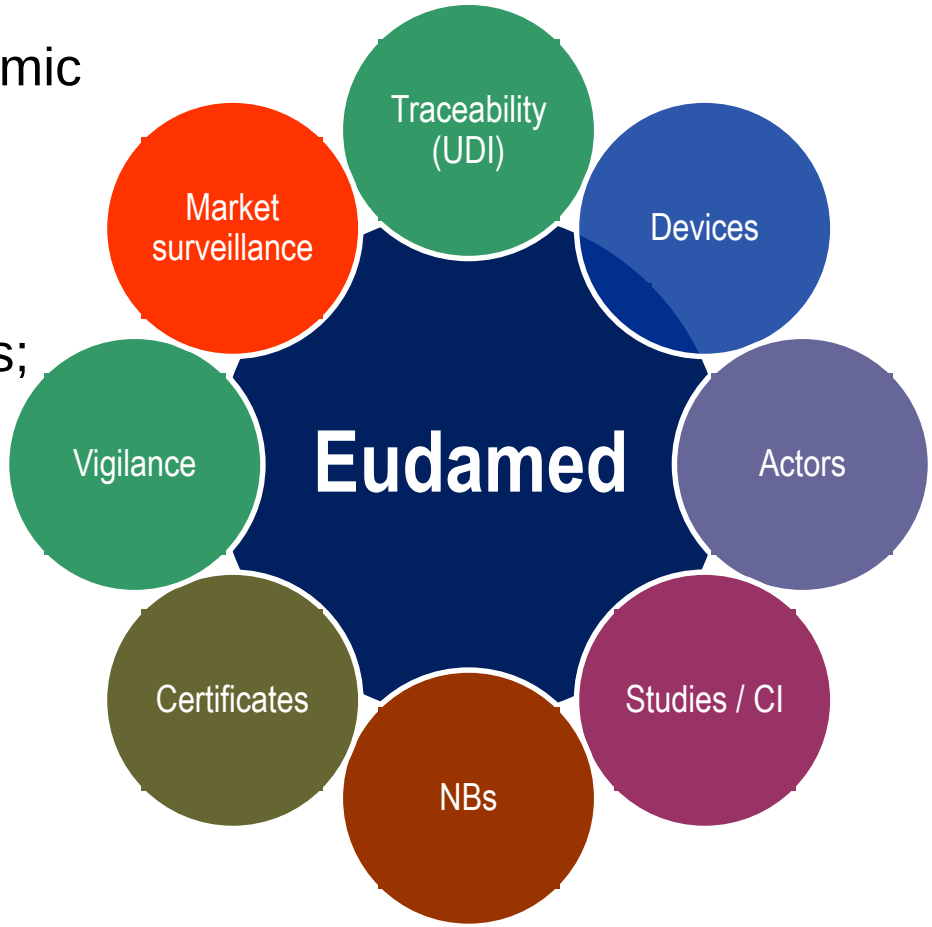
Article 30 on registration of economic operators;

Article 57 on notified bodies and on certificates;

Article 73 on clinical investigations;

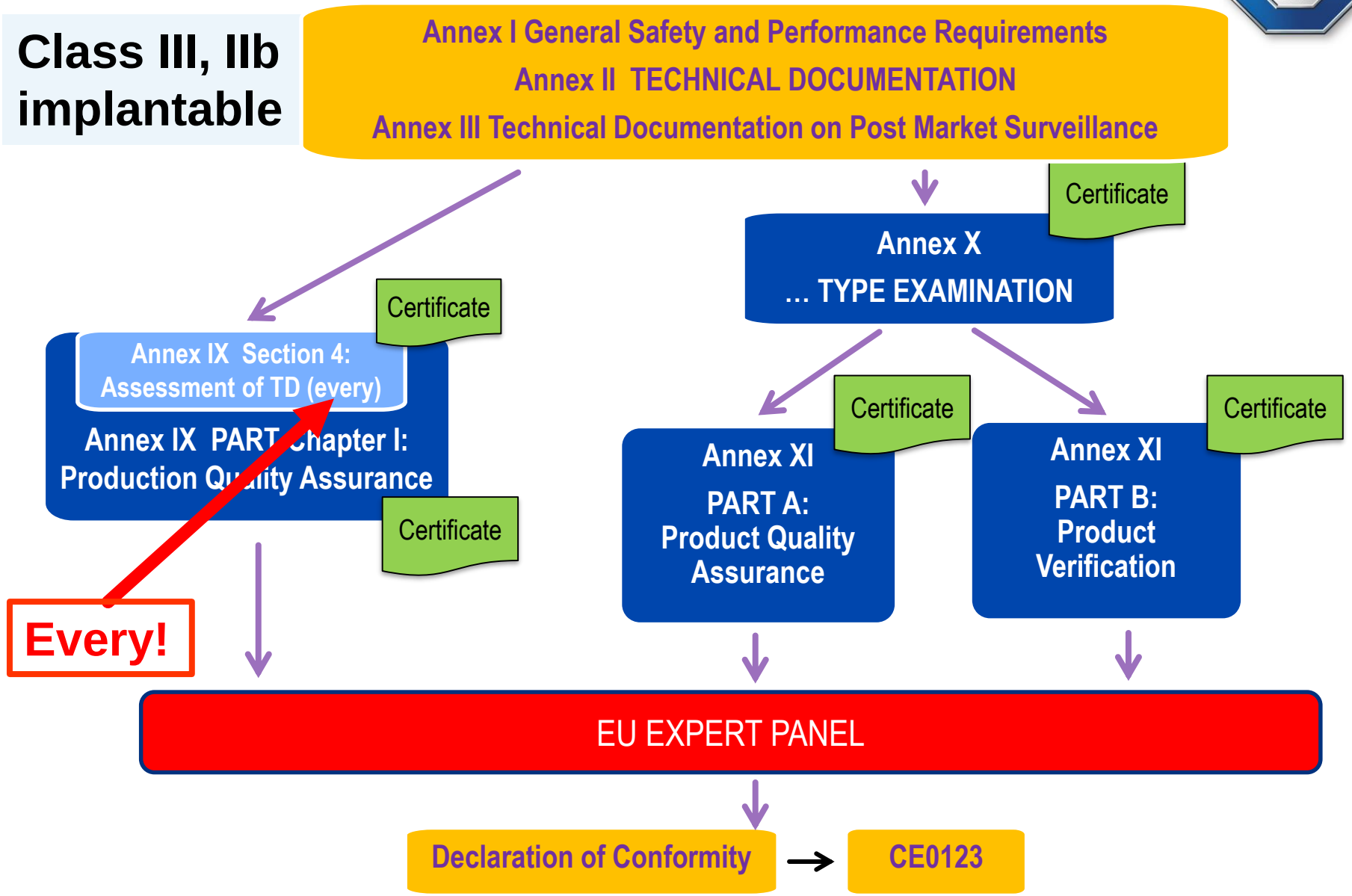
Article 92 on vigilance and post-market surveillance;

Article 100 on market surveillance;



Conformity Assessment Procedures MDR Article 52

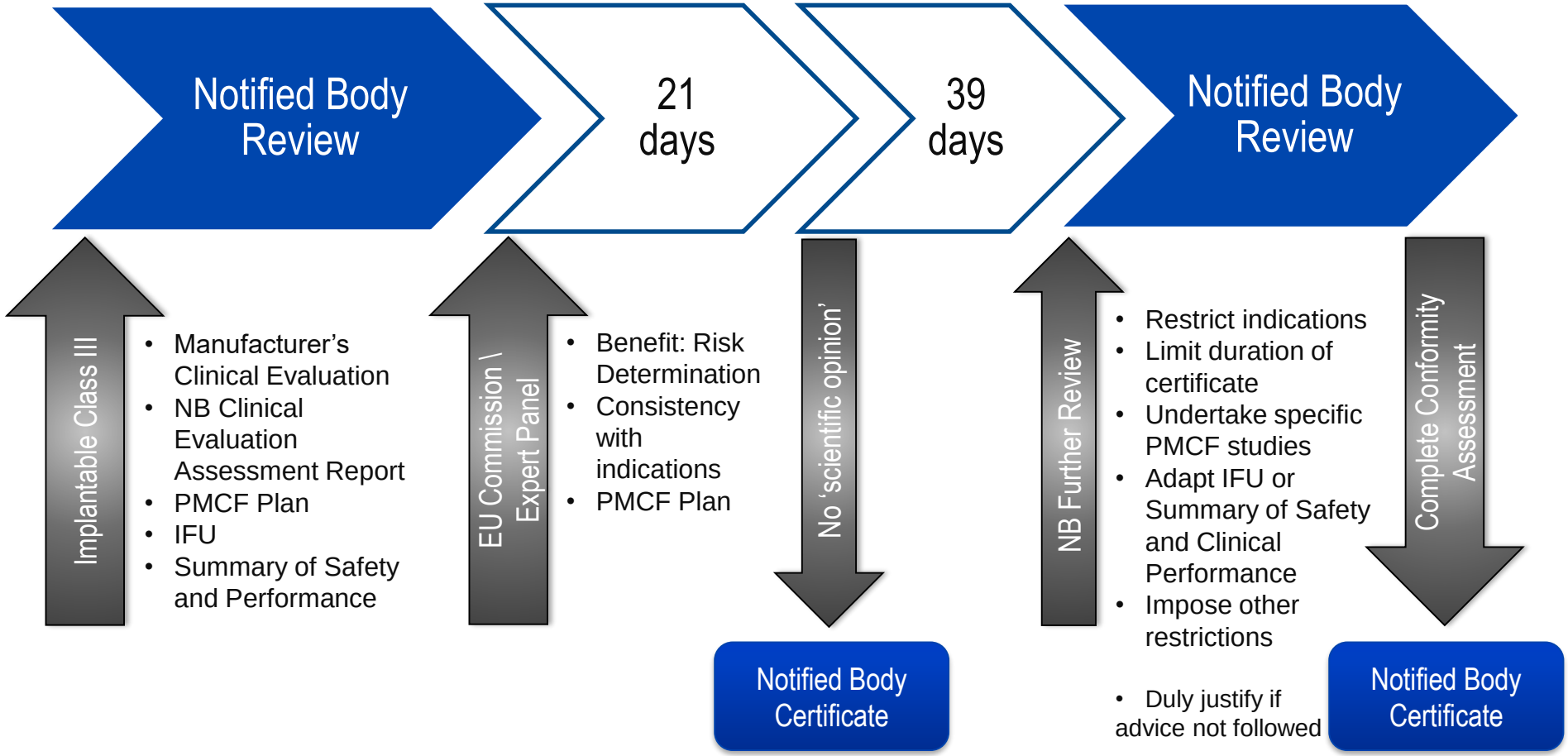
Class III, IIb implantable



Annex IX, Chapter II, Section 5.1 (Scrutiny)

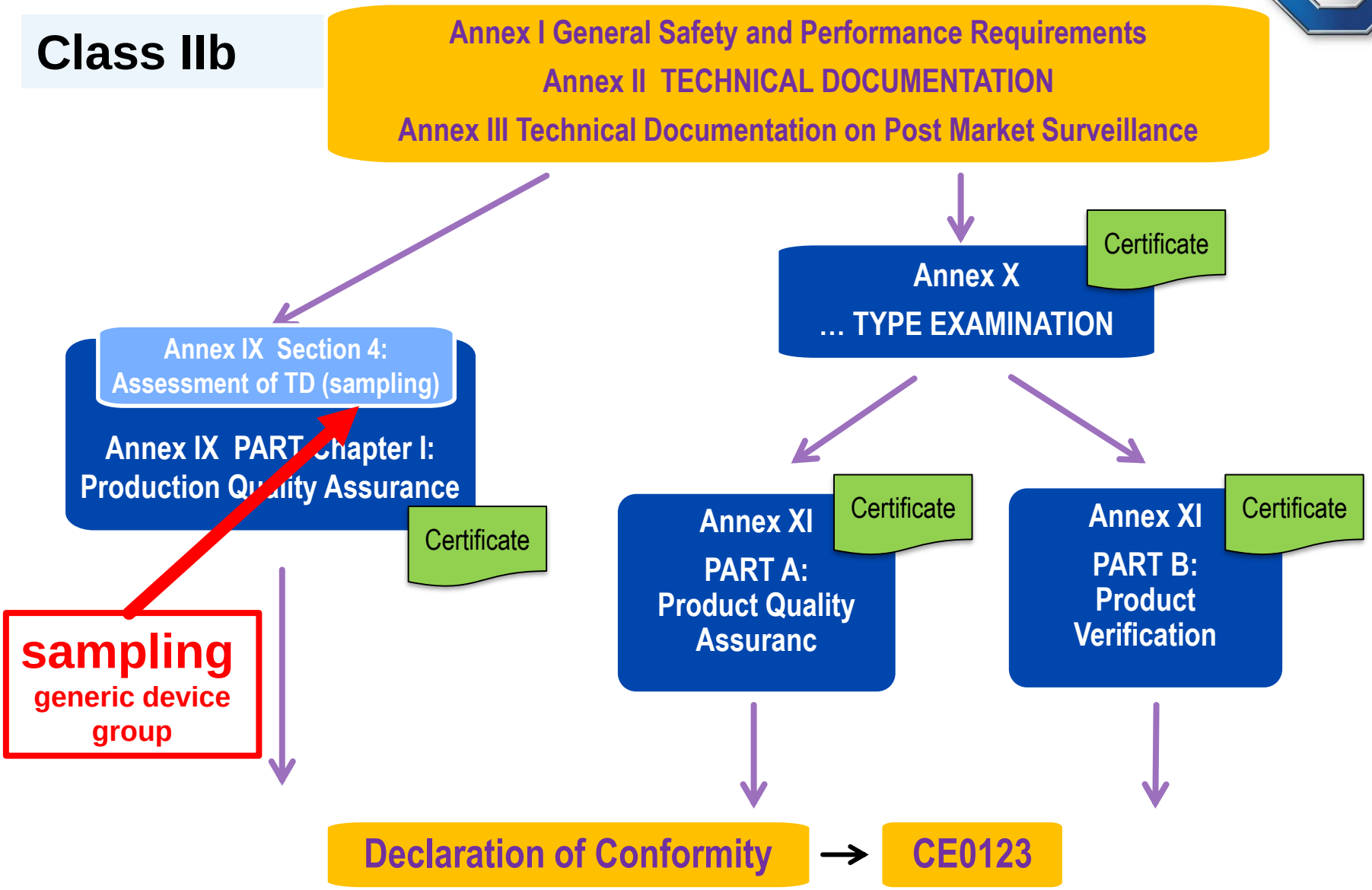
Class III implantable

Class IIb active devices intended to add or remove a medicinal substance



Conformity Assessment Procedures MDR Article 52

Class IIb



Conformity Assessment Procedures MDR Article 52

Class IIa

Annex I General Safety and Performance Requirements
Annex II TECHNICAL DOCUMENTATION
Annex III Technical Documentation on Post Market Surveillance

Annex IX Section 4:
Assessment of TD (sampling)

Annex IX PART I Chapter I:
Production Quality Assurance

Certificate

Annex XI Section 10:
Assessment of TD (sampling)

Annex XI PART A:
Product Quality Assurance

Certificate

Annex XI Section 18:
Assessment of TD (sampling)

Annex XI PART B:
Product Verification

Certificate

sampling
device category

Declaration of Conformity → CE0123

Overview

Clinical requirements

June 29, 2016 – Publication of the new Revision MEDDEV 2.7.1 Rev. 4

May 5, 2017 – Publication of the official MDR

June 2017 – Publication of the new Revision MEDDEV 2.7.1 Rev. 5 ???

Clinical requirements – MED DEV 2.7.1 rev4

- Life Cycle
- Methodology
- Documentation requirements including plans/protocols for appraisal, methods, clinical investigation, PMCF studies, registries and for related reports
- Examples
- Detailed information for sources of literature (MEDLINE, EMBASE, CENTRAL, ICTRP and clinical Trials.gov)
- Literature research: on device in question/equivalent device and on State of the art)
- Detailed principals of clinical evaluation
- Reference to relevant Directives in more details and better structure
- GAP analysis on compliance of clinical data generated outside of EU
- Points for sufficient clinical evidence (intended purpose, clinical performance and benefits, risk mitigation/avoidance, usability, target population)
- Requirements for updating CER
- Need and concept of PMCF studies
- Risk / benefit profile
- Qualification requirements of evaluator or evaluator team
- Scope of clinical evaluation before and after CE marketing
- State of the art /Current knowledge concept
- Scientific validity
- Relevance of data
- Weightening criteria for data
- Analysis to demonstrate the compliance to Essential Requirements
- Release criteria for a CER
- Structure and content of CER
- Equivalence (clinical, technical, biological)
- Considerations for a clinical investigation and state of the art, compare to alternative methods
- Role of NB

Clinical requirements – MED DEV 2.7.1 rev4

Clinical, technical and biological characteristics shall be taken into consideration for the demonstration of equivalence

For assuming equivalence:

- only be based on a single device
- all three characteristics (clinical, technical, biological)
- no clinically significant difference in the performance and safety of the device
- the differences between the device under evaluation and the device presumed to be equivalent need to be identified, fully disclosed, and evaluated
- manufactured via a special treatment (e.g. a surface modification, a process that modifies material characteristics)
- if measurements are possible, clinically relevant specifications and properties should be measured both in the device under evaluation and the device presumed to be equivalent

Clinical requirements – MED DEV 2.7.1 rev4

Clinical

- same clinical condition
- same intended purpose
- same site in the body
- in a similar population
- have no clinically significant difference

Clinical requirements – MED DEV 2.7.1 rev4

Technical

- be of similar design
- used under the same conditions of use
- have similar specifications and properties
- use similar deployment methods (if relevant)
- have similar principles of operation and critical performance requirements

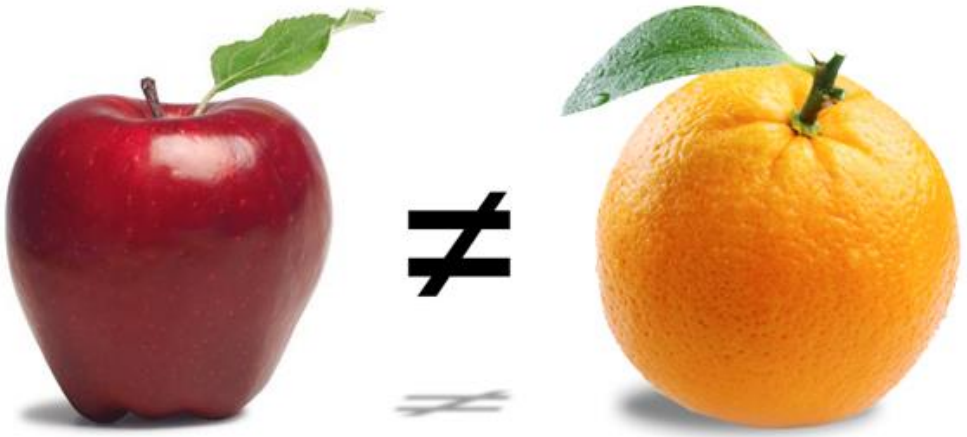
Biological

Use the same materials or substances in contact with the same human tissues or body fluids.

Exceptions can be foreseen for devices in contact with intact skin and minor components of devices.

In these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material.

Clinical requirements – MED DEV 2.7.1 rev4



The notified body should challenge the ability of the manufacturer to access information that are relevant to the demonstration of equivalence. Demonstration of equivalence might be difficult or impossible in case of limited access to the technical documentation of the devices.

Clinical requirements – MED DEV 2.7.1 rev4

Typically the clinical evaluation is updated:

- when the manufacturer receives new information from post-market surveillance that has the potential to change the current evaluation;
- if no such information is received, at least
  - annually if the device carries significant risks and/or is not yet well established;
  - every 2 to 5 years if the device is not expected to carry significant risks and is well established;
  - Justification

Clinical requirements - MDR

MDR

- (63) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical data that, for **class III medical devices and implantable medical devices should, as a general rule, be sourced from clinical investigations** to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the clinical investigation requirements.

Clinical requirements - MDR

Article 61 / 4

In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, except if:

- the device has been designed by modifications of a device already marketed by the same manufacturer
- the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device
- the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

Clinical requirements - MDR

Article 61 / 5 - a manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis
- the original clinical evaluation has been performed in compliance with the requirements of this Regulation,
- the manufacturer of the second device provides clear evidence thereof to the notified body.

Clinical requirements - MDR

Article 61 / 6
The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and devices falling into class III:

- which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation
- is based on sufficient clinical data
- is in compliance with the relevant product-specific common specification for the clinical evaluation of that kind of device, where such a common specification is available

Clinical requirements - MDR

Article 61 / 6 - The requirement to perform clinical investigations pursuant to paragraph 2a shall not apply to implantable devices and devices falling into class III:

- that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific common specification, where such a common specification is available.

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Reporting – SSCP – Article 32

Summary of Safety and Clinical Performance (SSCP) is for the USER and shall be:

- **Written by the manufacturer for class III and implantable devices** other than custom-made or investigational devices
- Written in a way that is **clear to the intended user** and, if relevant, **to the patient**
- **Updated annually with data from PMCFR** (if indicated) see Art. 83.3
- **Part of the documentation to be submitted to the notified body involved in the conformity assessment**
- **Validated by NB and final version of SSCP uploaded to EUDAMED**
- **Information where the SSCP can be found must be provided on the label of a device**

Reporting – PSUR – Article 86

Periodic Safety Update Report

Per device and where relevant per category or group of devices, the manufacturer shall prepare a **PSUR** summarizing the **results and conclusions** of PMCRF together with a rationale and description of any **preventive and corrective actions** taken.

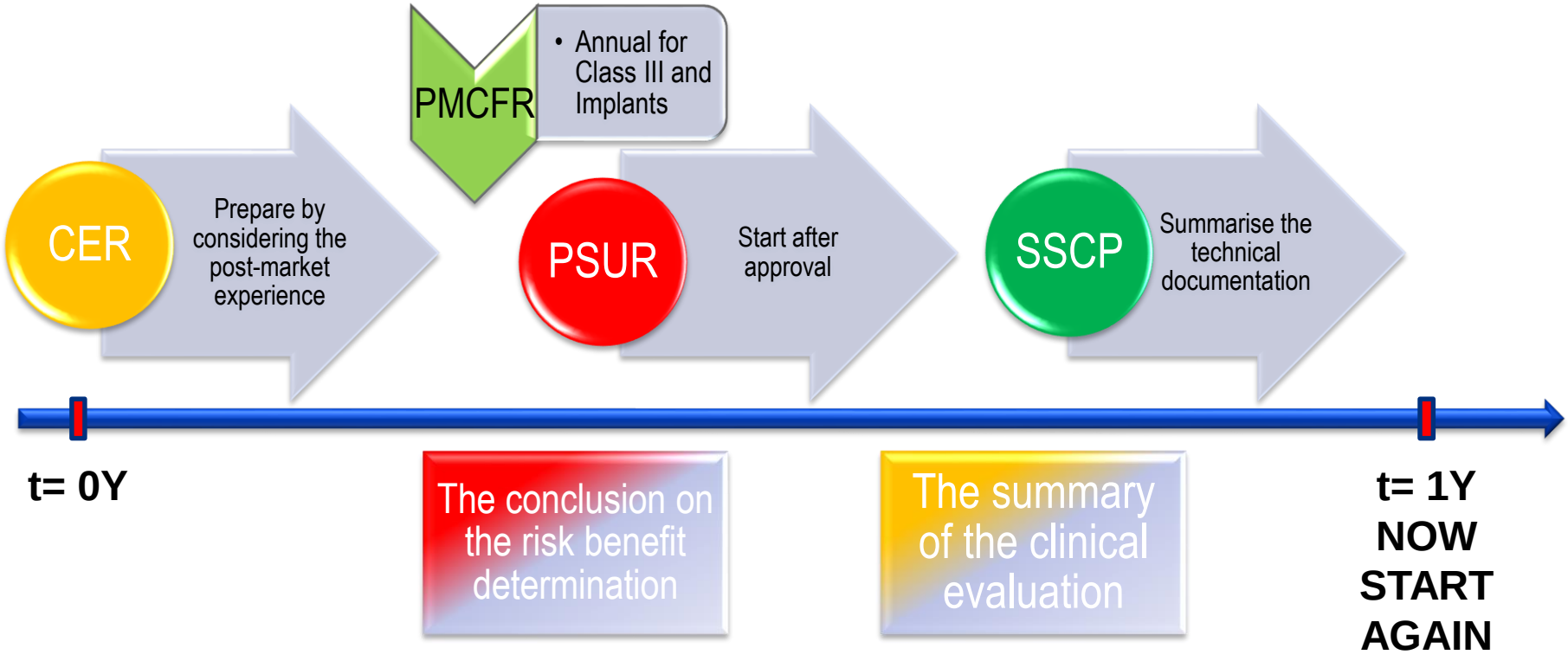
Throughout the lifetime of the device this report shall set out:

- The conclusion on the **benefit risk determination;**
- The main findings of the **Post Market Clinical Follow-up Report** (PMCFR);
- The **volume of sales** of devices estimate of the **population** that use the device and, where practicable, **the usage frequency**

Updated	**Class III and IIb - Annually;**
	Class IIa - Every 2 year;
Reviewed by NB	**Class III and Implantable - annually off site**
	Other devices – sampled during on site audit

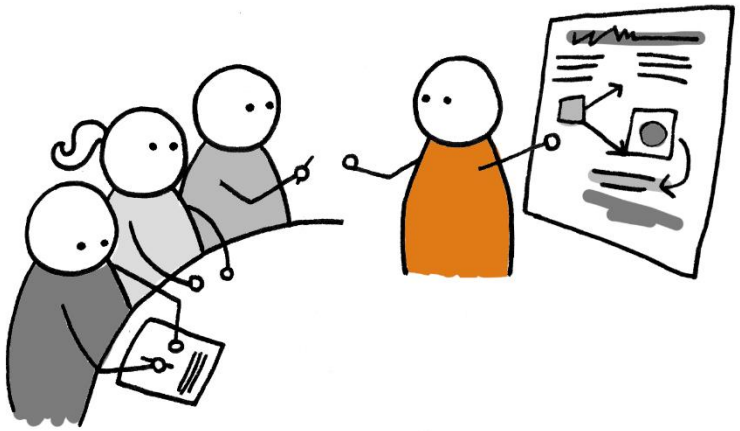
Reporting

CER: Clinical Evaluation Report	All
PMS: Post Market Surveillance Plan	All
PSUR: Periodic Safety Update Report	Class IIa, IIb and III
SSCP: Summary of Safety and Clinical Performance	Class III and Impl
PMCFR: Post-Market Clinical Follow-Up Evaluation	Class III and Impl

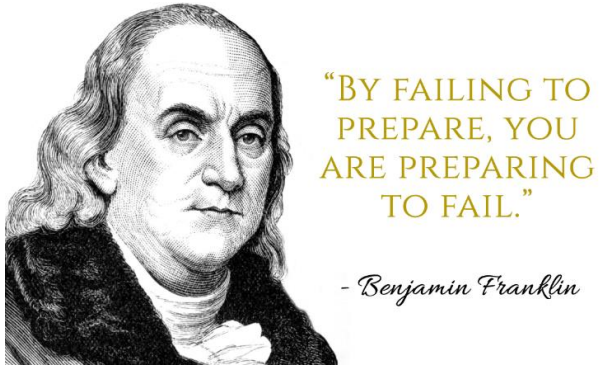


Everybody is impacted by this!

No Grandfathering!



Take away



If you start the preparation today
IT IS ALREADY LATE!

Consider pre-certification services by your NB!

Clinical audit
Mock evaluation of TD / DD
Mock MDR audit

Questions, Comments?

Questions?

- Tamas Borsai
  NAM Division Manager, Medical Health Services
- For Inquiries, please email me at:
  tborsai@tuvam.com

Global website: www.tuv-sud-america.com/medical

Stay informed and updated with our Healthcare & Medical Device newsletter: www.tuv-sud.com/essentials