IMPACT of the MDR

Medical Device Regulation
2017/745

Dr. Bassil Akra
VP Global Strategic Business Development
February 13, 2020

Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.

Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.

This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.

First Step - READ the Regulation

Structure of the MDR

Chapter I (Art. 1-3):
Scope & definitions

Chapter II (Art. 5-24):
Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement

Chapter III (Art. 25-34):
Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance (SSCP), European database on medical devices

Chapter IV (Art. 35-50):
Notified bodies

Chapter V (Art. 51-60):
Classification and conformity assessment, consultations, scrutiny

Chapter VI (Art. 61-82):
Clinical evaluation & clinical investigation

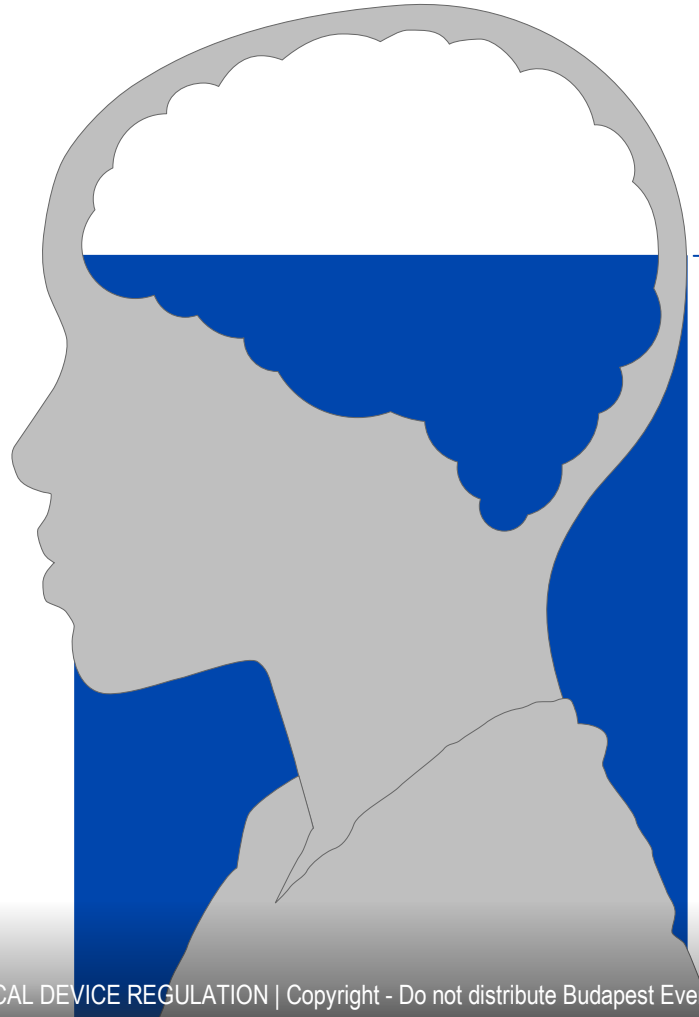
Chapter VII (Art. 83-100):
Post-market surveillance (PMS), post market clinical follow up (PMCF), vigilance, market surveillance, trends, periodic safety update report (PSUR)

Chapter VIII (Art. 101-108):
Cooperation between member states, expert laboratories, medical device coordination group, expert panels, device registers

Chapter IV (Art. 109-113):
Confidentiality, data protection, funding, penalties

Chapter X (Art. 114-123):
Final provisions

View of the EU Commission on the Designation/Notification Process



No Bottlenecks

☺ 44 MDR + 11 IVDR applications were received
☺ Covering all scopes under the new regulations

☹ 16 MDR (2018) + 22 (2019) Joint Assessments were done
☹ 5 IVDR (2018) + 2 (2019) Joint Assessments were done
☹ 2 MDR + 2 IVDR Joint Assessments will be done

☹ 10 Notified Bodies are designated and notified for the MDR
☹ 3 Notified Bodies are designated and notified for the IVDR
☹ 2 – 4 additional Notied Bodies are coming soon
☹ **1 MDR/1 IVDR Notified Body affected by BREXIT (Deadline 31.12.2020)**

NANDO

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

Bodies Found : 10

Search criteria :

Legislation : Regulation (EU) 2017/745 on medical devices
Procedure / Article or annex : ALL
Products : ALL
Horizontal technical competence : ALL

Search

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "Withdrawn/Expired/Suspended Notifications/NBs"

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
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 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Moving targets and short timelines – Still < 105 calendar days ☹

SUBMISSION DEADLINE EXTENDED!
Are you a top Medical Device Expert?
Join the European Commission's **Expert Panels on Medical Devices and *In Vitro* Diagnostic Devices** and make a difference for patients in Europe!

https://www.linkedin.com/pulse/status-expert-panel-eu-level-bassil-akra/

- ❑ Last submissions under the current legislative framework ended in November 2019
- ❑ First successful MDR Certifications are there but they are still limited
- ❑ Expert panels first available in Q3 2019 – Expected Q1/2 2020
- ❑ EUDAMED go-live in May 2022
- ❑ Common specifications for products without medical purpose in November 2019 – Expected Q1/2 2020
- ❑ Results of Brexit discussion are still unknown
- ❑ Two corrigenda published in 2019
- ❑ **Third** Corrigendum in 2020?

Common understanding documents “Guidance Documents”

Current Status

Various Task Forces of the EU Commission are working on:

- Guidance on sampling of medical devices – **Published**
- Explanatory note on MDR codes – **Published**
- Guidance and templates for PSURs
- Guidance and template for SSCPs – **Published**
- Guidance on classification of Software as a Medical Device – **Published**
- Guidance and templates for PMCFs
- Guidance for sufficient clinical data
- Guidance for equivalence approach – Gap Document to MEDDEV 2.7.1 Rev. 4
- Common specifications, Clinical Evaluation Guidance for Software, etc.
- Implementing act for reprocessing single use medical devices

32 documents endorsed as of December 2019

- 9 documents on UDI
- 2 documents on EUDAMED
- 16 documents on Notified Bodies
- 1 document on Clinical investigation and evaluation
- 2 documents on new technologies
- 4 documents on other topics

Scheer guidelines

Common understanding documents “Guidance Documents”

EUROPEAN MEDICINES AGENCY

MDR and IVDR - new/revised roles and responsibilities for EMA/NCAs

- “MDR Article 117” **[NEW]**
- Consultation on **companion diagnostics** by a NB **[NEW]**
- Consultation on **borderline products** by EC
- Consultation substance-based medical devices **(Rule 21)** **[NEW]**
- Consultation on medical devices with ancillary medicinal substance **(Rule 14)**

*Source: Armin Ritzhaupt at RAPS 2019

Article 1: Is your device a medical device?

Medical Devices (+ accessories):
"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,
— investigation, replacement or modification of the 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,
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 without an intended medical purpose:
Full list in Annex XVI:
— contact lenses
— liposuction devices
— brain stimulation equipment
— skin treatment or hair removal products
— etc.

AIMD now included

Tattooing products & piercings not included

Definitions on “Economic Operators”: Article 2 – MDR

REFERS TO:

01 Manufacturer

02 Authorised Representative

03 Distributor

04 Importer

PLUS:

Person that puts together systems or procedure packs – Article 22(1)

Person that sterilizes systems or procedure packs – Article 22(3)

Personal Responsible for Regulatory Compliance

The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the **quality management system** under which the devices are manufactured, before a device is released

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date

(c) the **post-market surveillance obligations** are complied with in accordance with Article 10(10)

(d) the **reporting obligations** referred to in Articles 87 to 91 are fulfilled

(e) in the case of **investigational devices**, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.

Personal Responsible for Regulatory Compliance

The person responsible for regulatory compliance shall suffer **no disadvantage** within the manufacturer's organisation in relation to the **proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation**.

Structure of the MDR

New chapters

Chapter I:
Scope & definitions

Chapter II:
Making available & putting into service of devices

Chapter III:
Devices' identification & traceability

Chapter IV:
Notified bodies

Chapter V:
Classification & conformity assessment

Chapter VI:
Clinical evaluation & clinical investigation

Chapter VII:
Post-market surveillance, vigilance & market surveillance

Chapter VIII:
Cooperation b/w "Economic Operators

Chapter IV:
Confidentiality, data protection, funding, penalties

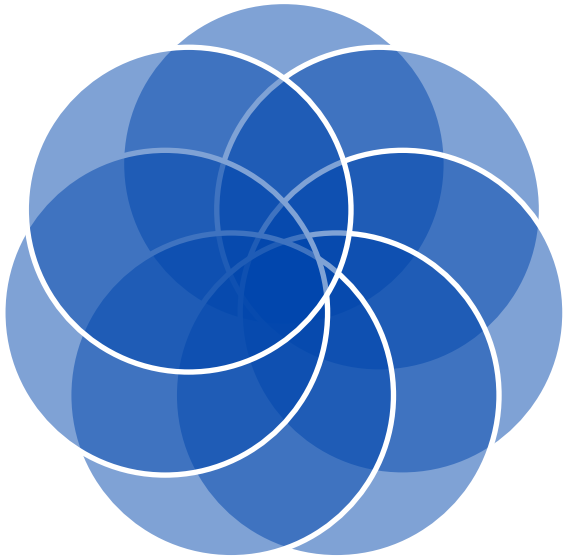
Chapter X:
Final provisions

Definitions

Duration of contact

(transient ⇔ short term ⇔ long term)

Injured skin or mucous membrane



Invasivness

- Body orifice (natural opening & external surface of eyeball & permanent artifical opening)
- Surgically invasive

Central nervous system

Reusable surgical instrument

Central circulatory system

Active device

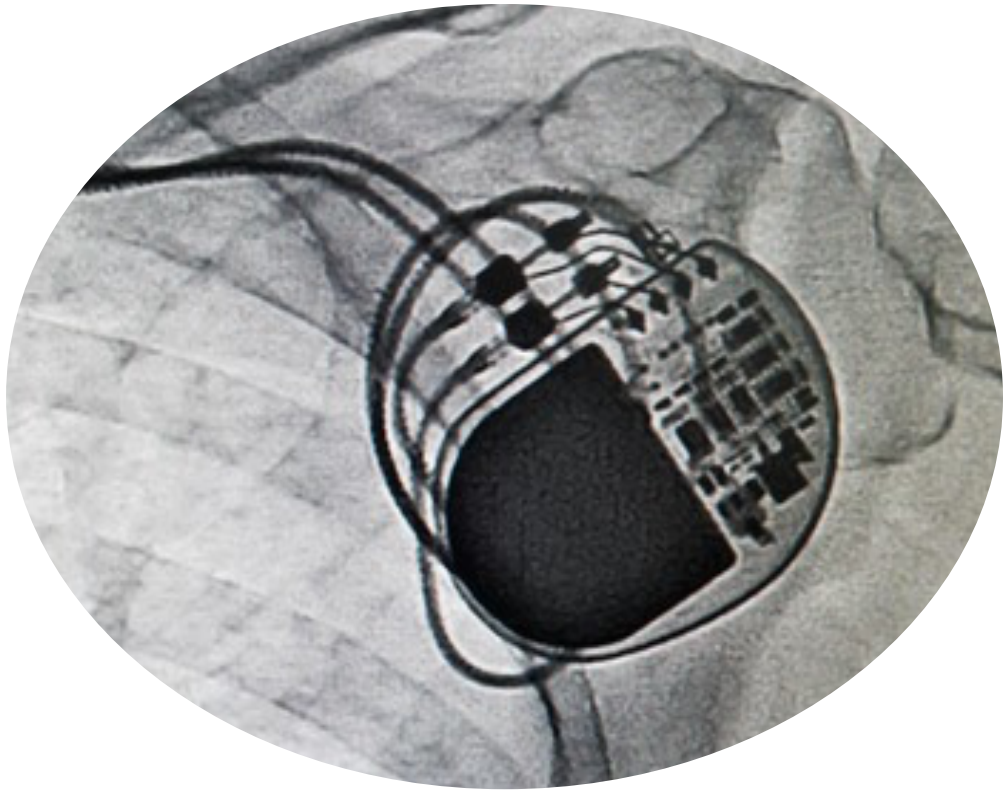
- Active therapeutic device
- Active device intended for diagnosis and monitoring

For more definitions see Annex VIII, chapter 1

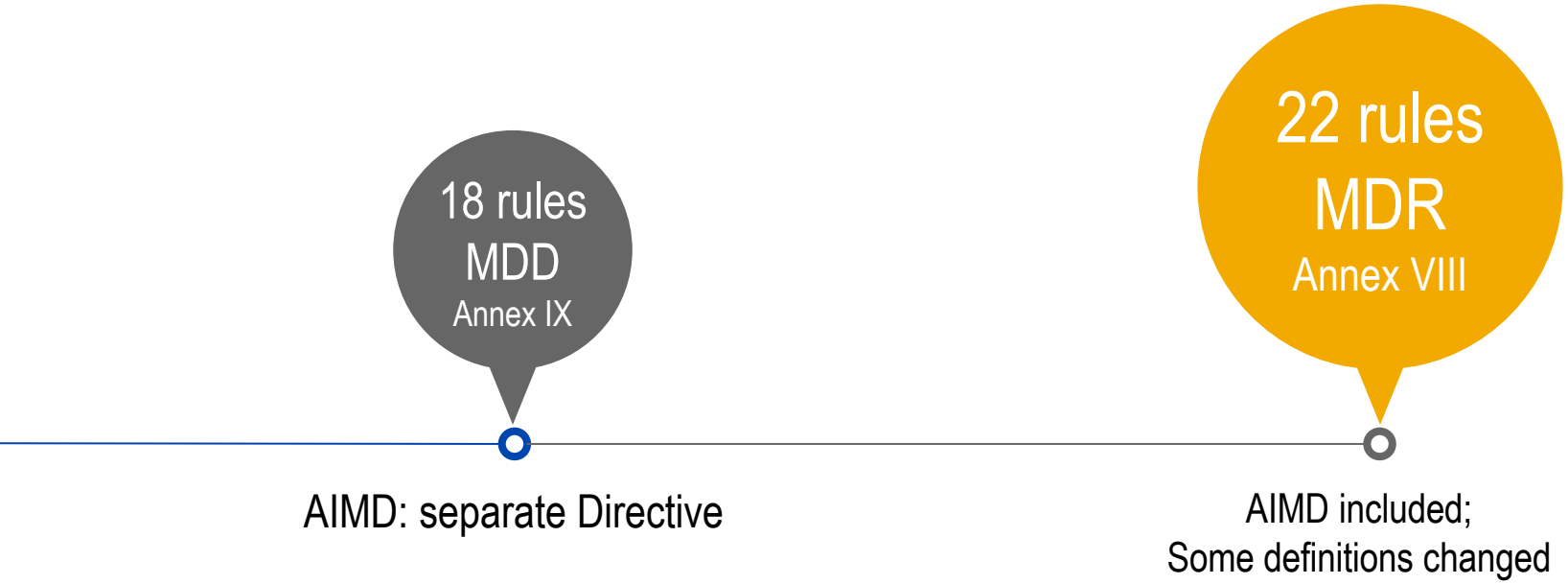
Implantable Medical Device

means any device, including those that are partially or wholly absorbed, which is intended:
— to be totally introduced into the human body, or
— to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.

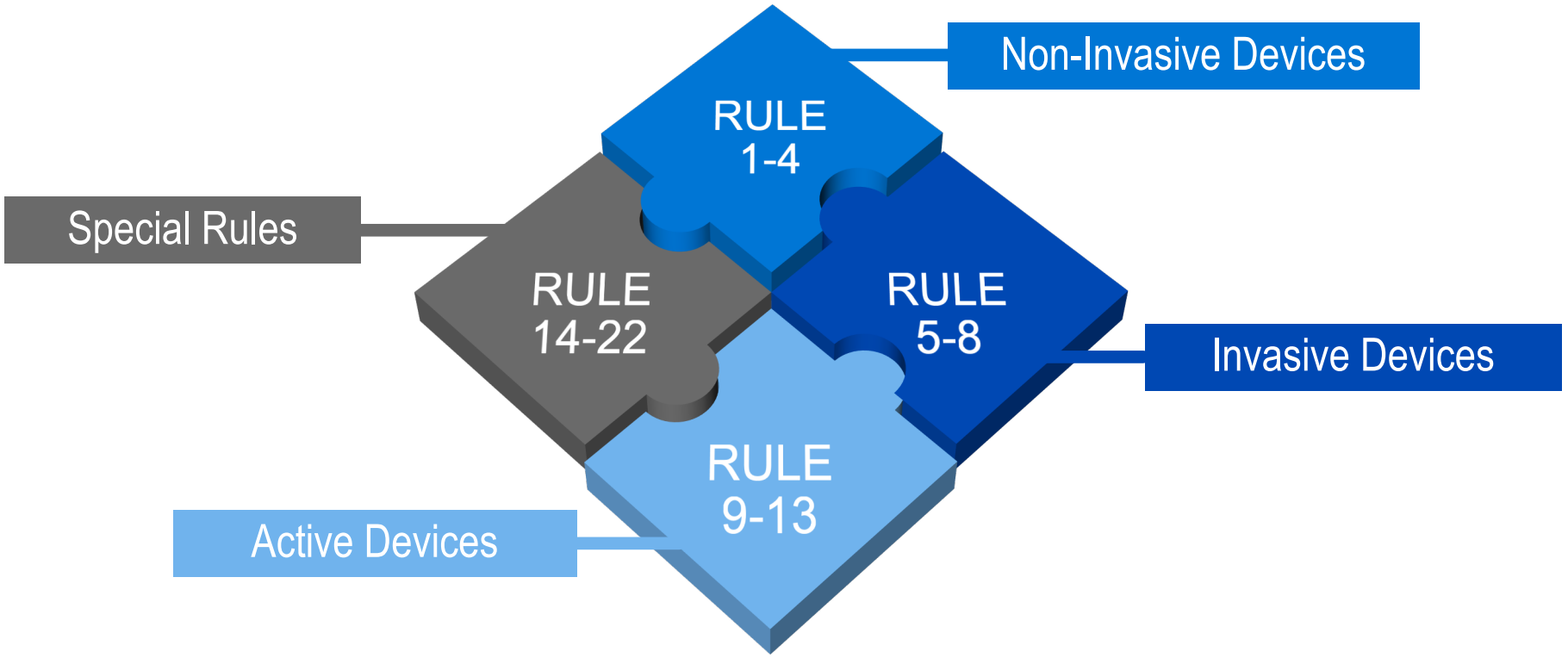
Any device intended to be partially introduced into the human body by **clinical intervention** and intended to remain in place after the procedure for **at least 30 days** shall also be deemed to be an implantable device



Changes in classification rules



Annex VIII: Classification



Applicable Annexes for Conformity Assessments

- I — General safety & performance requirements
- II — Technical documentation
- III — Technical documentation on PMS
- IV — EU declaration of conformity
- V — CE marking of conformity
- VI — Information to be submitted upon registration of devices & economic operators
- VII — Requirements to be met by notified bodies
- VIII — Classification rules
- **IX — Conformity assessment based on QMS & assessment of TD**
- **X — Conformity assessment based on type examination**
- **XI — Conformity assessment based on product conformity verification**
- XII — Certificates issued by a notified body
- **XIII — Procedure for custom-made device**
- XIV — Clinical evaluation and post-market clinical follow-up
- XV — Clinical investigations
- XVI — List of groups of products without an intended medical purpose
- XVII — Correlation table

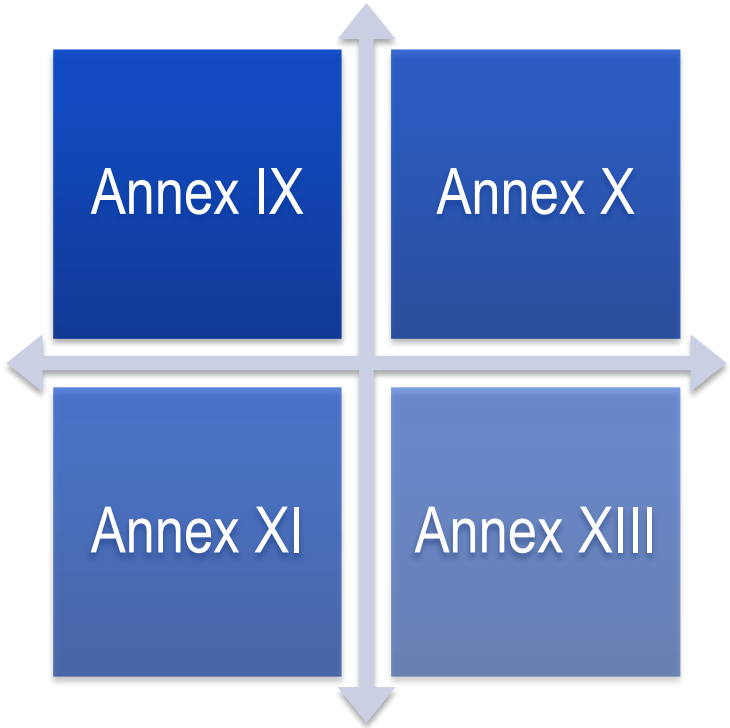
Conformity assessment procedures under new MDR

Chapter I:
Quality Management System

Chapter II:
Assessment of TD

PART A:
Production Quality Assurance

PART B:
Product Verification
(100% testing)



Type Examination
Annex X also to be combined with Annex XI

Custom-made devices

Conformity assessment procedures - Correlations

Annex VI (MDD)	• Product Quality Assurance - No longer available • Devices to be recertified through another procedure
Annex IV (MDD) → Annex XI, Part B (MDR)	• Product Verification • Sampling no longer allowed: testing of all produced devices
Annex V (MDD) → Annex XI, Part A (MDR)	• Production Quality Assurance
Annex II.3 (MDD) → Annex IX (MDR)	• Chapter I • Quality Management System
Annex II.4 (MDD) → Annex IX (MDR)	• Chapter II • Assessment of the technical documentation

Class I

Step 1 Product Assessment → General Safety and Performance Requirements (Annex I)

Step 2 Evidence of compliance →Technical Documentation (Annex II)

Step 3 Prepare Declaration of Conformity (Annex IV)

Step 4 Sign Declaration of Conformity

Class I sterile / measuring function / reusable surgical instruments

Option 1

Annex IX without Chapter II

Option 2

Annex II coupled with Part A of Annex XI

NB involvement limited to

- sterile conditions or
- conformity to the metrological requirements or
- aspects related to the reuse of the device (e.g. cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use)

Class IIa

Option 1

Annex IX without Chapter II

Option 2

Annex II/III coupled with Part A or Part B of Annex XI

Technical Documentation

Assessment of at least one representative device per category

Class IIb

Option 1

Annex IX without Chapter II

Option 2

Annex X with Part A or Part B of Annex XI

Technical Documentation

Assessment of at least one representative device per generic device group

Class IIb Implantables

Option 1

Annex IX including Chapter II

Option 2

Annex X with Part A or Part B of Annex XI

Technical Documentation

Assessment of each file → no sampling

Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors are exempted → sampling allowed

Class III

Option 1

Annex IX including Chapter II

Option 2

Annex X with Part A or Part B of Annex XI

Technical Documentation

Assessment of each file

Articles 52, 53 and 54 with Annexes IX and X: Additional procedures – Class III and Class IIb (Rule 12)

Class III implantables and Class IIb (Rule12)

- Consultation with expert panel of Commission

Medicinal substance

- Consultation with CA or EMA
- Substance derived from human blood/plasma → batch release documentation to NB

Tissue/cells of animal/human origin

- Consultation with CA or EMA

Device systemically absorbed to achive intended purpose

- Consultation with CA or EMA

Custom made devices

Class I / IIa / IIb / III (non implantable)

Annex XIII (self certification)

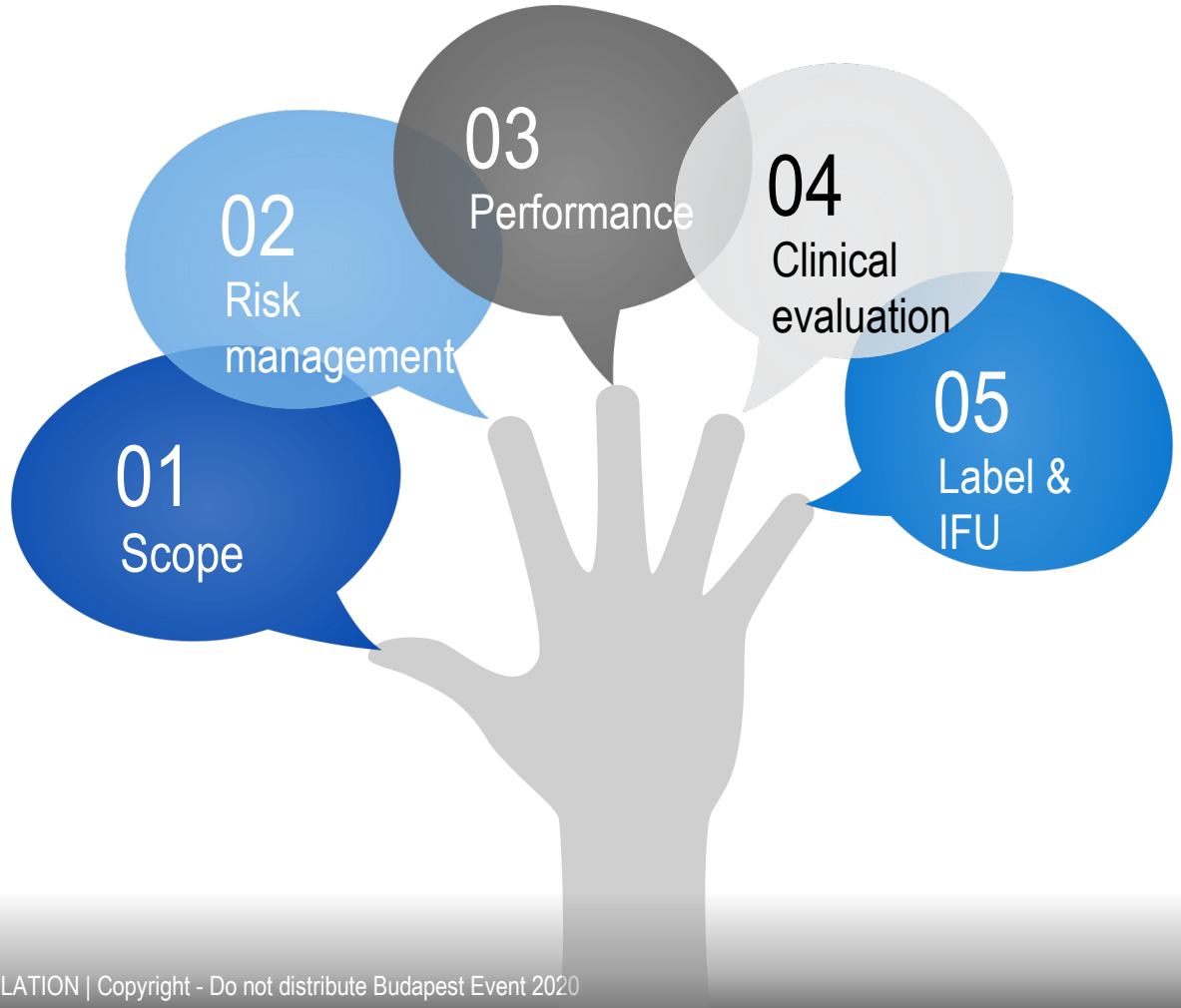
Class III implantable – Option 1

Annex XIII + Annex IX without Chapter II

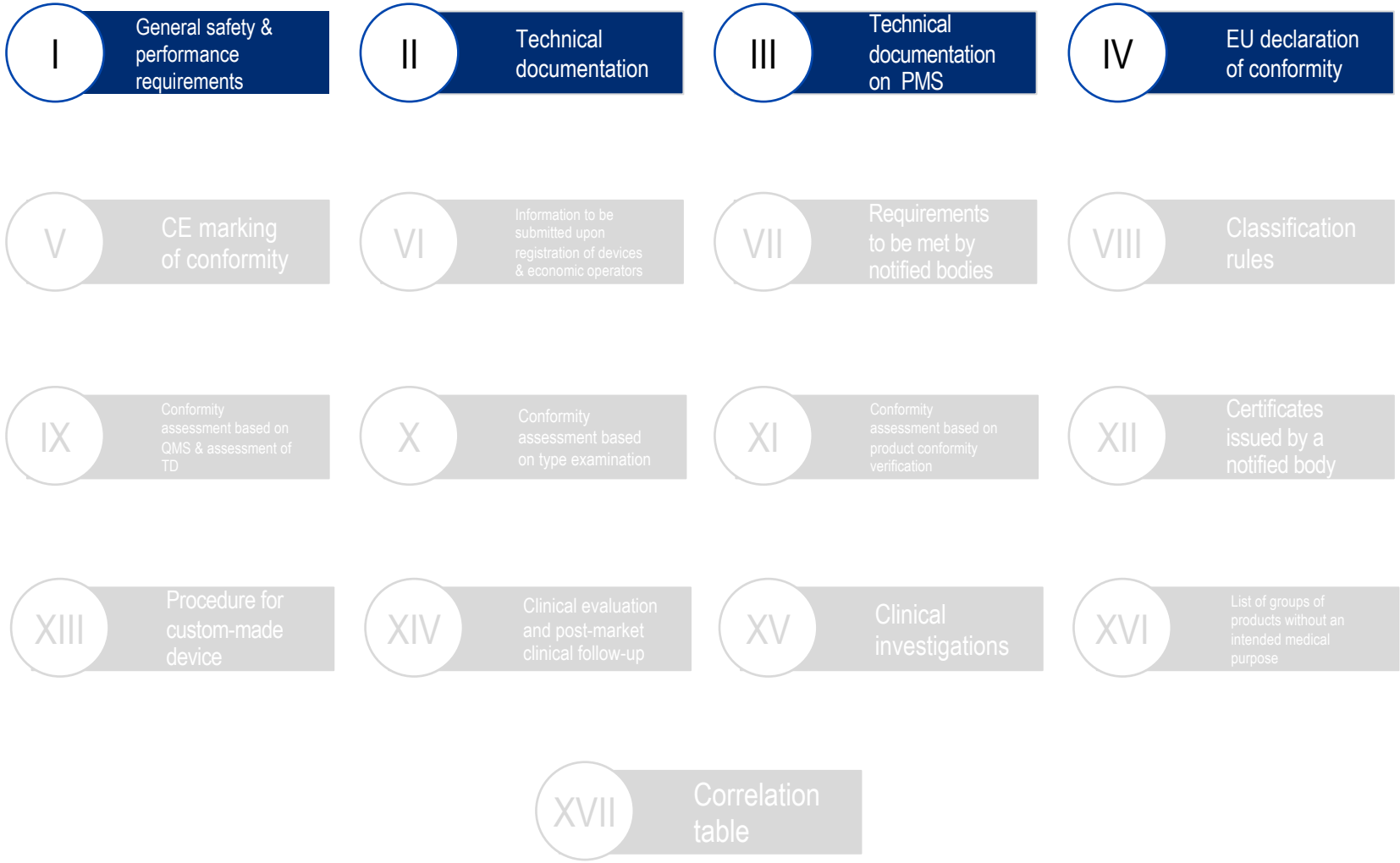
Class III implantable – Option 2

Annex XIII + Part A of Annex XI

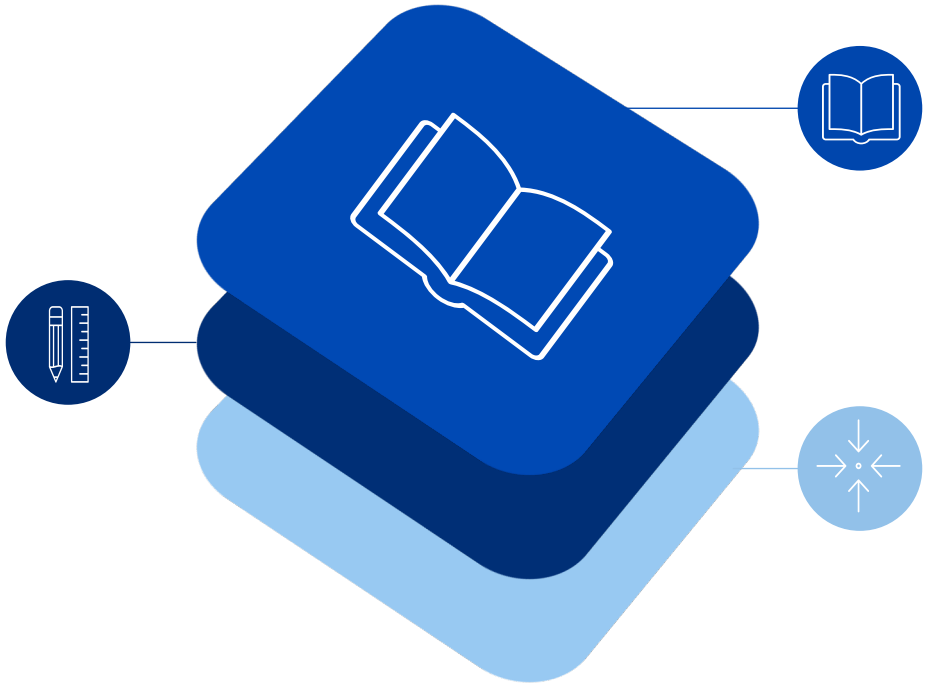
Conformity assessment for non-medical devices



Applicable Annex



GSPR Structure



Chapter II
- Requirements reg. design & manufacture
- Clauses 10 - 22

Chapter III
- Requirements reg. device information
- Clause 23

Chapter I
- General requirements
- Clauses 1 - 9

General requirements: Clauses 1-9

SPR 1: Performance & safety

SPR 2: Reduction of risks

SPR 3: Risk management system

SPR 4: Risk control measures & residual risks

SPR 5: Risks related to use

SPR 6: Device lifetime

SPR 7: Packaging, transport, storage

SPR 8: Risk-benefit ratio

SPR 9: Devices w/o medical purpose

Requirements regarding design & manufacture: Clauses 10-22

SPR 10: Chemical, physical & biological properties

SPR 11: Infection & microbial contamination

SPR 12: Devices incorporating a medicinal product; substances absorbed or locally dispersed

SPR 13: Devices incorporating materials of biological origin

SPR 14: Construction of devices & interaction with their environment

SPR 15: Devices with a diagnostic or measuring function

SPR 16: Protection against radiation

SPR 17: Electronic programmable systems & software

SPR 18: Active devices & devices connected to them

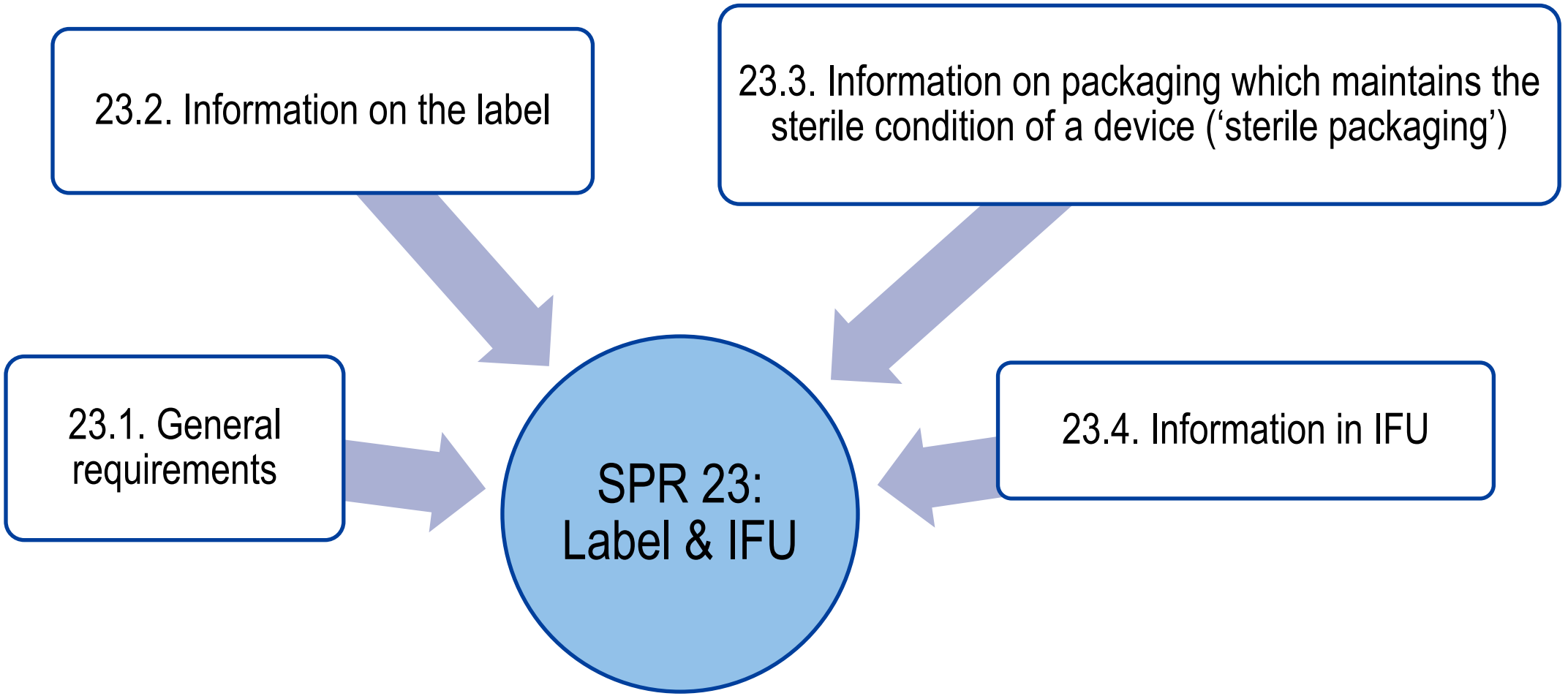
SPR 19: Particular requirements for active implantable devices

SPR 20: Protection against mechanical & thermal risks

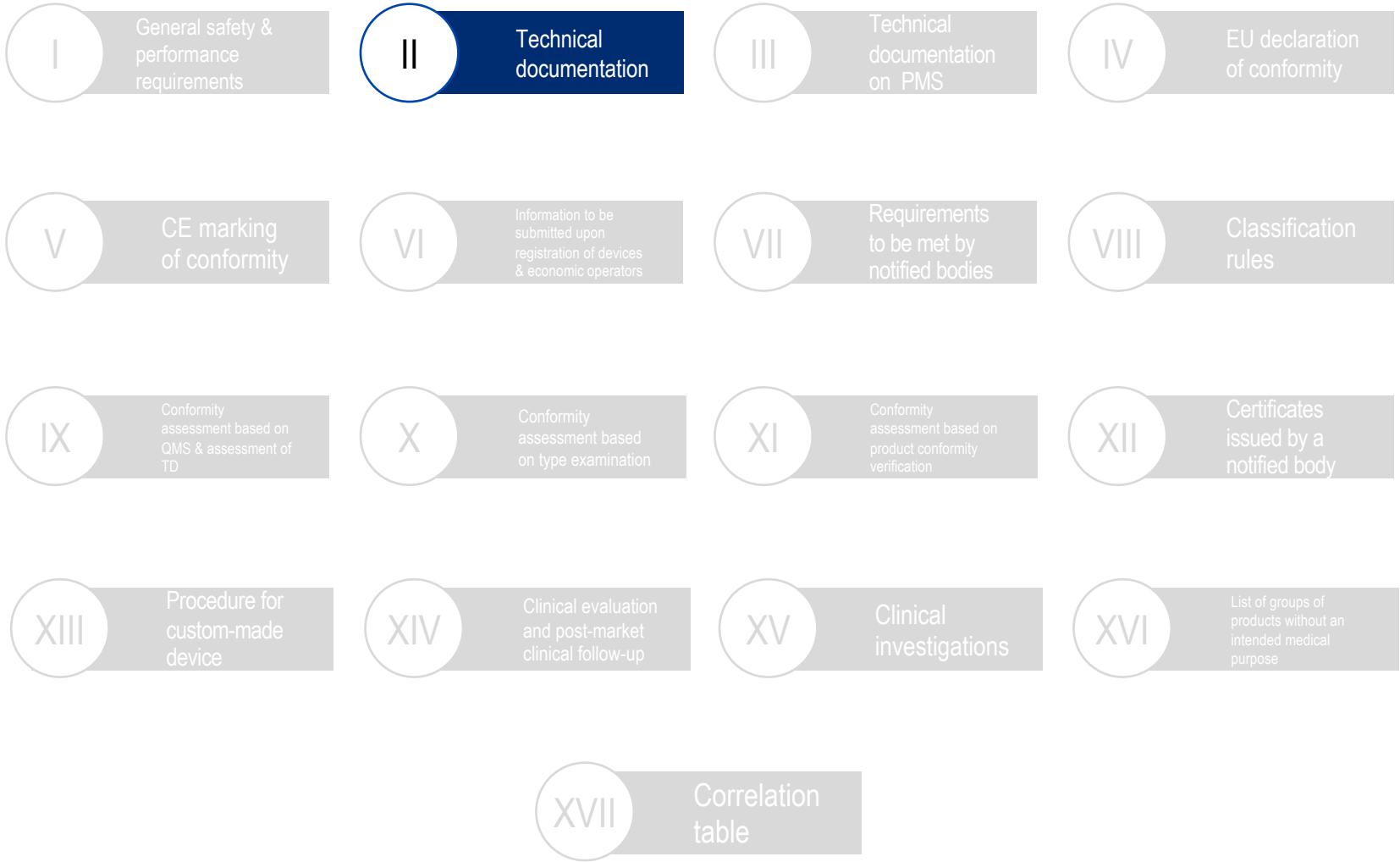
SPR 21: Protection against the risks posed to the patient or user by devices supplying energy or substances

SPR 22: Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

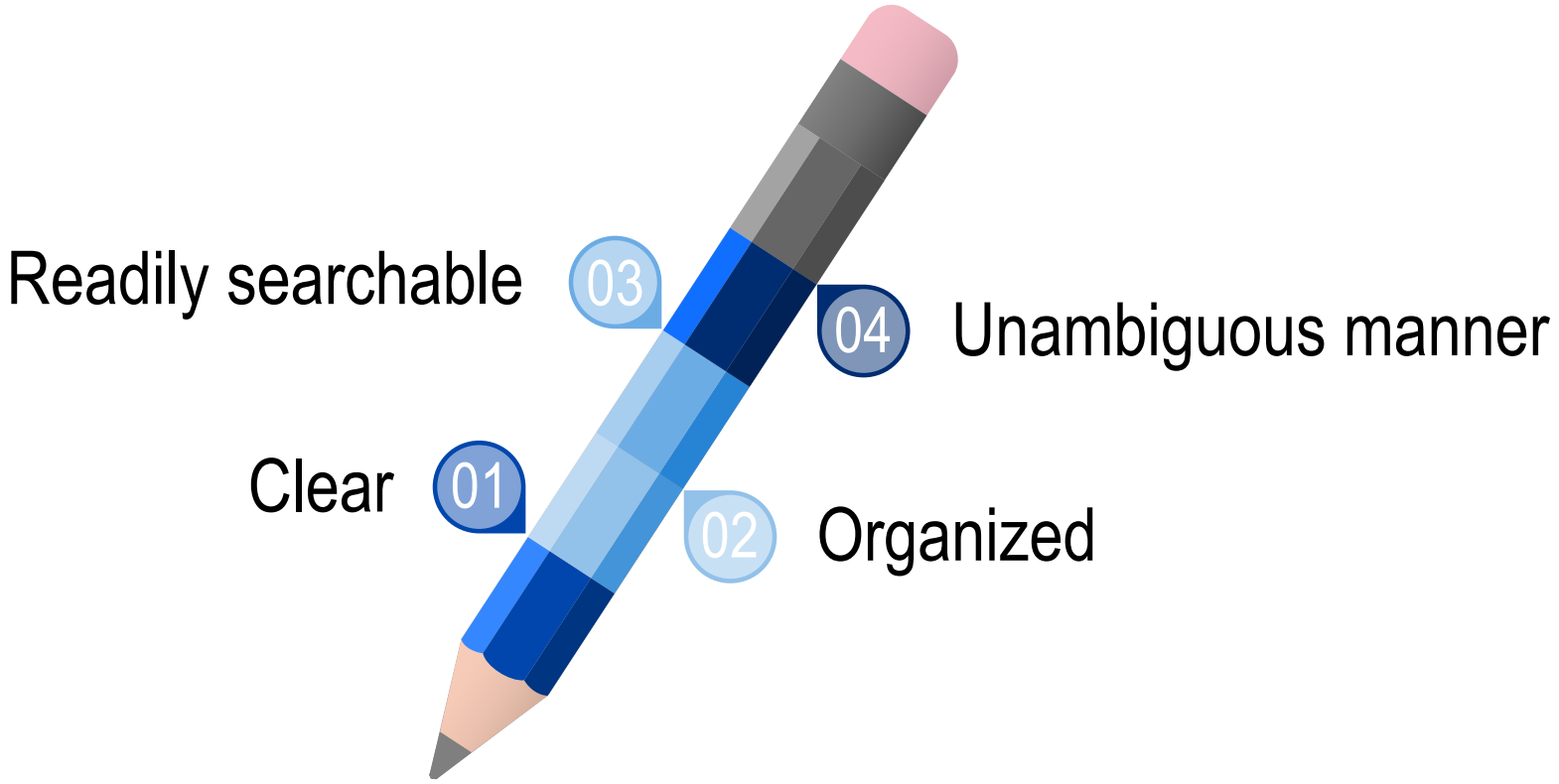
Requirements regarding the information supplied with the device: Clause 23



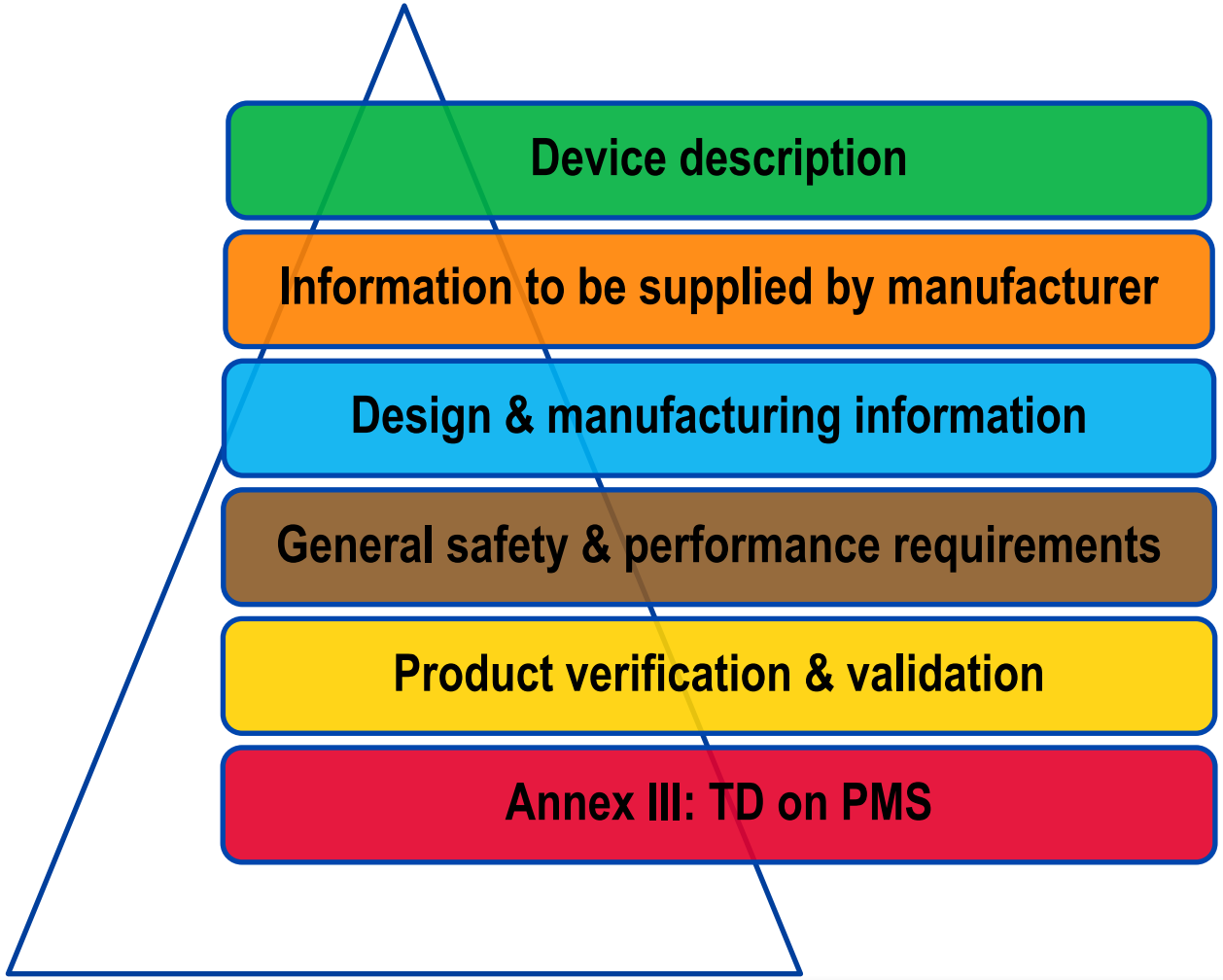
Applicable Annex



Technical documentation shall be presented in a…

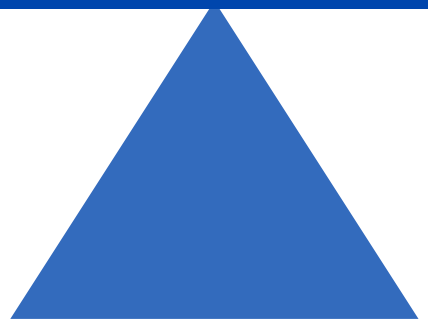


TD Requirements: What does it include?

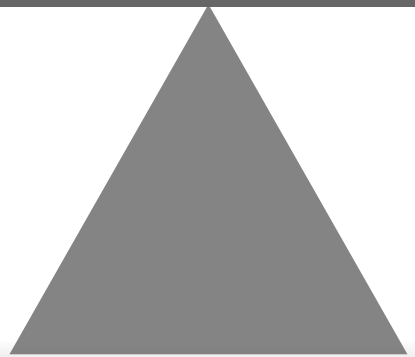


Article 32: Summary of safety & clinical performance (SSCP)

In case of **class III & implantable devices**, other than custom-made or investigational devices, manufacturer shall draw up a SSCP



Manufacturer shall mention on **label or IFU** where the SSCP is available



SSCP shall include at least the following aspects:

- **Identification of the device and the manufacturer**, incl. basic UDI-DI and single registration number SRN
- **Intended purpose** of device, incl. indications, contra-indications & target populations
- **Device description**, incl. a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device
- **Possible diagnostic or therapeutic alternatives**
- **Reference to harmonized standards and common specifications**
- **Summary of clinical evaluation** as referred to in annex XIII, and relevant information on **PMCF**
- **Suggested profile and training for users**
- **Information** on any **residual risks** and any **undesirable effects, warnings and precautions**

The SSCP shall be…

written in a way that is clear to the intended **user and, if relevant, to the patient**

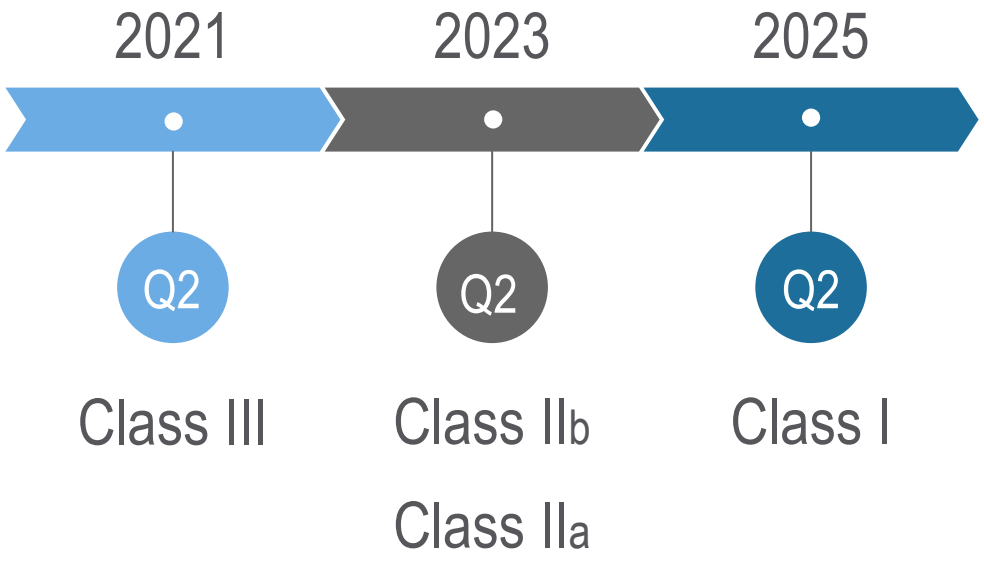
made available to public via Eudamed

part of the conformity assessment in accordance with Article 52

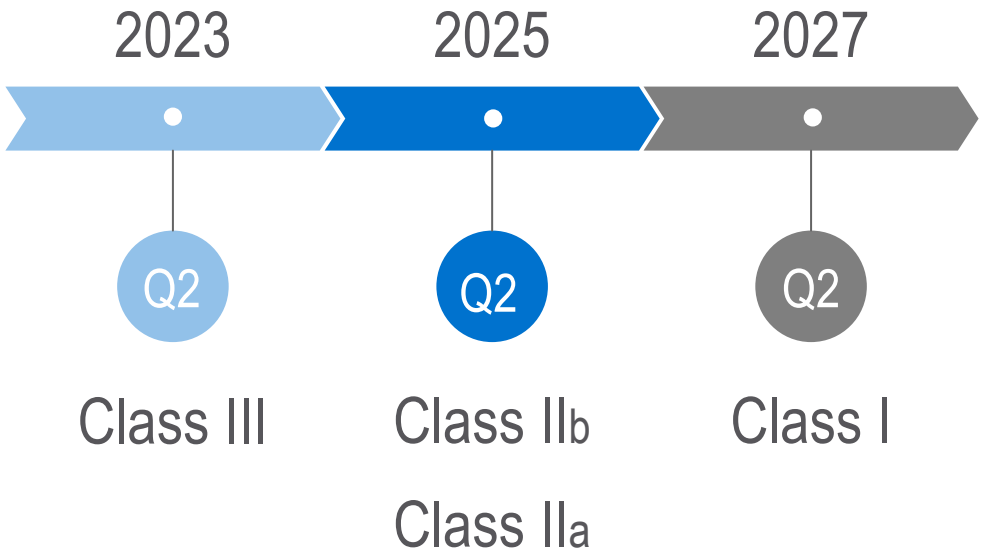
validated by NB

NB has to upload validated final SSCP to Eudamed

UDI timeline acc. device classes for labeling & usage



Timeline direct part marking for reusable surgical instruments



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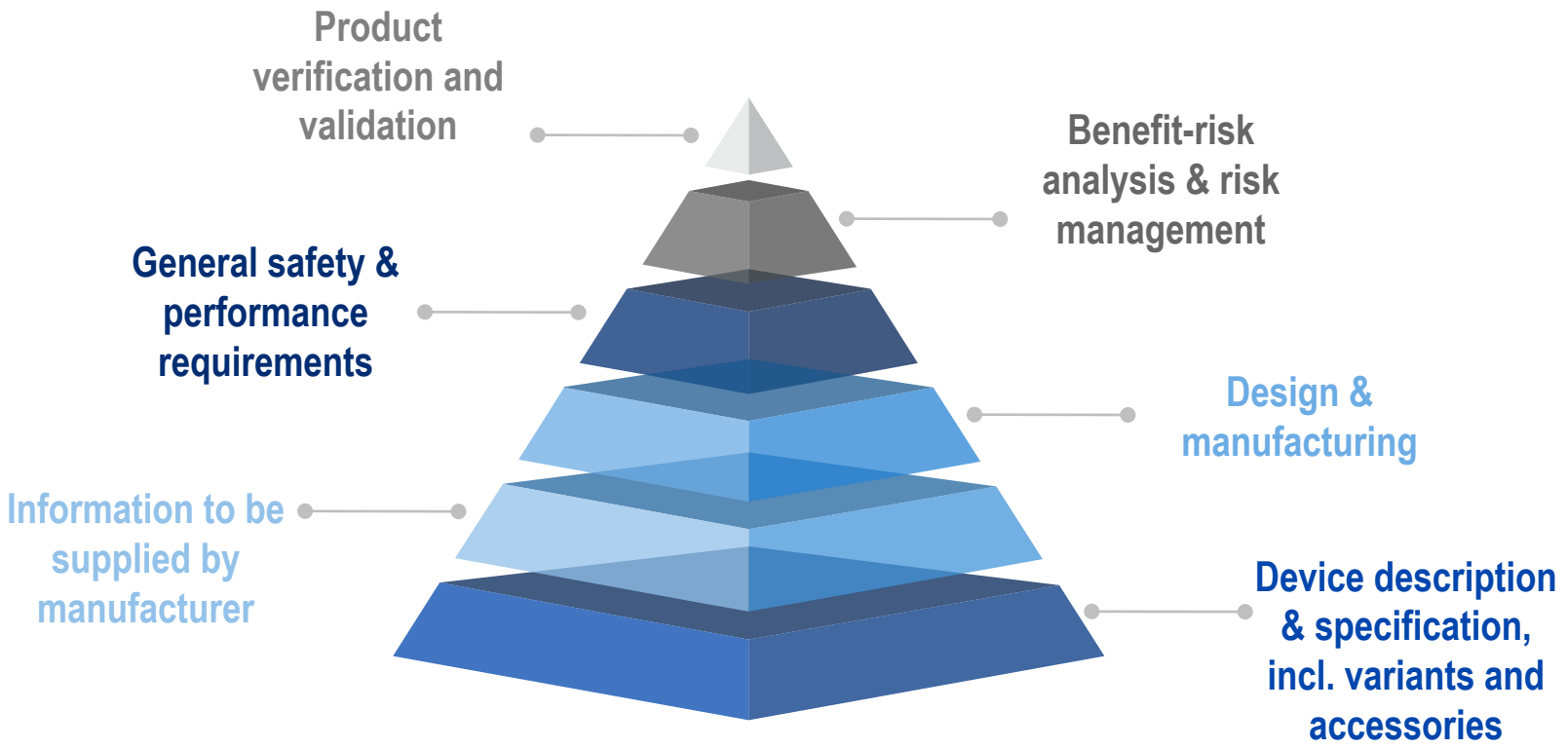
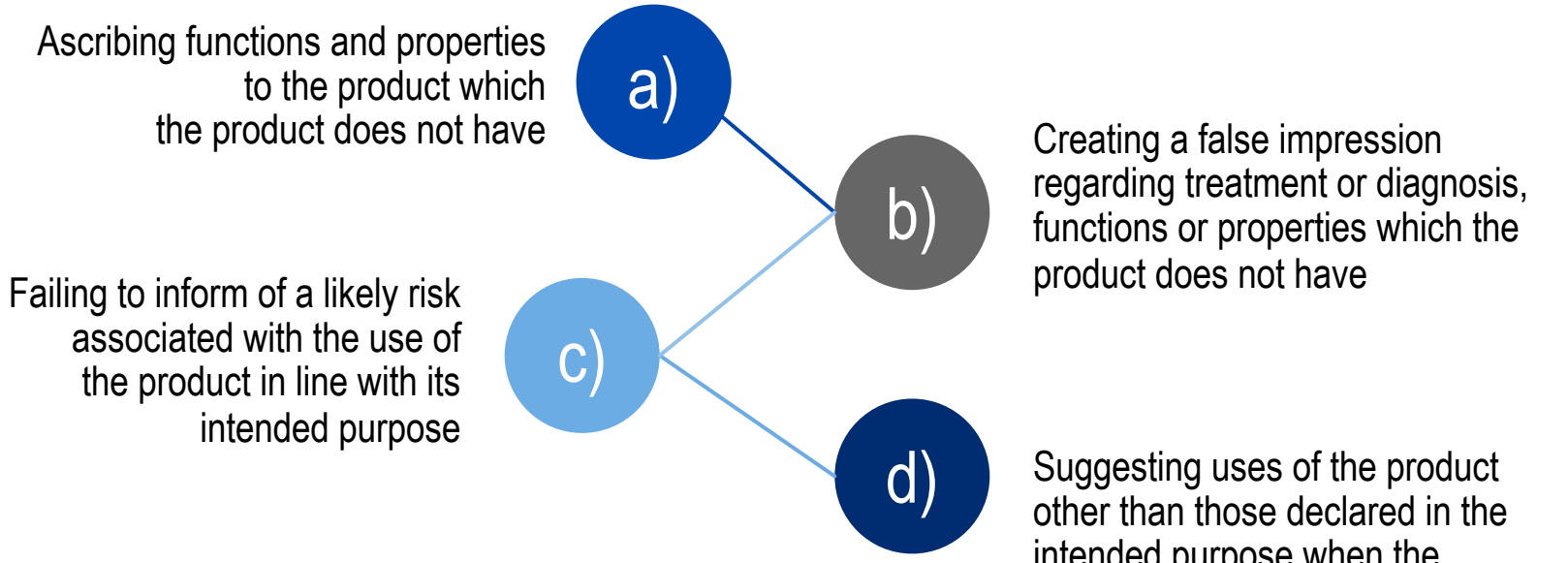
What is your marketing department planning to claim?

Keep your duties in mind!



The MDR is requiring very specific and clear claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:



Clause 23 of GSPR is requiring more transparency

Information supplied by manufacturer

- **Website to be updated**

IFU

- **Specification of clinical benefits to be expected**
- **Links to summary of safety & clinical performance**

Label

- Indication that device contains or incorporates
  1. a medicinal substance, incl. human blood or plasma derivative, or
  2. tissues/cells (or derivatives) of HO
  3. tissues/cells (or derivatives) of AO (commission regulation (EU) no. 722/2012)
- Unique Device Identification (UDI) carrier acc. Article 24 & Annex V Part C
- Qualitative composition of device & quantitative information on main constituents(s)

The notified body will scrutinize your evidence in a different and more stringent way

- **4.5.1 The notified body shall review….**

- manufacturer's procedures & documentation relating to clinical evaluation..
- …address the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I

These procedures referred to in the first paragraph shall take into consideration
available common specifications, guidance and best practice documents, plus harmonized standards……
– even if the manufacturer does not claim to be in compliance

- **4.5.5 The notified body shall examine, validate and verify that…**

- manufacturers' procedures & documentation adequately address:
  - the planning, conduct, assessment, reporting and updating of the clinical evaluation (Annex XIV)
  - post-market surveillance and PMCF,
  - the interface with the risk management process,
  - the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I, and
  - the conclusions drawn with regard to the clinical evidence and drawing up of the clinical evaluation report.

Do you know your device?

*"The manufacturer shall specify and justify the **level of clinical evidence** necessary to demonstrate compliance with the relevant **general safety and performance requirements** which shall be appropriate to the characteristics of the device and its intended purpose."*

Did you check the level on evidence on your own device?

01

The clinical evaluation shall be **thorough and objective**, and take into account both **favorable and unfavorable** data.

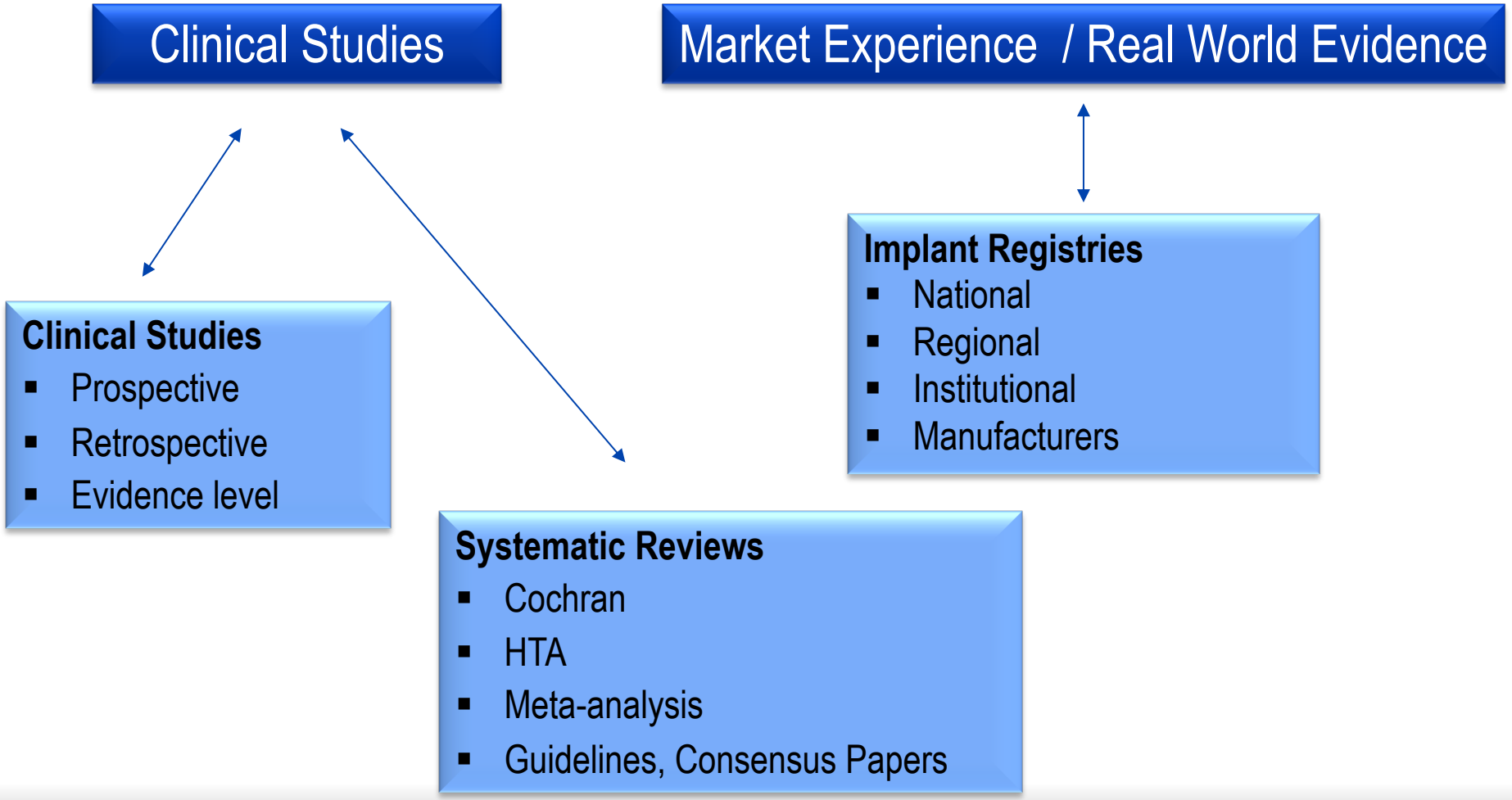
02

Its depth and extent shall be **proportionate and appropriate** to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's **claims** in respect of the device.

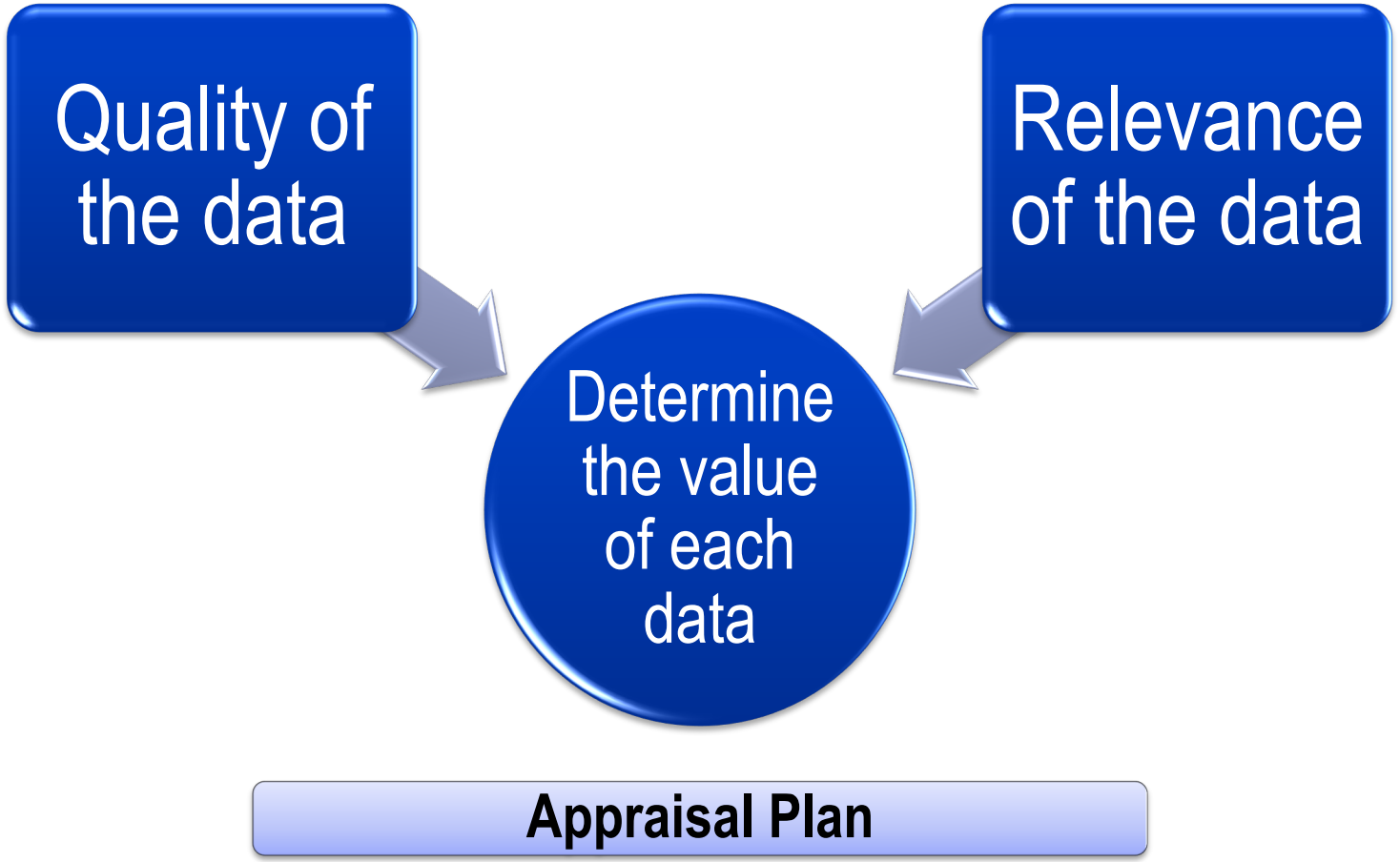
03

A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be **demonstrated**

Stage 1 – Identification of pertinent data



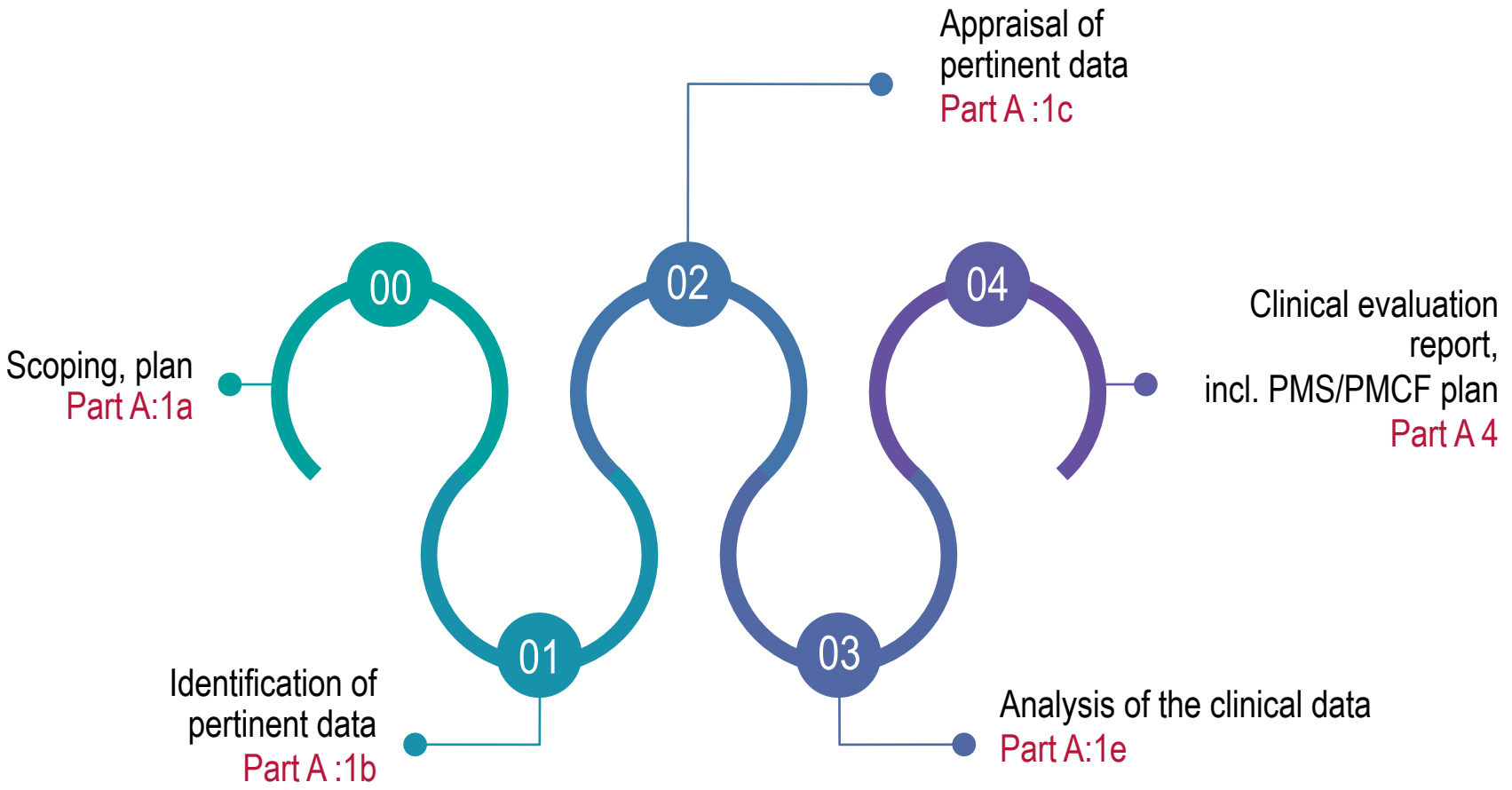
Stage 2 – Appraisal of pertinent data



Stage 3 – Analysis of clinical data

The goal of the analysis stage is to determine if the appraised data sets available for a medical device **collectively demonstrate compliance** with each of the Essential Requirements pertaining to the **clinical performance and clinical safety of the device**, when the device is used according to its intended purpose.

Art. 61 and Annex XIV, A: Will your compliance to MEDDEV help you?



Did you check the difference between MDD and MDR?

MDD

- the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated

MDR

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

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
- reports ***published in peer reviewed scientific literature*** on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up

Are you still allowed to and can you demonstrate equivalence?

- These characteristics shall be **similar to such an extent** that there would be **no clinically significant difference in the clinical performance and safety of the device**.
- Based on **proper scientific justification.**
- **Sufficient levels of access** to the data on devices to which Manufacturer is **claiming equivalence**
- **Results in CER , which is part of the TD**

In case no equivalence can be demonstrated clinical investigations need to be performed

Equivalence approach, only possible if clinically…

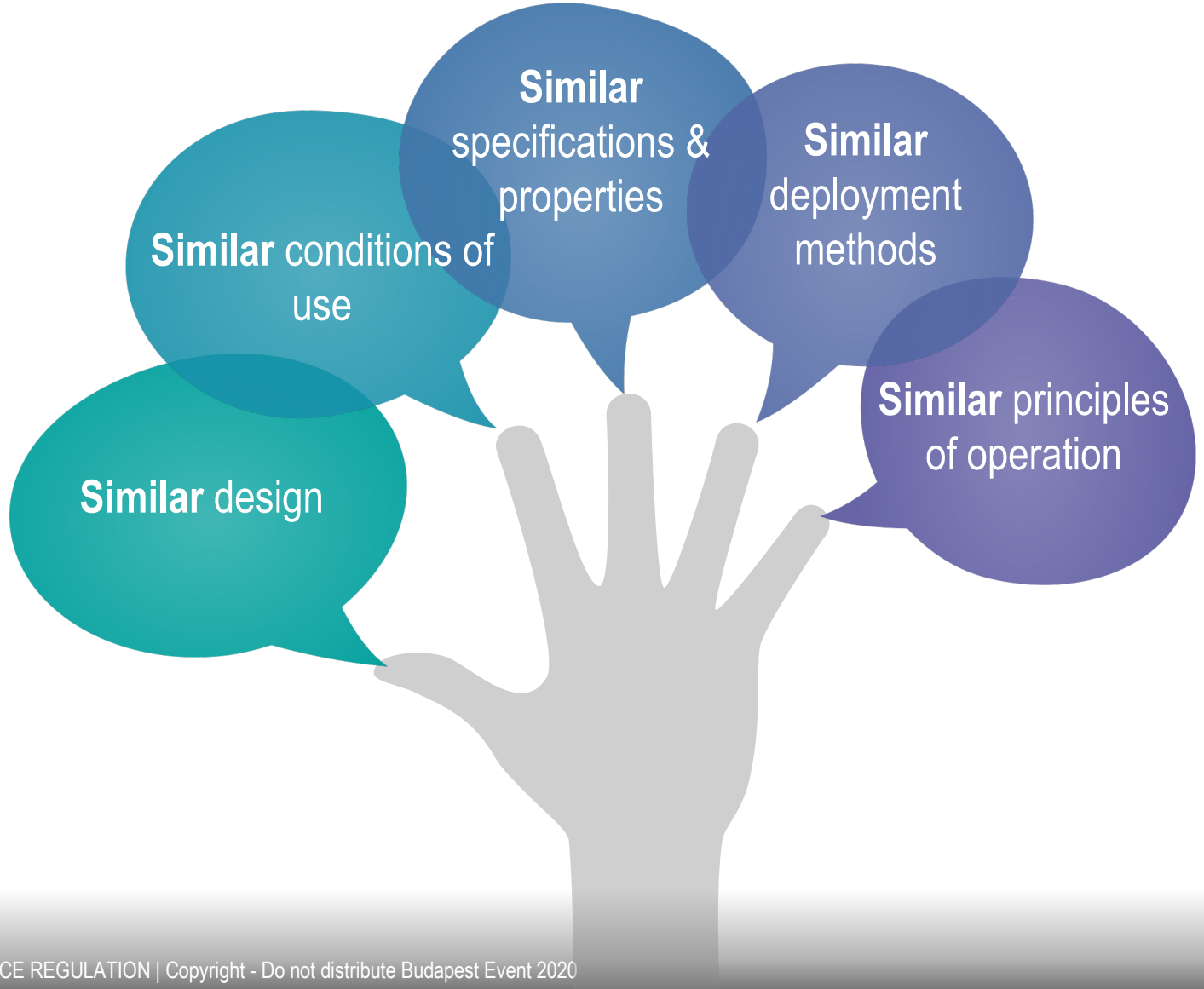
- **Same clinical condition or purpose**, including
- **Similar severity and stage of disease, at the**
- **Same site in the body**, in a
- **Similar population, including as regards age, anatomy and physiology**
- **Same kind of user**
- **Similar relevant critical performance** in view of the expected clinical effect for a specific intended purpose

Equivalence approach, only possible if biologically…

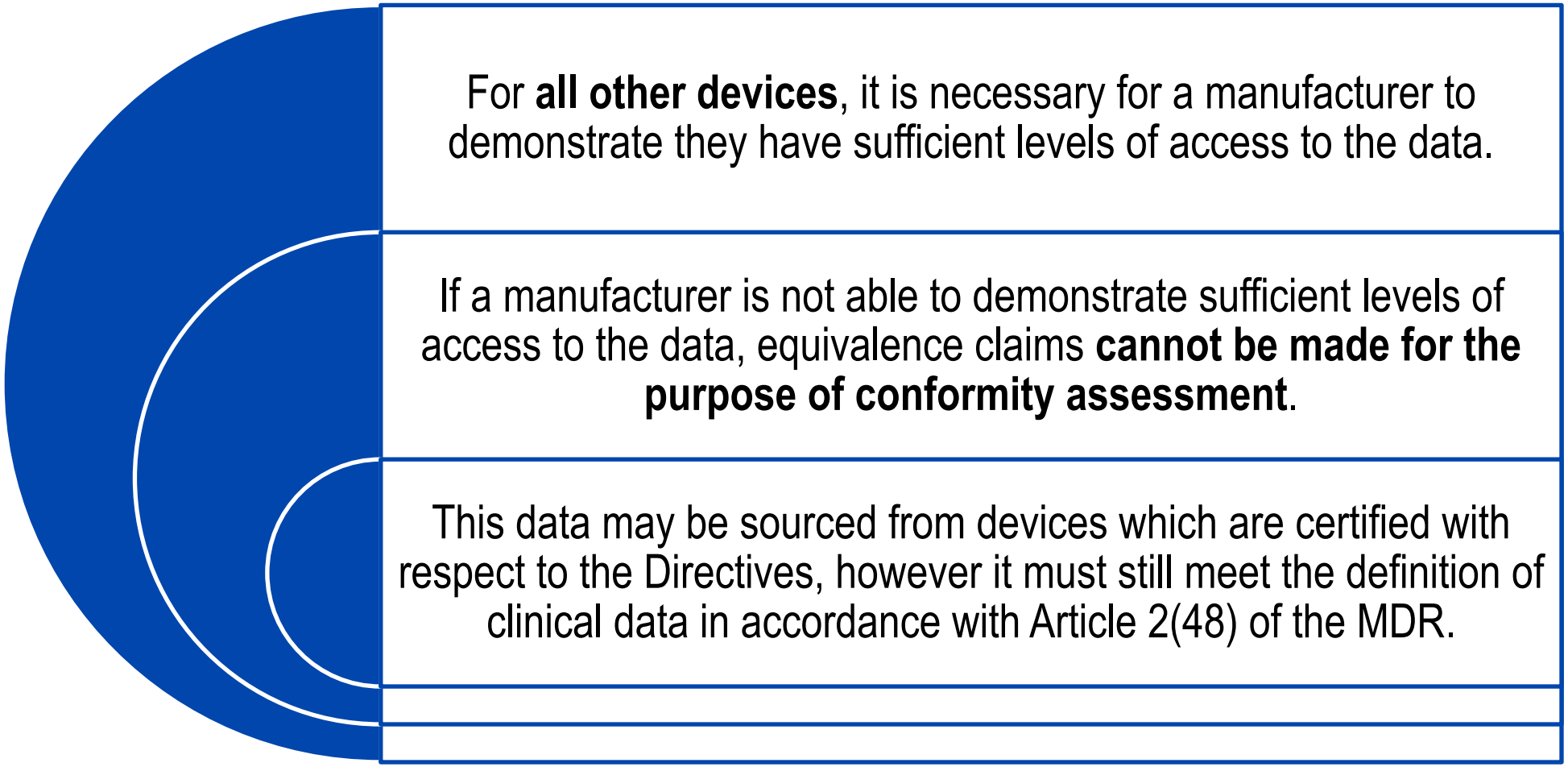
The device uses the

- **same materials or substances** in contact with the
- **same human tissues or body fluids** for a
- **similar kind and duration of contact** and
- **similar release characteristics** of substances, including degradation products and leachable

Equivalence approach, only possible if technically…



General Rules for Class IIa and IIb not implantable



MDD vs. MDR - Clinical Investigations

MDD

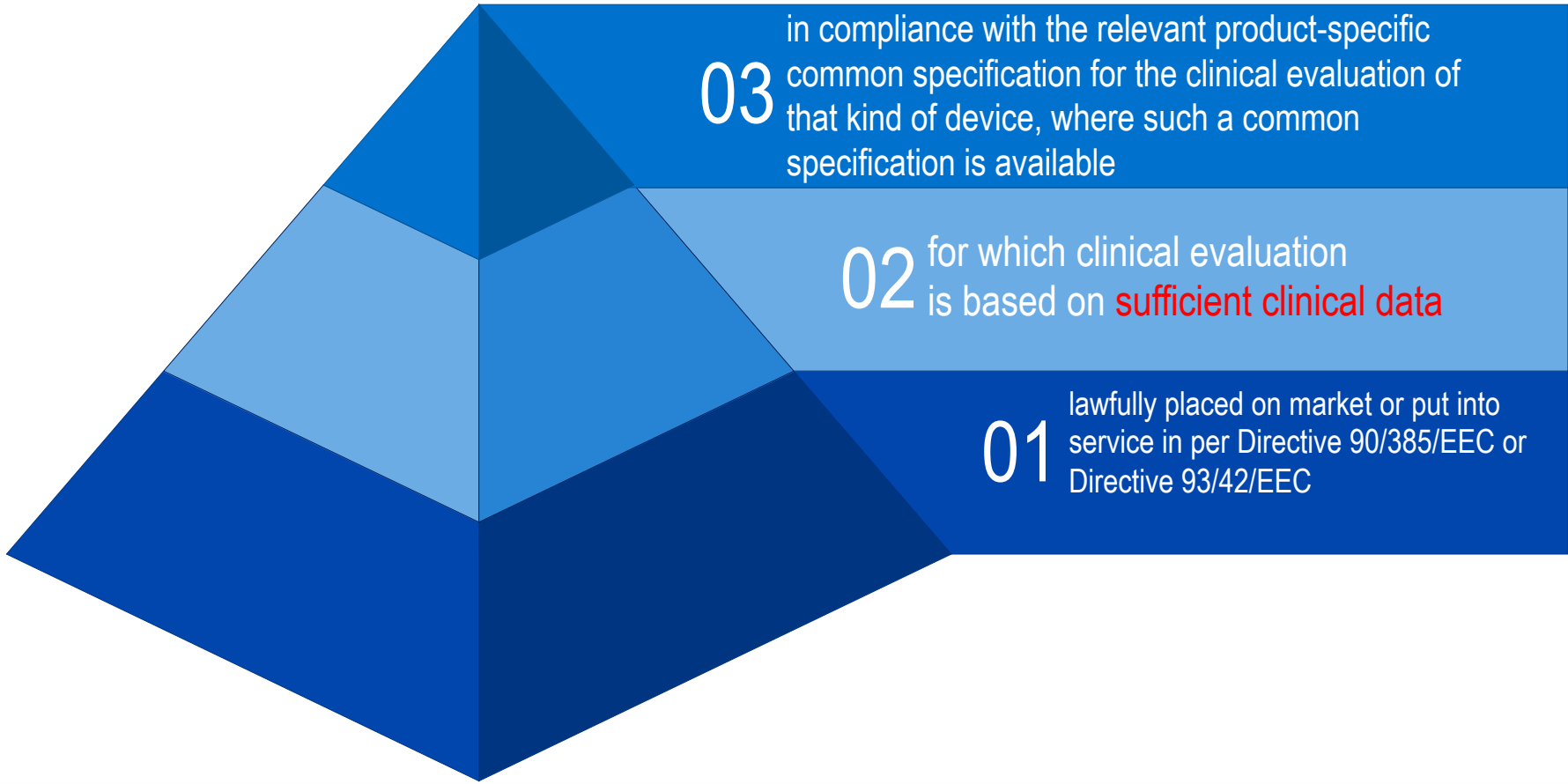
- Annex X, 1.1a
- In the case of **implantable devices and devices in class III clinical investigations shall be performed** unless it is duly justified to rely on existing clinical data.

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.

Article 61. 6.a: Exemptions to perform clinical investigations

For implantable & Class III medical devices:



Article 61. 6.b: More exceptions from clinical investigations for…

EU Regulation - Article (61) 6.b

Sutures	**Staples**	**Dental fillings**
Dental braces	**Tooth crowns**	**Screws**
Wedges	**Plates**	**Wires**
Pins	**Clips**	**Connectors**

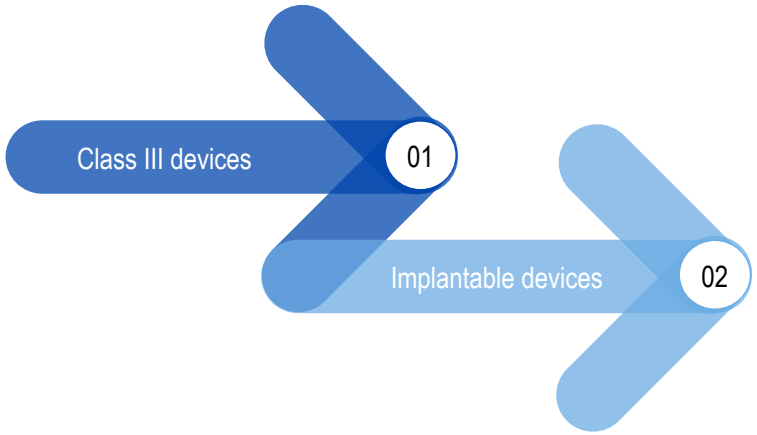
→ Clinical evaluation based on **sufficient clinical data**

→ Clinical evaluation in compliance with relevant product-specific common specification, where such common specification available

Belongs your device to either the Class III or Implantable category?

Clinical investigations might not be relevant:

Clinical investigations expected for:



Equivalence same manufacturer

01 MDR - Art. 61, 4

Equivalence not same manufacturer

02 MDR - Art. 61, 5

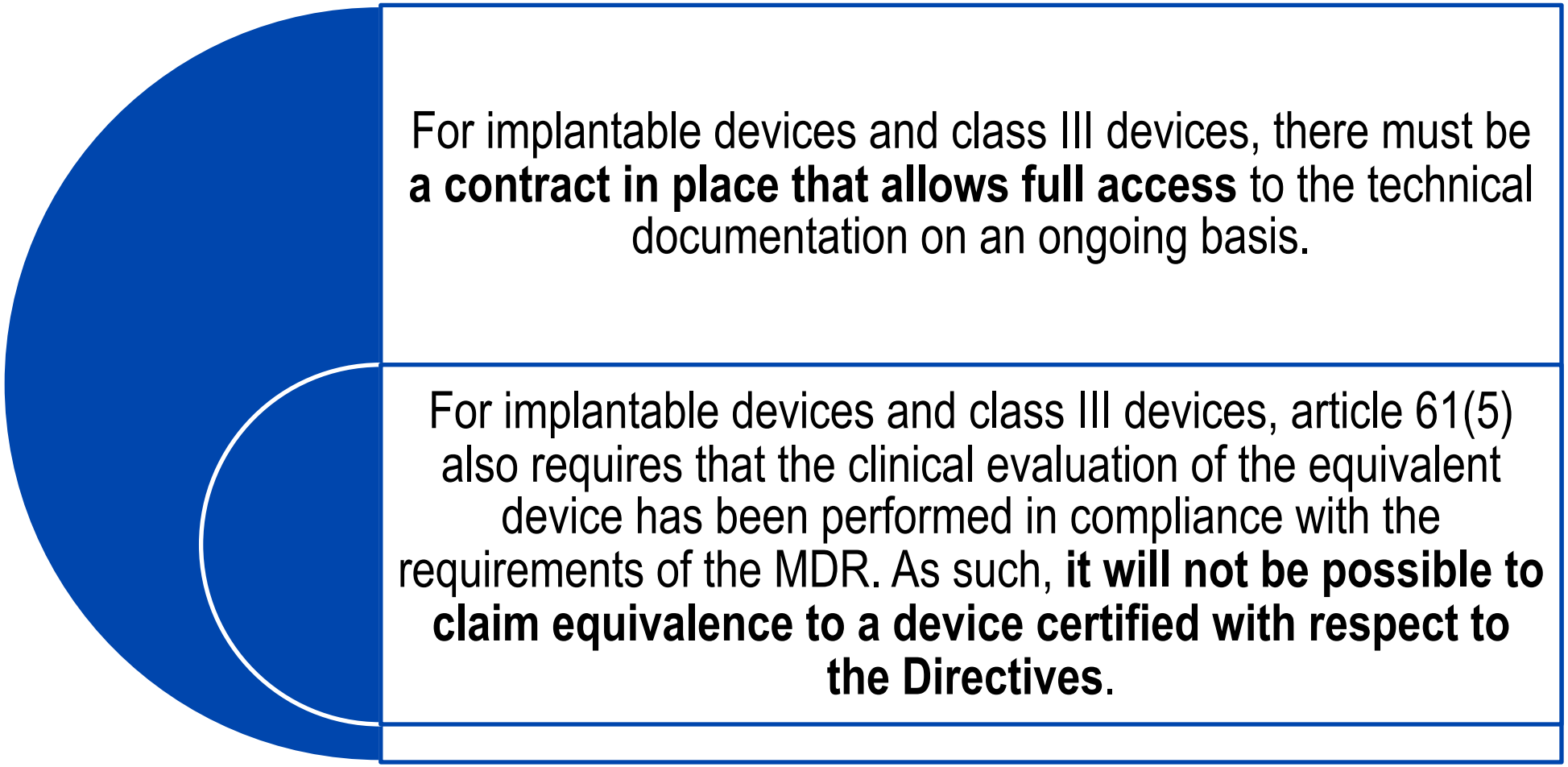
Legacy devices

03 MDR - Art. 61,6a

List of devices, some of which were up classified

04 MDR - Art. 61,6b

General Rules for Class III and implantable devices



Article 61 (2): Voluntary Consultation

For class III devices and for certain class IIb devices (rule 12), a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations

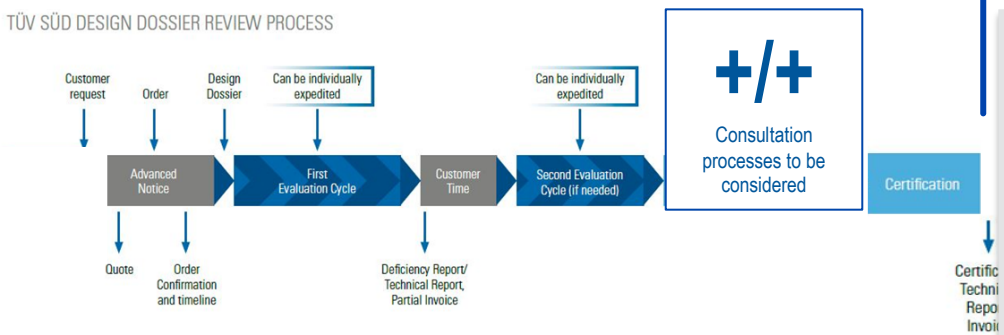
Article 54.3 and 55: Scrutiny

Class III implants and class IIb devices (rule 12) - after MDR - CE marking

Certification, NB Decisions,
Scrutiny / Notification

NB decides on Certification

NB issues the final Assessment Report, including a justification on divergent views (link to consultation process)



Art. 55: Scrutiny submission is required for cases were a consultation was performed.
By NB via EUDAMED /electronic system to
- **Competent Authorities**.

Include:
SSCP, IFU, Scientific Opinion, Assessment Report that includes justification on divergent views

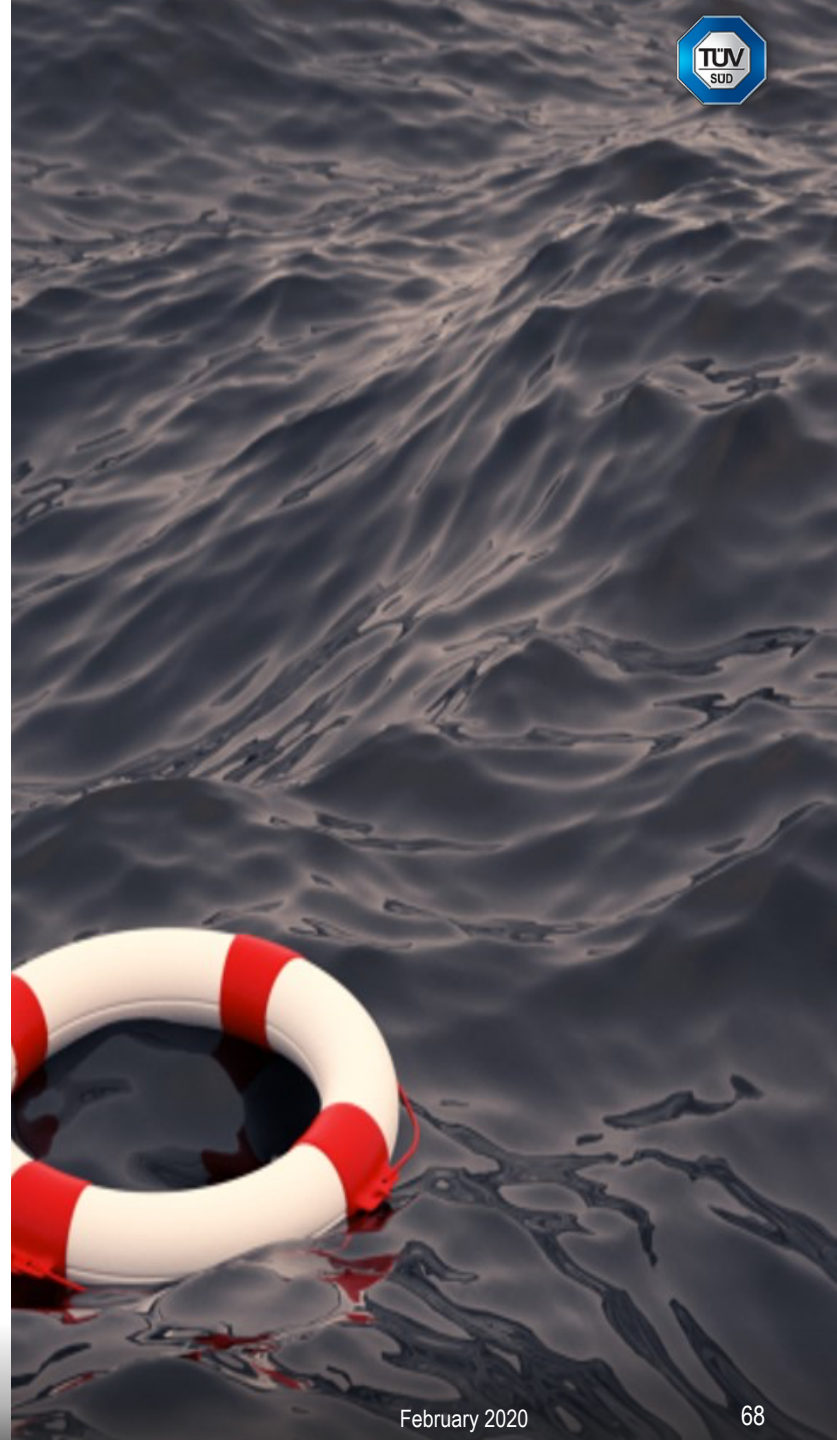
Art 54.3: In any case when a **CER was assessed by NB a notification** via EUDAMED /electronic system to
- **Competent Authorities,**
- **National Authority responsible for NB and**
- **Commission** is required.

Include: **Clinical Evaluation Assessment Report** with a rational whether or not a consultation applied

Post-Market Surveillance

Annex III – Technical Documentation on Post Market Surveillance - Content

- Post-market surveillance plan
- Post Market Clinical Follow Up Plan – or justification why not applicable
- Periodic Safety Update Report & Post Market Surveillance Report



Article 83.2: Post-Approval requirements on PMS

The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

PMS-Plan: Requirements in Annex III, 1.1

Proactive & systematic data collection

Who collects what, how often, from which sources?

Appropriate data assessment

How and by whom are the collected data assessed?

Suitable indicators & threshold values

Indicators/threshold values linked to benefit-risk analysis & risk management?

Effective complaint investigation

What are methods and tools for investigation and analysis of market-related experience?

Trend reporting incl. significant increase

Statistically significant increase in frequency/severity of incidents? → link to vigilance system?

Communication with stakeholders

Are methods & protocols for communication with CA, NB, EO and users effective?

Procedure for PMS & PSUR & SSCP

Are procedures for PMS system, PMS plan and PSUR available and compliant?

Procedure for CAPA

Are procedures to initiate appropriate measures available?

Tools for traceing devices

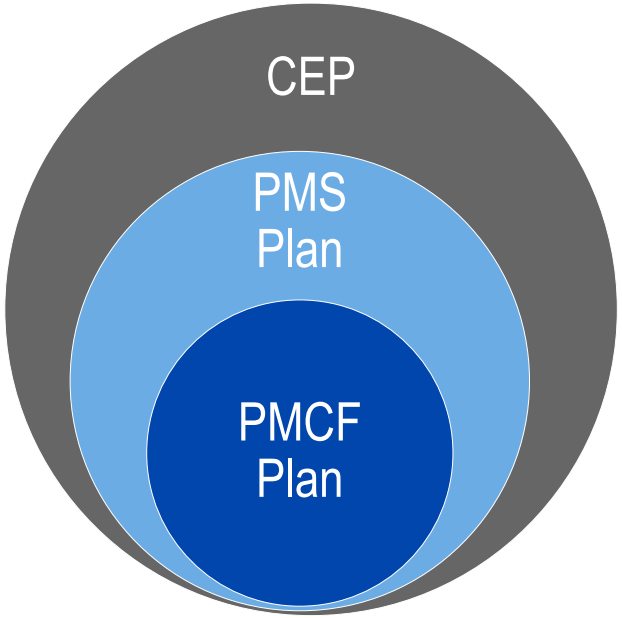
Are the tools to trace and identify devices effective?

PMCF Plan

Is there a PMCF or a justification why not?

Art. 83, 84: PMS and Annex II + III, XIV, B: PMCF

- **PMCF** is a continuous process to update the clinical evaluation and is part of the PMS plan
- The **manufacturer** shall proactively collect & evaluate clinical data…with the aim of:



- Confirm the safety & performance throughout expected lifetime
- Identify previously unknown side-effects
- Monitor the identified side-effects and contraindications
- Identify and analyze emerging risks on the basis of factual evidence
- Ensure the continued acceptability of benefit /risk ration
- **Identify systematic misuse or off-label use**, with a view to verify that the intended purpose is correct
- Consider any preventive & corrective actions

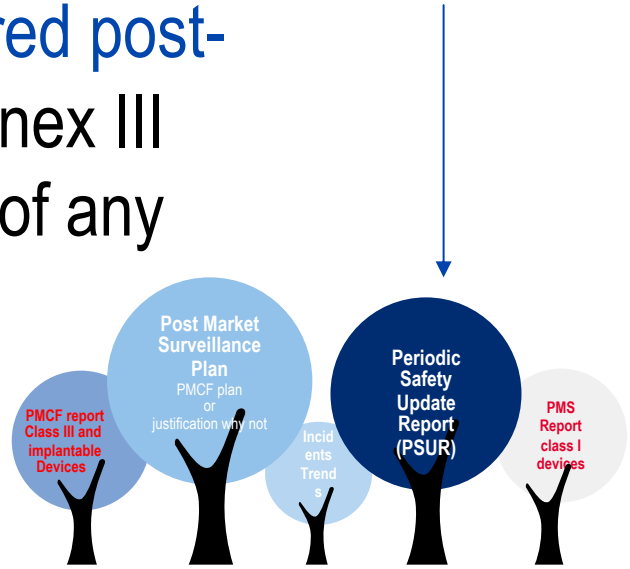
Annex XIV Part B: PMCF - Plan

- **PMCF** plan shall include:

- **General methods & procedures** of PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;
- **Specific methods & procedures** of PMCF to be applied, such as evaluation of suitable registries or PMCF studies;
- Rationale for the appropriateness for above points
- Reference to the relevant parts of the clinical evaluation report and to the risk management
- Specific objectives to be addressed by the PMCF
- Evaluation of the clinical data related to equivalent or similar devices
- Reference to relevant CS, standards and guidance on PMCF
- Detailed & adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer

Article 86: Periodic Safety Update Report (PSUR)

Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarizing the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex III together with a rationale and description of any preventive and corrective actions taken.



Except for class I devices → here: PMS report sufficient

Article 86: Periodic Safety Report Update (PSUR)

CE-marked Devices

- The PSUR shall be updated at least **annually** for **Class IIb and Class III devices.**

- **Updated every two years** for **Class II a**

Custom-made Devices

- PSUR shall be part of the technical documentation as specified in Annexes II and III.

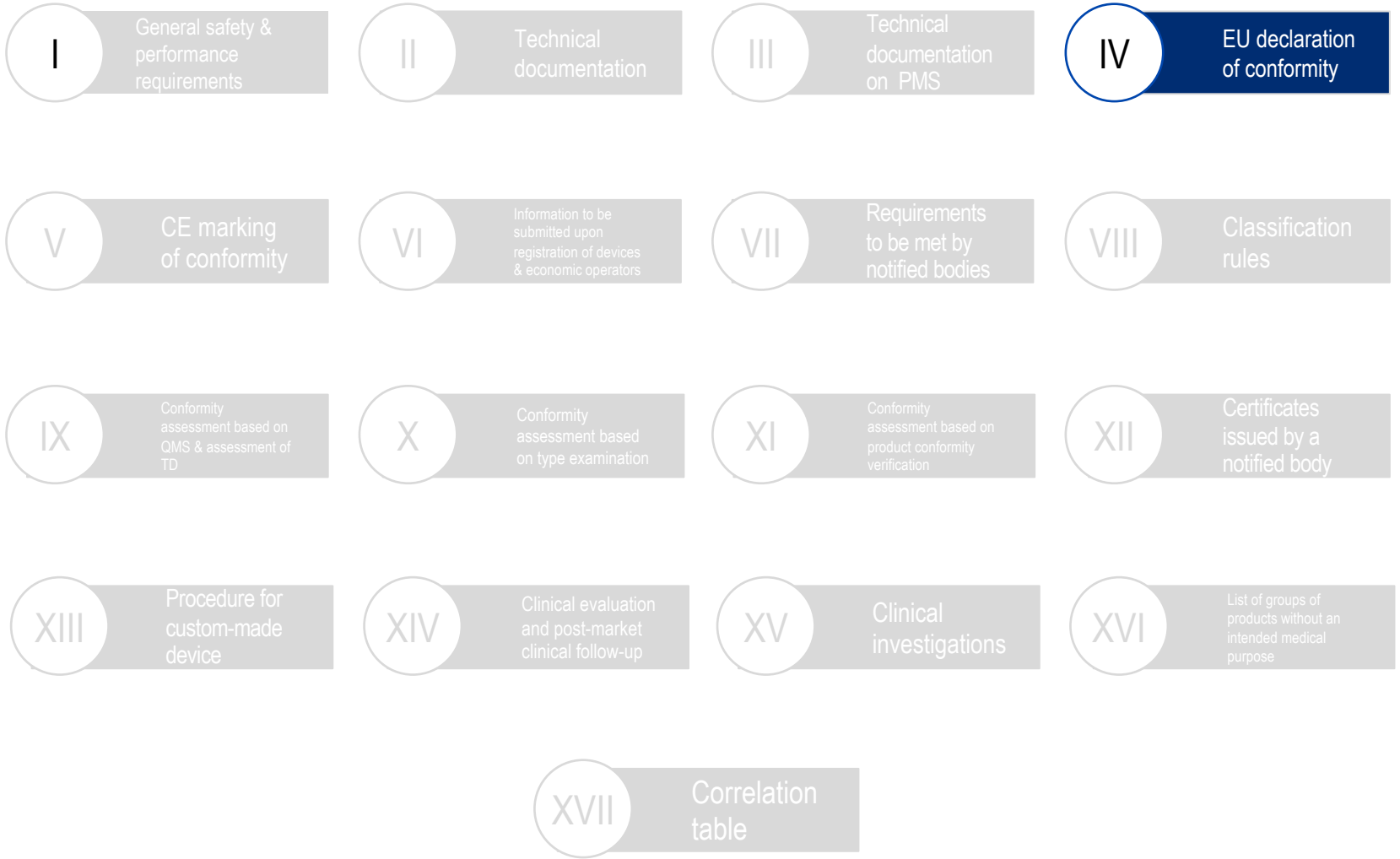
- PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

Periodic Safety Update Report (PSUR)

- Conclusion on benefit risk determination
- Main findings of PMCF Report

- Sales volume of devices & estimate of population using device involved
- Where practicable, usage frequency of device.

Applicable Annex



ANNEX IV - EU DECLARATION OF CONFORMITY (1)

The EU declaration of conformity shall contain all of the following information:

01 Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established.

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

03 The Basic UDI-DI as referred to in Part C of Annex VI.

04 Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3.

05 Risk class of the device in accordance with the rules set out in Annex VIII.

ANNEX IV - EU DECLARATION OF CONFORMITY (2)

The EU declaration of conformity shall contain all of the following information:

06 A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

07 References to any CS used and in relation to which conformity is declared.

08 Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued.

09 Where applicable, additional information.

10 Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

Definitions on Incident // Serious Incident

In MDR, any corrective maintenance activity is a suspected 'incident'

(64) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

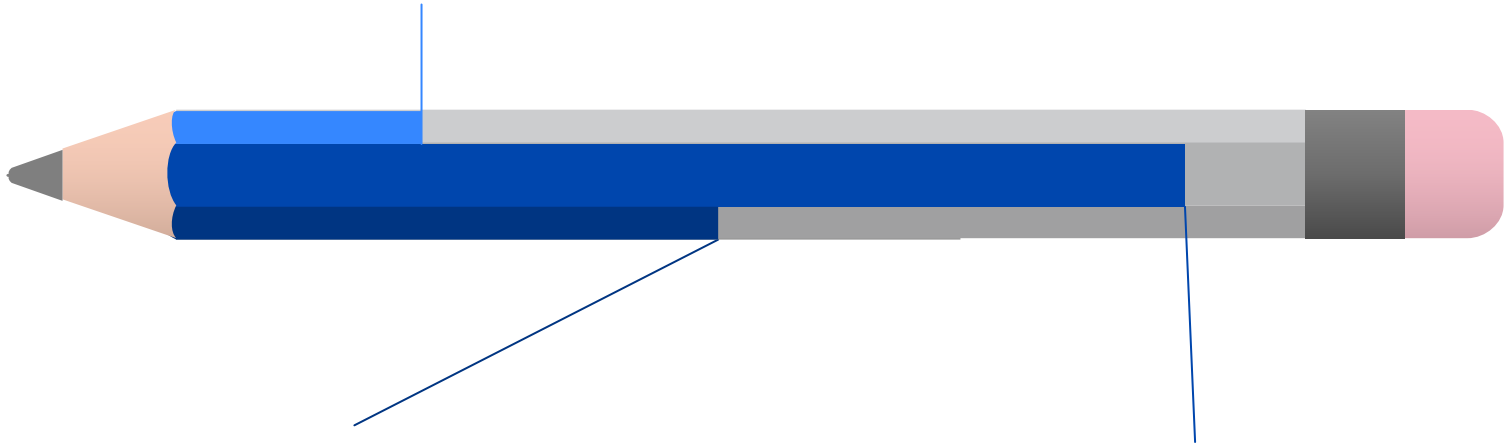
'Serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

(65)
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat;

Article 87: Serious Incident - Timelines of Reporting

Serious Public Health Threat

Immediately not later than 2 Days manufacturer becomes aware of that threat



Death or serious deterioration of state of health (actual)

Immediately not later than 10 Days after the date on which manufacturer becomes aware

Any other serious incident

Immediately any serious incident 15 Days after manufacturer becomes aware

Articles 87-89: Other Obligations: Vigilance , FSCA and FSN

Incidences

(a) any serious incident (Union market) except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting (Art 88)

(b) any field safety corrective action (Union market), including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

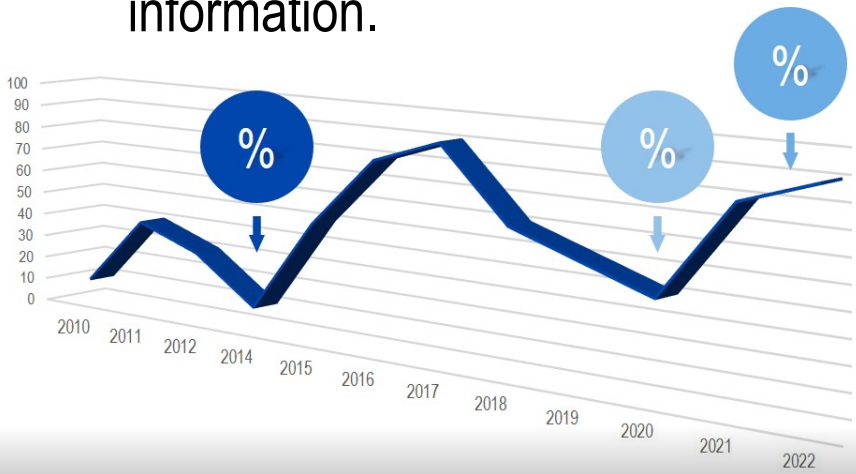
FSCA & FSN

- Cases of urgency: manufacturer needs to undertake FSCA immediately,
- Other cases: the manufacturer shall, without undue delay, report the FSCA -point (b) in advance
- Analysis of FSCA and ensure Field Safety Notice-FSN (Art 89).

Article 88: Trend Reporting

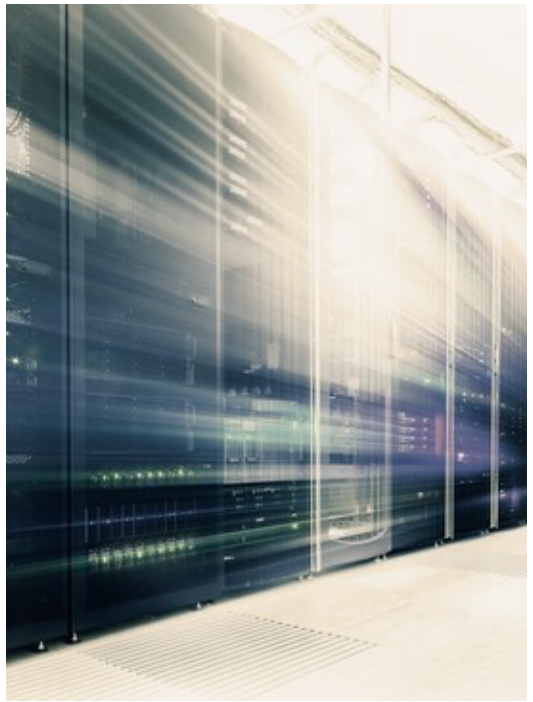
- Manufacturers shall report, by means of the electronic system referred, any statistically significant increase in the frequency or severity **of incidents** that are not serious incidents or that are **expected undesirable side-effects that could have a significant impact on the benefit-risk analysis** referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

- The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.



Article 33: European database on medical devices (Eudamed)

…should integrate different electronic systems to collate & process information regarding:



- Devices on market
- Relevant economic operators
- Certain aspects of conformity assessment
- Notified bodies, scope of designation
- Certificates
- Clinical investigations
- Vigilance & market surveillance

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Dr. Bassil Akra
Vice President
Strategic Business Development
Global Medical Health Service
Bassil.Akra@tuev-sued.de
Phone: +49 89 5008 4421
Fax: +49 89 5008 4403

Contact us:
www.tuv-sud.com
info@tuv-sud.com

Follow us on social media:

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