Medical Device Certification in the EU

Medical Device Regulation

2017/745

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TÜV SÜD

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

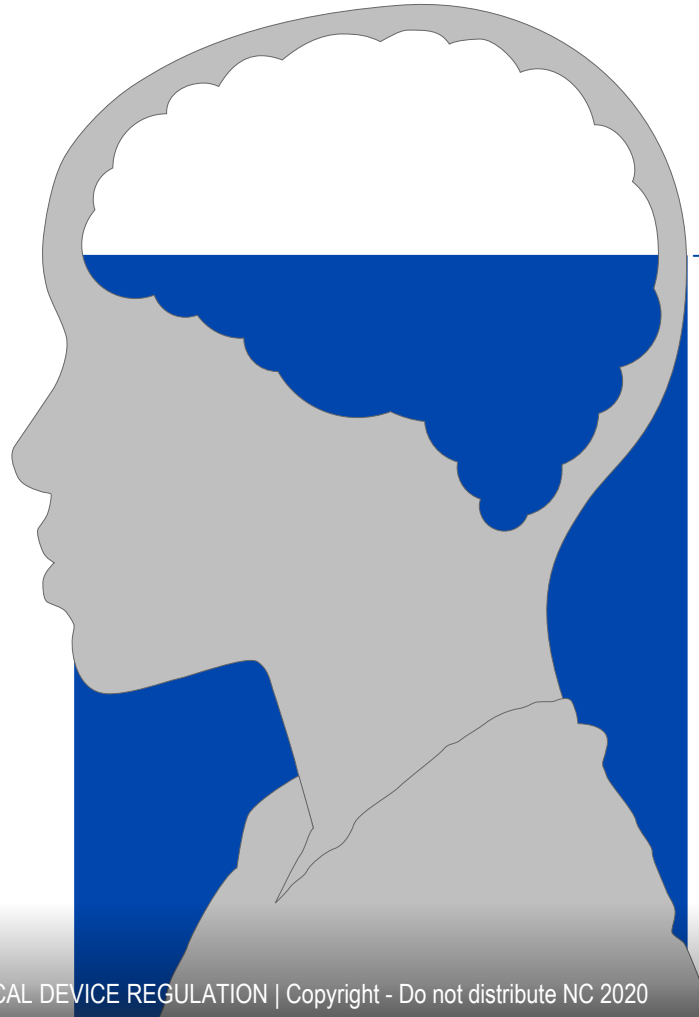
Chapter VII (Art. 83-100):
Post-market surveillance (PMS), post market clinical follow up (PMCF), vigilance, market surveillance, trends, periodic safety update report (PSUR)

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

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

Article 1: Is your device a medical device?

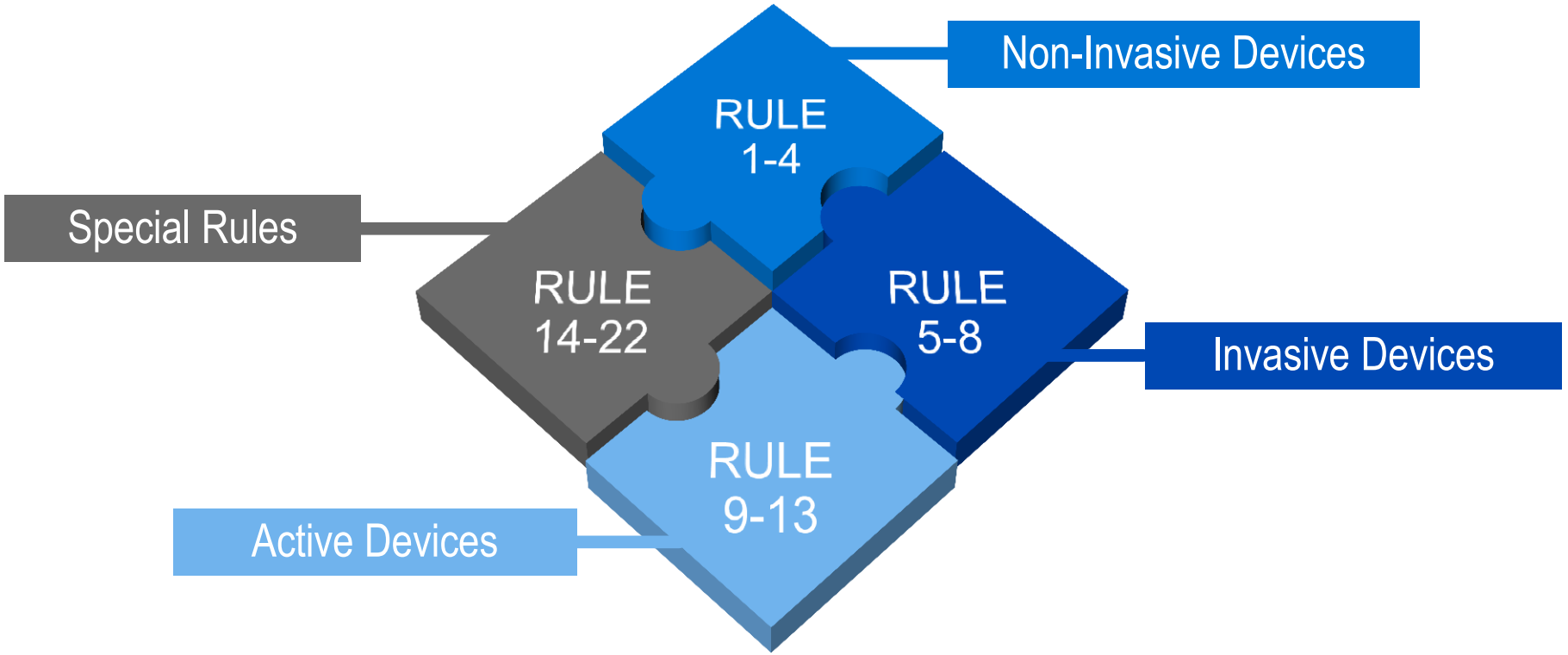
Medical Devices (+ accessories):
"any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, **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

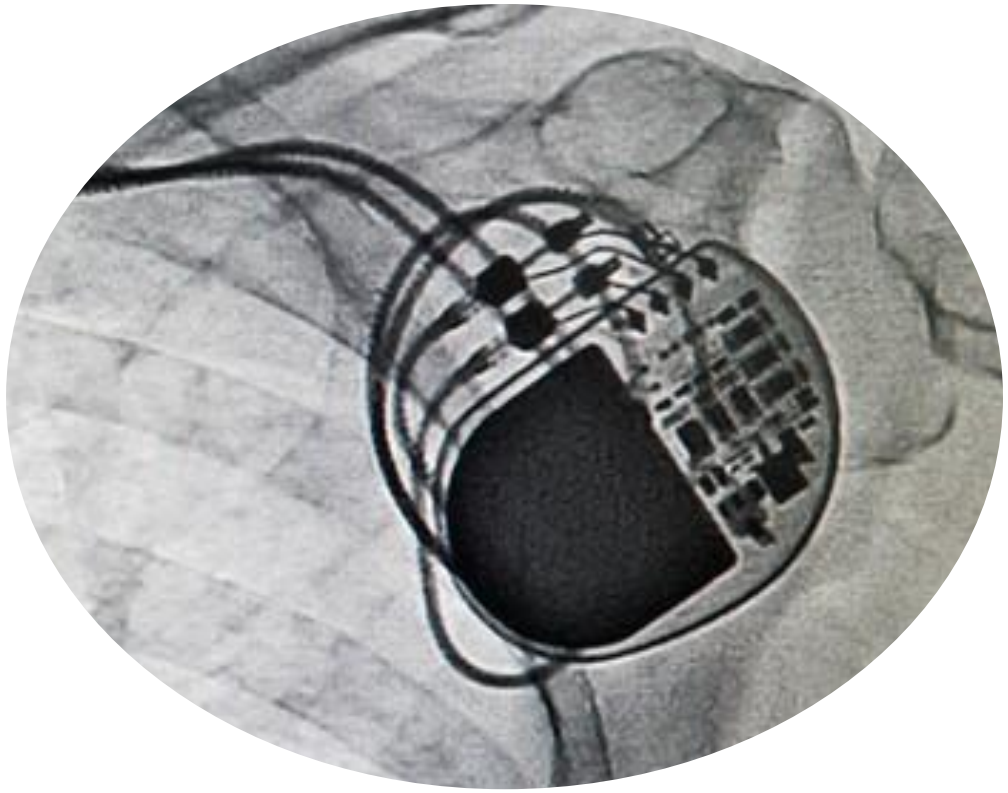
Annex VIII: Classification



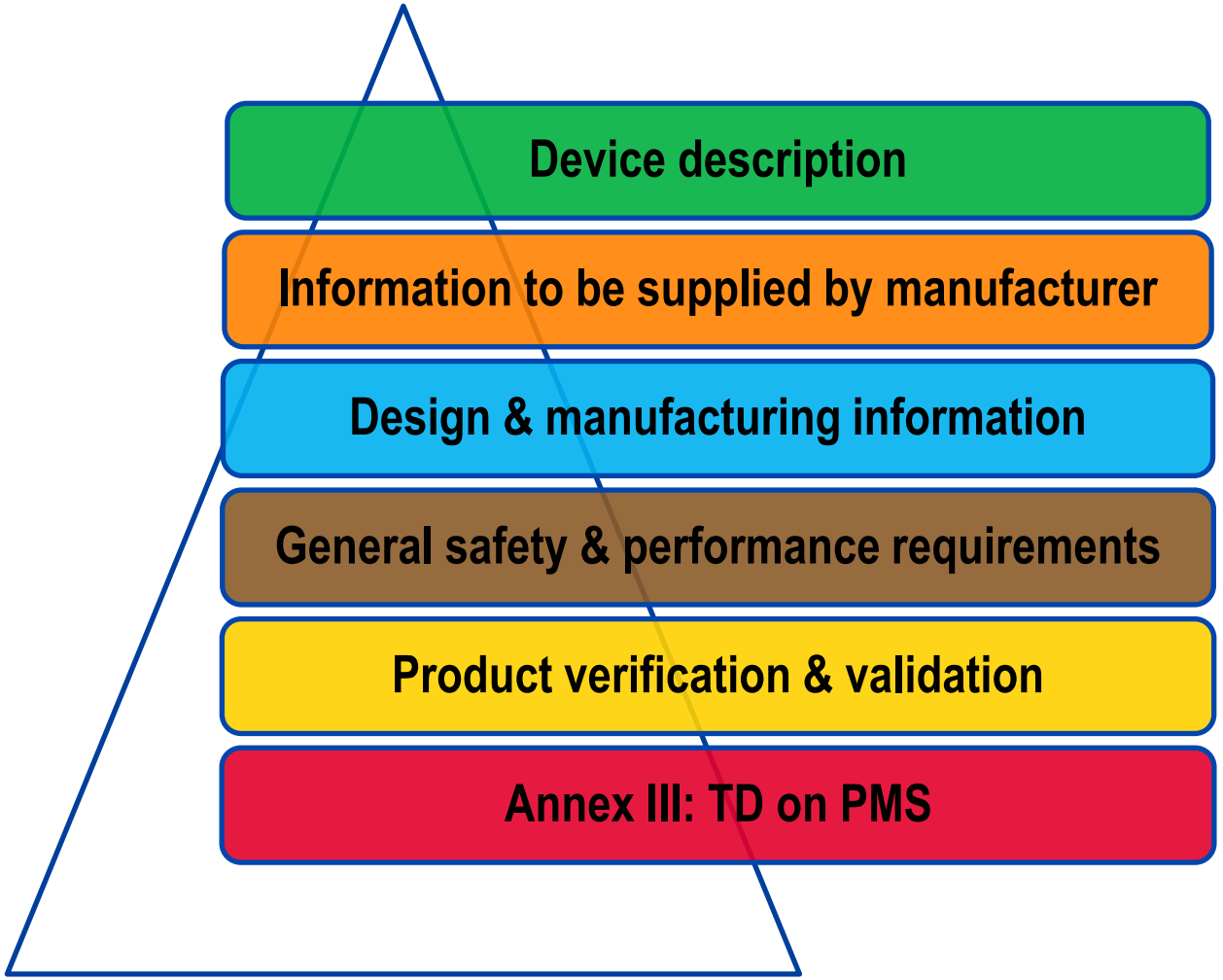
Implantable Medical Device

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

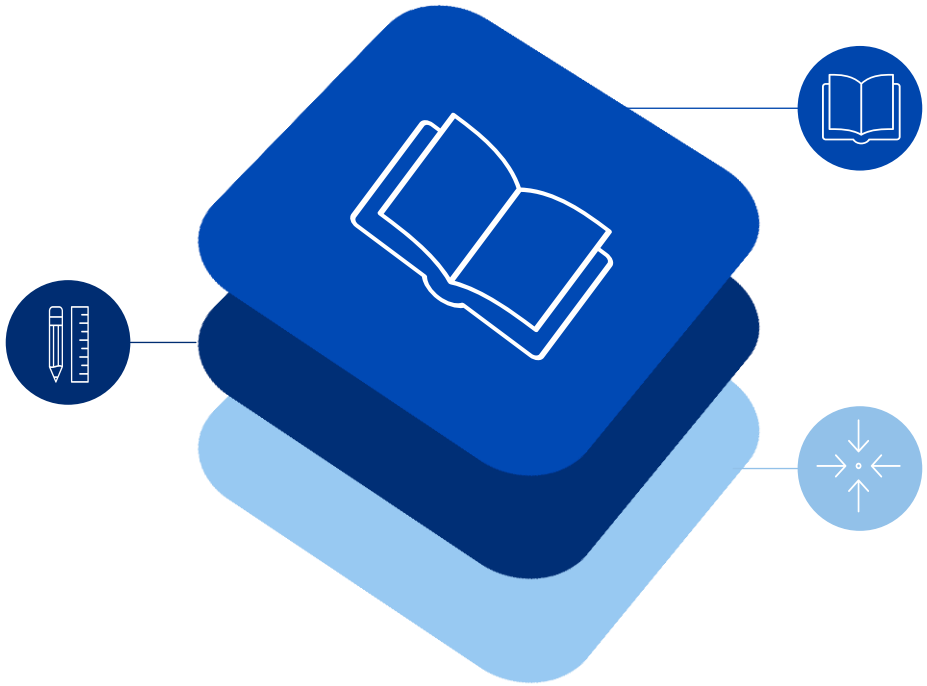


TD Requirements: What does it include?



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

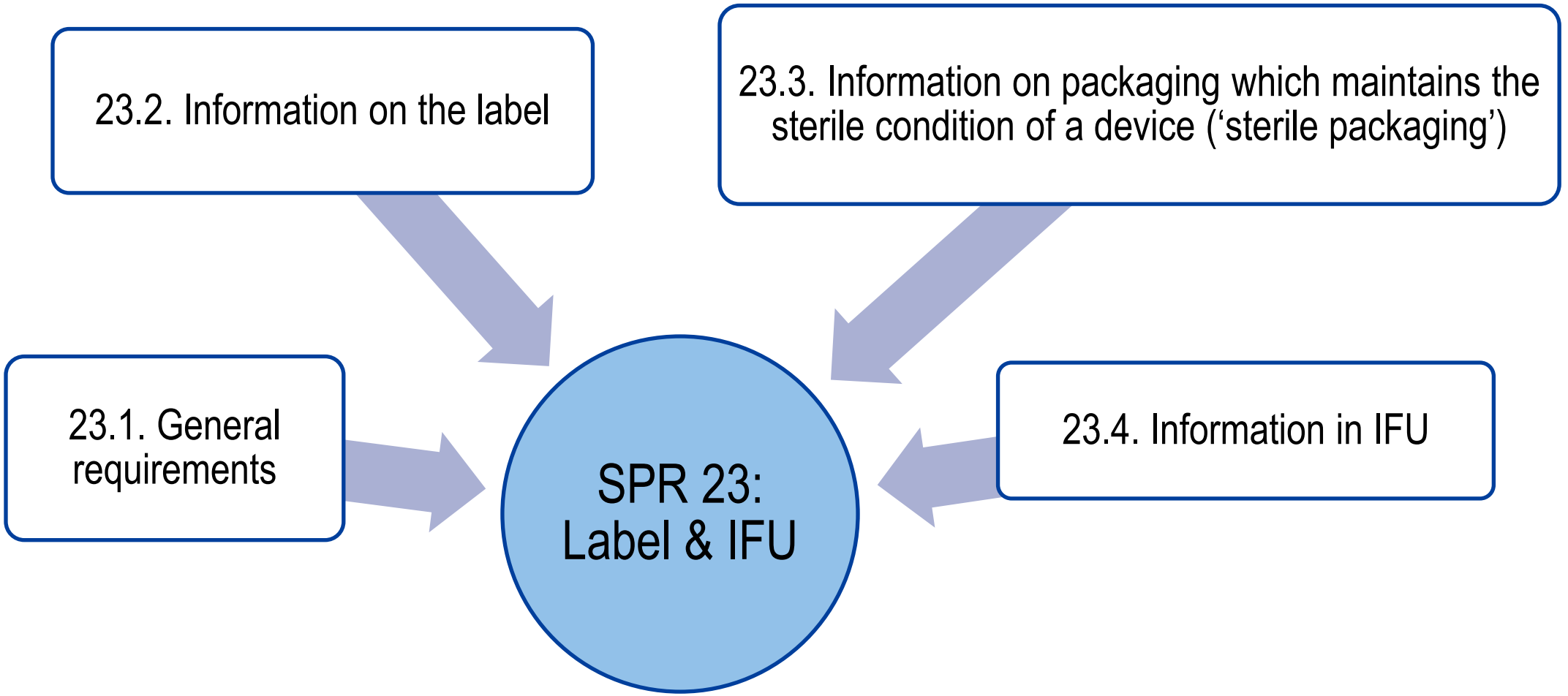
SPR 19: Particular requirements for active implantable devices

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



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

Post-Market Surveillance

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.

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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