Regulatory, quality and clinical affairs

NX-451 – What to know when working with medical devices

Session 3

Kim Rochat

last update 2025-03-09

Regulatory compliance - Medical Device Regulation

EU 2017/745

- Recitals
- Articles (123)
- Annex I
- Annex II
- Annex III
- …
- Annex VIII
- Annex IX

The European Medical Device Regulation:

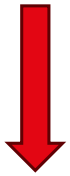
- Regulation Recitals => General principles
- Articles of the regulation (123)
- Annex I: General Safety and Performance Requirements (23)
- Annexes II & III: Technical Documentation Requirements
- Annex VIII: Classification Rules
- Annex IX: Conformity assessment based on a QMS & Tech Doc
- Annex XV: Clinical investigation
- Annex XVI: List of groups of products without an intended medical purpose

Regulatory compliance - Medical Device Regulation

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.



Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

MDR Annex I – General Safety & Performance Requirements

EU 2017/745

- Recitals
- Articles (123)
- **Annex I**
- Annex II
- Annex III
- …
- Annex VIII
- Annex IX

- The Annex I of the European Medical Device Regulation provides essential requirements any medical device place on the EU Market shall achieve.
- The manufacturer shall demonstrate that each of the applicable requirements has been achieved, and the relevant documentation is part of the technical documentation.
- To demonstrate compliance, manufacturer shall provide evidence based on generally acknowledged state of the art.
- In the CE Marking process, the notified body will verify the evidence provided by the manufacturer, this is part of the Conformity Assessment Procedure.

MDR Annex I – General Safety & Performance Requirements

How to design

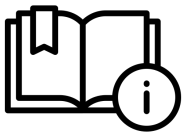
Chapter I of Annex I MDR defines general safety and performance requirements, ensuring that medical devices are designed to minimize risks and provide clinical benefits throughout their lifecycle.

Safety characteristics

Chapter II of Annex I MDR sets safety characteristics to minimize risks associated with the design and the use of the device

Material and packaging

Materials and packaging must be biocompatible, durable, and maintain sterility if required



Information supplied

Chapter III of Annex I MDR sets requirements for labeling and instructions to ensure safe use and risk communication.

Chapter 1

General requirements

Chapter 2

Requirements regarding design and manufacture

Chapter 3

Requirements regarding the information supplied with the device

MDR Annex I – GSPR Details

Chapter 1 - General requirements

1. Intended purpose, safety of patients, users and other persons
2. Reduction of risks
3. Risk management system
4. Risk control measures
5. Risks related to use error
6. Device performance shall not be adversely affected
7. Device design, manufacture, packaging
8. Risk reduction, acceptable risk-benefit ratio
9. General safety requirements for devices without an intended medical purpose as described in in annex XVI

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MDR Annex I – GSPR Details

Chapter 2 - Requirements regarding design and manufacture

1. Chemical, physical and biological properties
2. Infection and microbial contamination
3. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances/substance combinations that are absorbed by or locally dispersed in the human body
4. Devices incorporating materials of biological origin
5. Construction of devices and interaction with their environment
6. Devices with a diagnostic and measuring function
7. Protection against radiation
8. Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves
9. Active devices and devices connected to them
10. Particular requirements for active implantable devices
11. Protection against mechanical and thermal risks
12. Protection against the risks posed to the patient or user by devices supplying energy or substances
13. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

MDR Annex I – GSPR Details

Chapter 3 - Requirements regarding the information supplied with the device

1. Label and instructions for use
    - General requirements
    - Information on label
    - Information on the packaging which maintains the sterile condition of a device
    - Mandatory information in general
    - information to be supplied to the patient with an implanted device

MDR Annex I – State of the art

GENERAL REQUIREMENTS

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

State of the art - definition

"*developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience. (…) It embodies what is* ***currently and generally accepted*** *as* ***good practice in technology and medicine*** *and (…) does not necessarily imply the* ***most technologically advanced solution****. The state of the art (can also be) referred to as the 'generally acknowledged state of the art' "*

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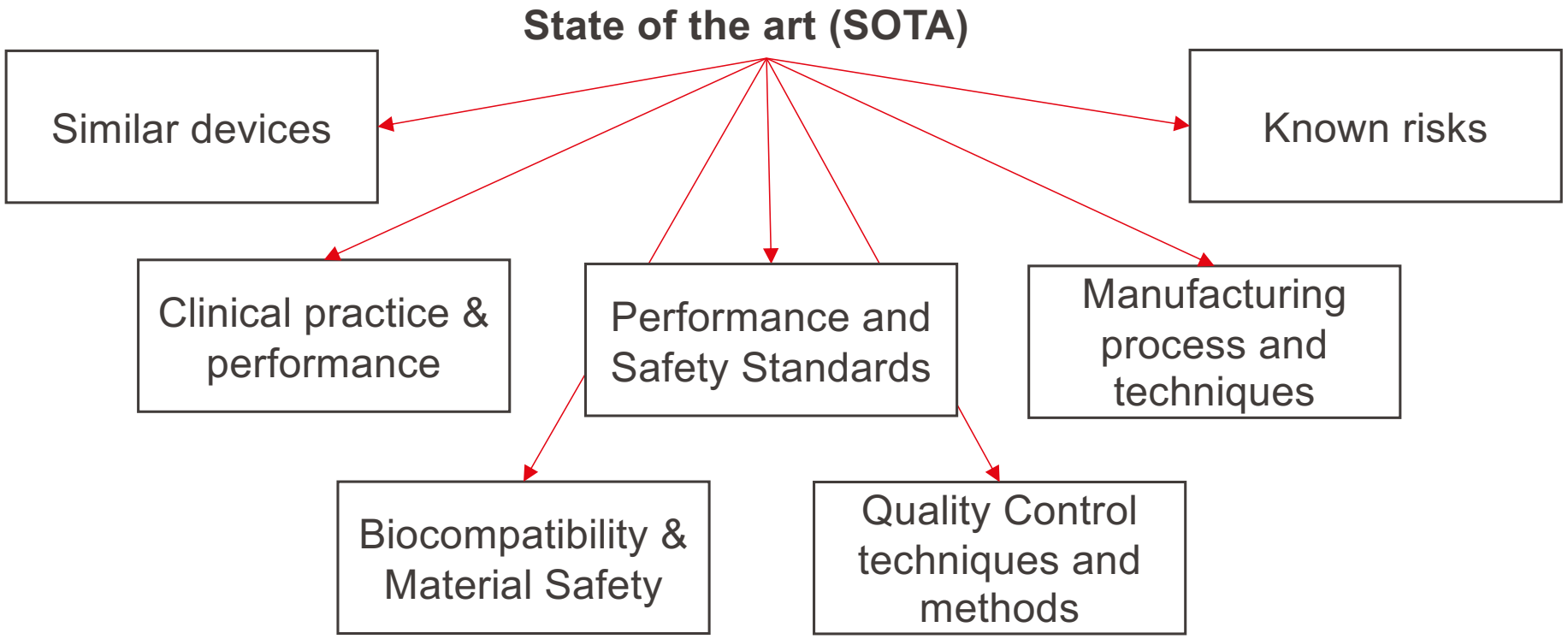
MDR Annex I – State of the art



When working on a (new) device, ensure you have established the state of the art, so you rely on proper evidence and background information.

MDR Annex I – State of the art

State of the art - sources

Peer-reviewed articles / scientific literature

- Research papers evaluated by experts to ensure accuracy and quality before publication. When researchers publish these articles to share innovative findings, improve knowledge, and influence practices they contribute to the State of the Art.
- In the context of MDR, peer-reviewed research helps demonstrate the latest evidence on medical device safety and performance, supporting regulatory compliance.

Technical standards

- Standards are edited by International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) Technical Committees
- Standards are documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose (i.e. ISO 9001, ISO 13485, ISO 14971)
- Recognized method to demonstrate compliance to GSPR requirements (Harmonized Standards)

MDR Annex I – State of the art

State of the art - sources

Common Specifications (CS)

- Common specifications are detailed practical rules setting out how particular types of devices should comply with certain requirements of the MDR/IVDR. They are established by the European Commission when no harmonised standards exist, or they are not sufficient or when there is a need to address public health concerns
- Manufacturers must follow the specifications or show that they have adopted solutions of a level of safety and performance that is at least equivalent.

Guidelines

- Guidelines are published by organization such as MDCG (Medical Device Coordination Group), NBOG (Notified Body Operations Group), IMDRF (International Medical Device Regulators Forum), Notified bodies guidance, Competent Authorities guidance, Medical Society guidance, etc.
- These guidance usually represent the current thinking on a specific regulatory aspect or on a scientific question.

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MDR Annex I – State of the art - Example

Common Specifications (CS)

Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices (Text with EEA relevance)

CHAPTER I
SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules for the application of Article 17(3) of Regulation (EU) 2017/745, where national law has permitted reprocessing of single-use devices and a Member State has decided not to apply all of the rules relating to manufacturers' obligations laid down in that Regulation as regards single-use devices that are reprocessed and used within a health institution.

This Regulation also lays down rules where a Member State has chosen to apply Article 17(3) of Regulation (EU) 2017/745 also as regards single-use devices that are reprocessed by an external reprocessor.

https://eur-lex.europa.eu/eli/reg_impl/2020/1207/oj

MDR Annex I – State of the art

Guidelines

Medical Devices

Medical Device Coordination Group Document MDCG 2021- 24

MDCG 2021-24

Guidance on classification of medical devices

October 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article
2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a represent
Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official po
Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the Eu
binding interpretations of Union law.

IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/AIML WG/N88 FINAL: 2025

Good machine learning practice for medical device development: Guiding principles

MDR Annex I – State of the art

Guidelines – MDCG Guidelines

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

- Annex XVI products – 2*
- Borderline and Classification – 5*
- Class I Devices – 1*
- Clinical investigation and evaluation -17*
- COVID-19 – 11*
- Custom-Made Devices – 1*
- Eudamed – 4*
- European Medical Device Nomenclature (EMDN) – 8*
- Implant cards – 2*
- In-house devices – 1*
- Authorised Representatives, Importers, Distributors – 3*
- Article 10a – interruption or discontinuation of supply – 3*
- In Vitro Diagnostic medical devices (IVD) – 14*
- New technologies – 5*
- Notified bodies – 29*
- Person responsible for regulatory compliance (PRRC) – 1*
- Post-Market Surveillance and Vigilance (PMSV) – 8*
- Standards – 1*
- Unique Device Identifier (UDI) -14*
- Other topics – 8*

* documents, template, Q/A, etc. (over 137)

MDR Annex I – State of the art

Technical standards

MDR Annex I – General standards

ISO 13485 - Quality management systems — Requirements for regulatory purposes

ISO 13485 outlines the requirements for a comprehensive quality management system that organizations must meet to demonstrate their ability to provide medical devices and related services that consistently meet regulatory and customer requirements.

ISO 14971 - Application of risk management to medical devices

ISO 14971 provides a framework for applying risk management to medical devices, focusing on identifying, evaluating, controlling, and monitoring risks throughout the device's lifecycle to ensure safety and compliance with regulatory standards.

IEC 62366-1 - Application of usability engineering to medical devices

IEC 62366-1 outlines the requirements for applying usability engineering to medical devices, emphasizing the design and evaluation of devices to ensure they are safe, effective, and user-friendly for the intended users in real-world conditions.

MDR Annex I – General standards

IEC 62304 - Medical device software – Software life cycle processes

IEC 62304 defines the life cycle processes for medical device software, covering the development, maintenance, and risk management of software to ensure its safety, effectiveness, and compliance with regulatory requirements throughout its lifecycle.

IEC 60601-1 - General requirements for basic safety and essential performance

IEC 60601-1 sets the general requirements for the basic safety and essential performance of medical electrical equipment, ensuring that devices are designed and manufactured to minimize risks to patients, users, and operators.

ISO 10993 - Biological evaluation of medical devices

ISO 10993 provides guidelines for the biological evaluation of medical devices, focusing on assessing the biocompatibility of devices to ensure their safety when in contact with the human body.

MDR Annex I – General standards

ISO 20417 Information to be supplied by the manufacturer

ISO 20417 specifies the requirements for the information that manufacturers must provide with medical devices, ensuring that users and healthcare professionals have the necessary details for safe and effective use of the devices.

ISO 15223-1 Symbols to be used with medical device labels, labelling, and information to be supplied

ISO 15223-1 outlines the general requirements for symbols to be used on medical device labels, labeling, and information supplied, ensuring clear, standardized communication of important safety and usage information to users and healthcare professionals.

ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice

ISO 14155 sets the guidelines for good clinical practice in the clinical investigation of medical devices, ensuring the protection of human subjects and the reliability and quality of clinical data collected during trials.

MDR Annex I – Product related standards

ISO 14534 - Contact lenses and contact lens care products - Fundamental requirements

ISO 14534 specifies the requirements for ophthalmic devices, particularly contact lenses and contact lens care products, focusing on safety, performance, and labeling to ensure they meet regulatory and user needs.

Cardiovascular implants — Endovascular devices — Part 2: Vascular stents

ISO 25539-2 specifies requirements for the design, testing, and performance of vascular stents used in the treatment of arterial diseases, ensuring their safety, effectiveness, and regulatory compliance.

EN 1060-1 - non-invasive sphygmomanometers – General requirements

EN 1060-1 specifies general requirements for non-invasive sphygmomanometers and their accessories, which, using an inflatable cuff, are employed for the non-invasive measurement of arterial blood pressure. It addresses aspects such as performance, efficiency, and mechanical and electrical safety to ensure accurate and reliable blood pressure measurements..

MDR Annex I – Use of standards

Requirement from GSPR

11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

→ **Sterile conditions, sterile packaging**

→ **ISO 11607-1 - Packaging for terminally sterilized medical devices**

ISO 11607-1:2019 specifies requirements for materials, sterile barrier systems, and packaging systems intended to maintain the sterility of terminally sterilized medical devices until use.

→ **Requirement and guidance form the standards**

MDR Annex I – Demonstration of conformity

Use of the template provided in MDCG 2021-8

Requirements from GSPR | Applicability | Method / standard | Relevant document

General safety and performance requirement (GSPR)	Does GSPR apply to the invest. device? Yes/No	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
CHAPTER I, **GENERAL REQUIREMENTS**				
1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.				
2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.				

MDR Annex I – Demonstration of conformity

Use of the template provided in MDCG 2021-8

General Requirements	Applicable [Yes/No]	Internal Documents	Standard	Comments
14. Construction of devices and interaction with their environment				
14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	No	N/A	N/A	Device has no physical features, as it is a software
(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	No	N/A	N/A	Listed environmental conditions are not applicable to Device
(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	No	N/A	N/A	Device Test is a stand-alone software device
(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	Yes	- DOC401 Risk Management Plan - DOC02 Risk Analysis - DOC403 Risk Management Report - DOC620 IEC 82304-1 Compliance Matrix - DOC612-IEC 62304 Compliance Matrix - DoC614-1-0 Infrastructure Adequacy review	- ISO 14971:2019 - IEC 62304:2015 - IEC 82304 :2017 - ISO 27001 :2017	None

MDR Harmonized standards

- Harmonized standards are technical standards which provide a presumption of conformity with the regulation (Article 8 MDR).
- The European Commission publishes the list of harmonized standards in the Official Journal of the EU (OJEU).
- Total number of standards harmonized under the previous directive is 264, while total number of standards for the MDR will only be 63.
- The objective is to speed up market access by reducing the regulatory burden and offering a clear framework for meeting MDR requirements.

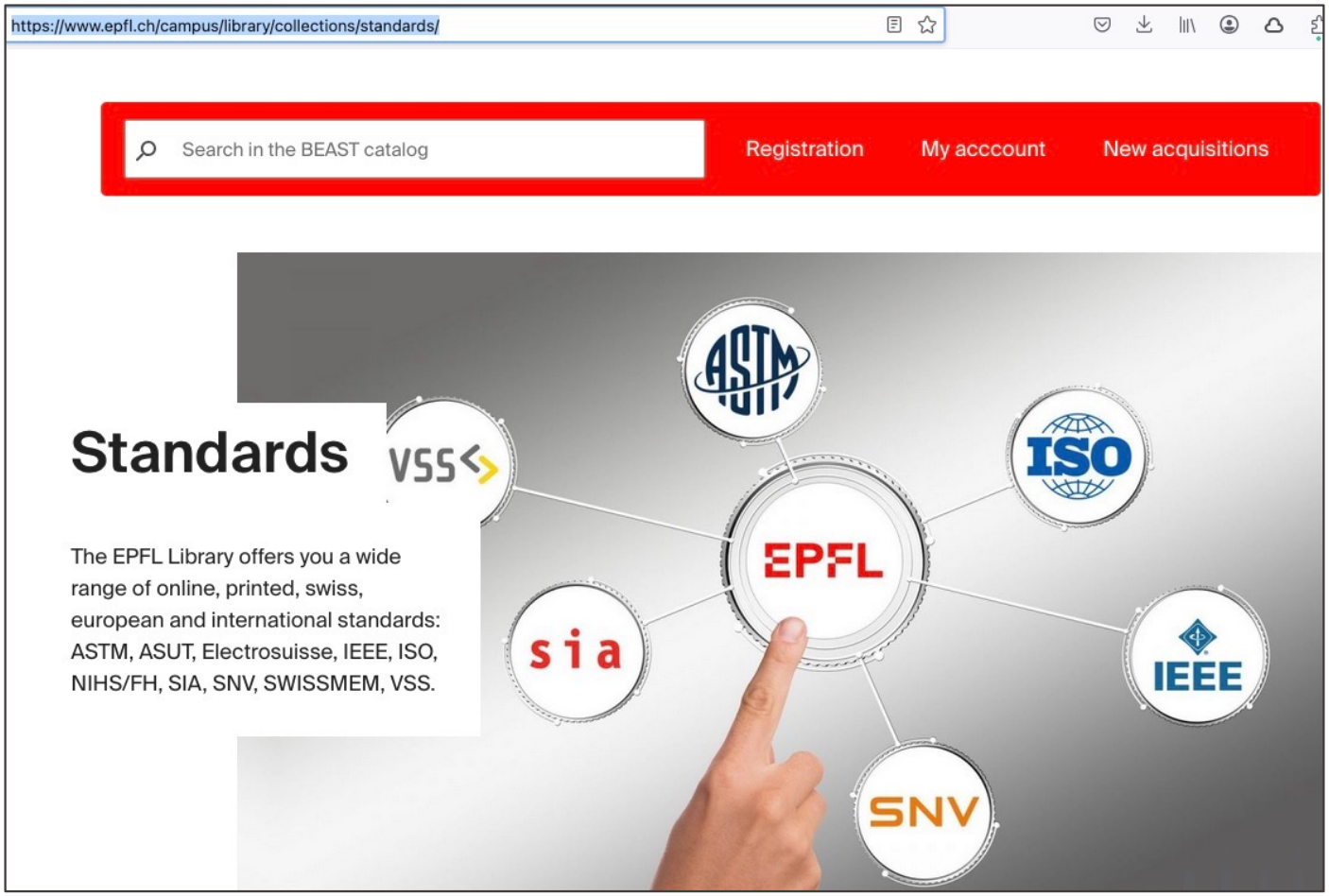
Example: you need to deliver a sterile device => 11737

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)
2017/745	CEN	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	19/07/2021	OJ L 256 - 19/07/2021

Link to Harmonized standards: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

MDR - Access to standards

https://www.epfl.ch/campus/library/collections/standards/



MDR Annex II & III – Technical Documentation

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

4. Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

MDR Annex II & III – Technical Documentation

Key domains of Annex II & III

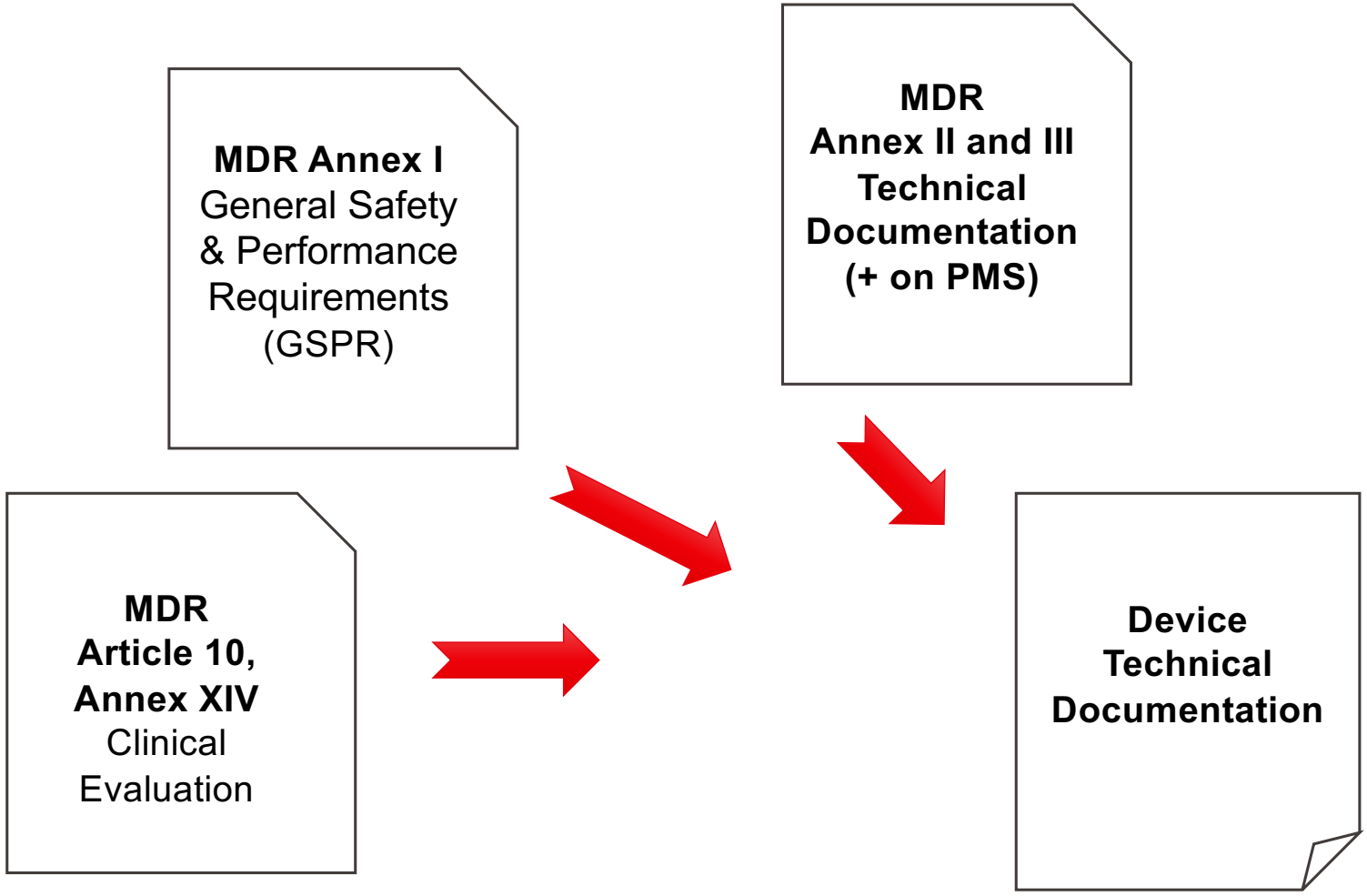
1. **Device Description and Specification**
   - General description, intended purpose, and classification.
   - Versions, accessories, and variants of the device.
   - Raw materials and manufacturing processes.
2. **Labeling and Instructions for Use (IFU)**
   - Labels, symbols, and packaging specifications.
   - Instructions for use (mandatory unless exempted).
3. **Design and Manufacturing Information**
   - Detailed description of design and manufacturing processes.
   - Control measures and quality assurance during manufacturing.
4. **General Safety and Performance Requirements (GSPR)**
   - Evidence of compliance with applicable GSPR (Annex I).
   - Justifications for any non-applicable requirements.

MDR Annex II & III – Technical Documentation

Key domains of Annex II & III

5. **Benefit-Risk Analysis and Risk Management**
   - Risk management file based on ISO 14971.
   - Benefit-risk analysis and mitigation measures.
6. **Product Verification and Validation**
   - Pre-clinical and clinical data supporting performance and safety.
   - Software validation (if applicable).
   - Electrical, mechanical, and biological safety testing.
   - Sterilization, packaging validation, and shelf-life data.
7. **Clinical Evaluation and Post-Market Surveillance (PMS)**
   - Clinical evaluation report (CER) and clinical data.
   - Post-market surveillance (PMS) plan and periodic reports.

MDR Annex II & III – Technical Documentation



MDR Annex II & III – Technical Documentation

ISO 13485 - Quality management systems — Requirements for regulatory purposes

ISO 13485 outlines the requirements for a comprehensive quality management system that organizations must meet to demonstrate their ability to provide medical devices and related services that consistently meet regulatory and customer requirements.

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;

b) specifications for product;

c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;

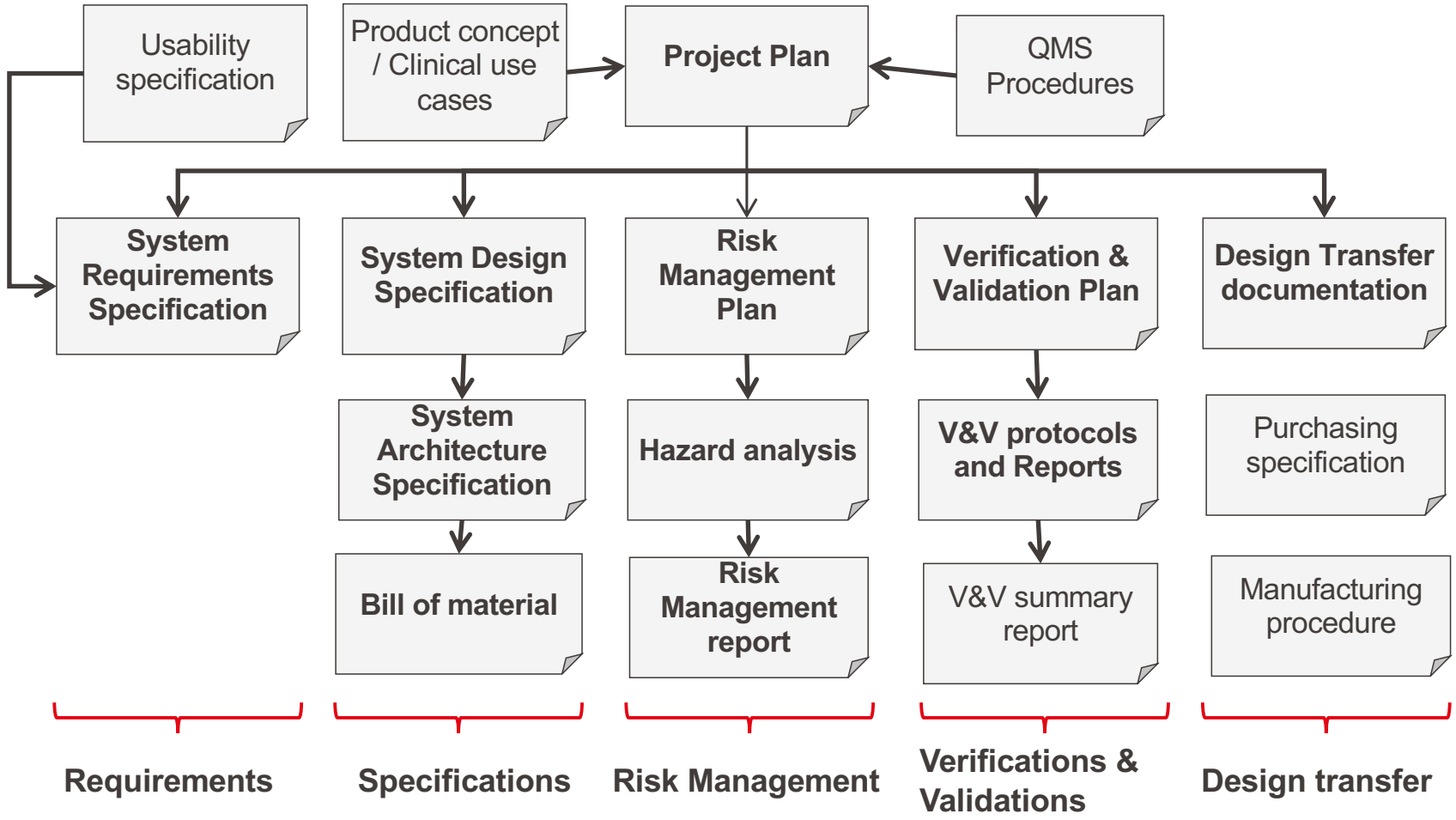
d) procedures for measuring and monitoring;

e) as appropriate, requirements for installation;

f) as appropriate, procedures for servicing.

MDR Annex II & III – Technical Documentation

Simplified vision of a technical documentation



MDR Annex II & III – Technical Documentation

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Key items per development phase

Development phase	Key deliverables
Users Requirements definition	• Product brief / Concept (key features, intended use) • User Requirements Specification (URS) • Initial risks assessment • IP Review (Freedom to operate)
Development planning	• Project development plan • Risk management plan • Planned documentation
Requirements analysis and product Design	• System Requirements specification, Hardware Requirements specification, Software Requirements specification, • Packaging & labelling requirements • Risks analysis with control measures • Use specification, User interface specification • System Verification Plan

MDR Annex II & III – Technical Documentation

Key items per development phase

Development phase	Key deliverables
Implementation and verification	• System design specifications (hardware, mechanical, electrical etc.) • Drawing, schematics, assembly plans, etc. • Packaging specification • Development of manufacturing process map • Development of the first prototypes
Verification and validation	• Development of verifications and validations protocols • Execution of test, development of test reports • Usability study report • Clinical investigation report
Design transfer	• Manufacturing documents (i.e. work instructions, etc.) • Manufacturing quality plan, Purchasing specifications • Supplier qualifications reports • Validation master plan • Process validation reports

MDR Annex II & III – Technical Documentation

Table of content of a Software Medical Device – Class IIa

01-General
- 100 Master document List
- 101-Product Presentation
- 102-Device Roadmap
- 103-Software developement plan
- 104-Review logs
- 105-MDR Submission Checklist

02-Requirements
- 121-Use cases
- 122-Use specification
- 123-Requirements Specifications

03-Specifications
- 301-Architecture & Detailled design
- 302-UI Specification

04-Risk Management & Usability
- 401-Risk Management Plan
- 402-Risk Analysis
- 403-Risk Management Report
- 404-Usability Engineering File

05-Labeling & UDI
- 501-Instruction for Use
- 502-User interface
- 503-Screen interface
- 504-Labeling specification
- 505-Language specification

06-Verification & Validation
- 601-V&V Plan
- 602-Functional testing protocol
- 603-Functional testing report
- 604-Clinical function verification protocol
- 605-Clinical function verification report
- 606-Usablity testing protocol
- 607-Usability testing report
- 608-User Acceptance Test protocol
- 609-User Acceptance Test report
- 610-62304 Compliance Matrix
- 611-Infrastructure adequacy review
- 612-Labelling and content inspection protocol
- 613-Labelling and content inspection report
- 616-V&V Matrix
- 617-V&V report
- 618-62366-1 Compliance Matrix
- 619-82304-1 Compliance Matrix

07-Clinical Data
- 701-Clinical evaluation plan
- 702-Clinical evaluation report
- 703-Literature
- 704-Clinical data
- 705-PMS Plan
- 708-PMCF & PMS Plan
- 709-PMCF & PMS Plan

08-Regulatory
- 801-Declaration of conformity
- 802-Regulatory note
- 803-GSPR Checklist
- 805-Expert opinion
- 806-Declaration of conformity

09-Production of Service
- 901-Supplier quality agreement
- 902-Software release report
- 903-Released versions & UDI
- 904-Product Release meeting notes

Over 1000 pages!

MDR Annex IX, X & X – Conformity assessment

"Conformity assessment" means the process demonstrating whether the requirements of the Regulation relating to a device have been fulfilled; (Art 1, MDR)

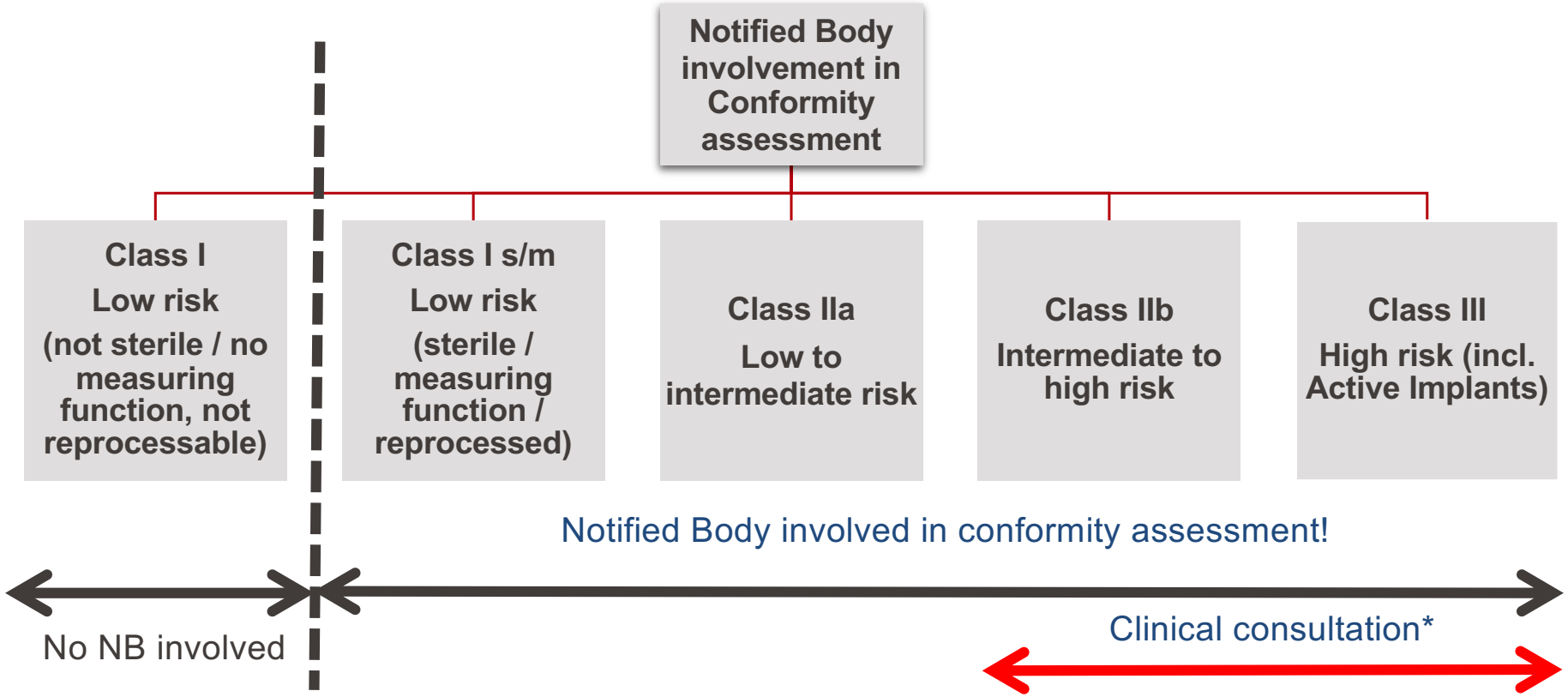
- Conformity assessment is the **responsibility of the manufacturer**

*"We declare **under our sole responsibility** that the medical device "xyz" of class IIb **meets all the provisions** of the Regulation EU 2017/745 which applies to it…"*

- Depending on the risk involved with the device, a **Notified Body** must be involved

MDR Annex IX, X & X – Conformity assessment

"Conformity assessment" means the process demonstrating whether the requirements of the Regulation relating to a device have been fulfilled; (Art 1, MDR)



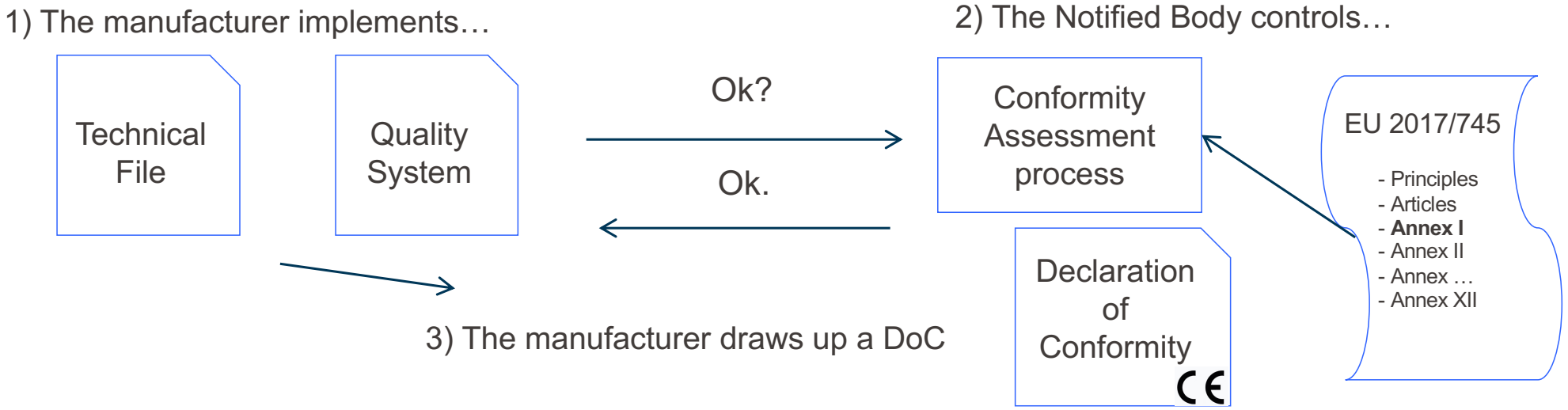
**Only for class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal products*

MDR Annex IX, X & X – Conformity assessment

There are two main ways to demonstrate conformity assessment 1) Annex IX 2) Annex X & XI

Annex IX of MDR 2017/745 outlines the Conformity Assessment Based on a Quality Management System and Assessment of the Technical Documentation

- Quality Management System (QMS) Assessment is performed by the Notified Body to ensure compliance with the MDR and ISO 13485.
- The manufacturer submits technical documentation for at least one representative device per generic device group for review by the Notified Body who check compliance with GSPR



MDR Annex IX, X & X – Conformity assessment

Annex X describes the Type Examination procedure. This process involves a Notified Body evaluating a representative sample of a device

- The manufacturer submits a representative device sample along with technical documentation.
- The Notified Body examines the design and manufacturing process to verify compliance with GSPR.
- The Notified Body conducts conducts inspections, laboratory tests, and performance evaluations if necessary.
- The manufacturer must inform the Notified Body of any modifications to the device that could affect compliance.

Annex XI outlines two conformity assessment procedures that manufacturers can follow to demonstrate compliance with the Medical Device Regulation (MDR) 2017/745. These procedures most of the time used in addition to the procedure defined in Annex X

- Part A (Production Quality Assurance) → Requires a full QMS but allows self-declaration after approval.
- Part B (Product Verification) → No QMS needed, but each device or batch is tested by the Notified Body.

MDR Annex IX, X & X – Conformity assessment

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1) The manufacturer implements…

Technical File

Ok?

Ok.

2) The Notified Body controls…

Conformity Assessment process

EU 2017/745

- Principles
- Articles
- **Annex I**
- Annex II
- Annex …
- Annex XII

3) The Notifies body controls…

Each devices 

or

Production Management system

3) The notified body draws up a PoC

Product certificate

CE

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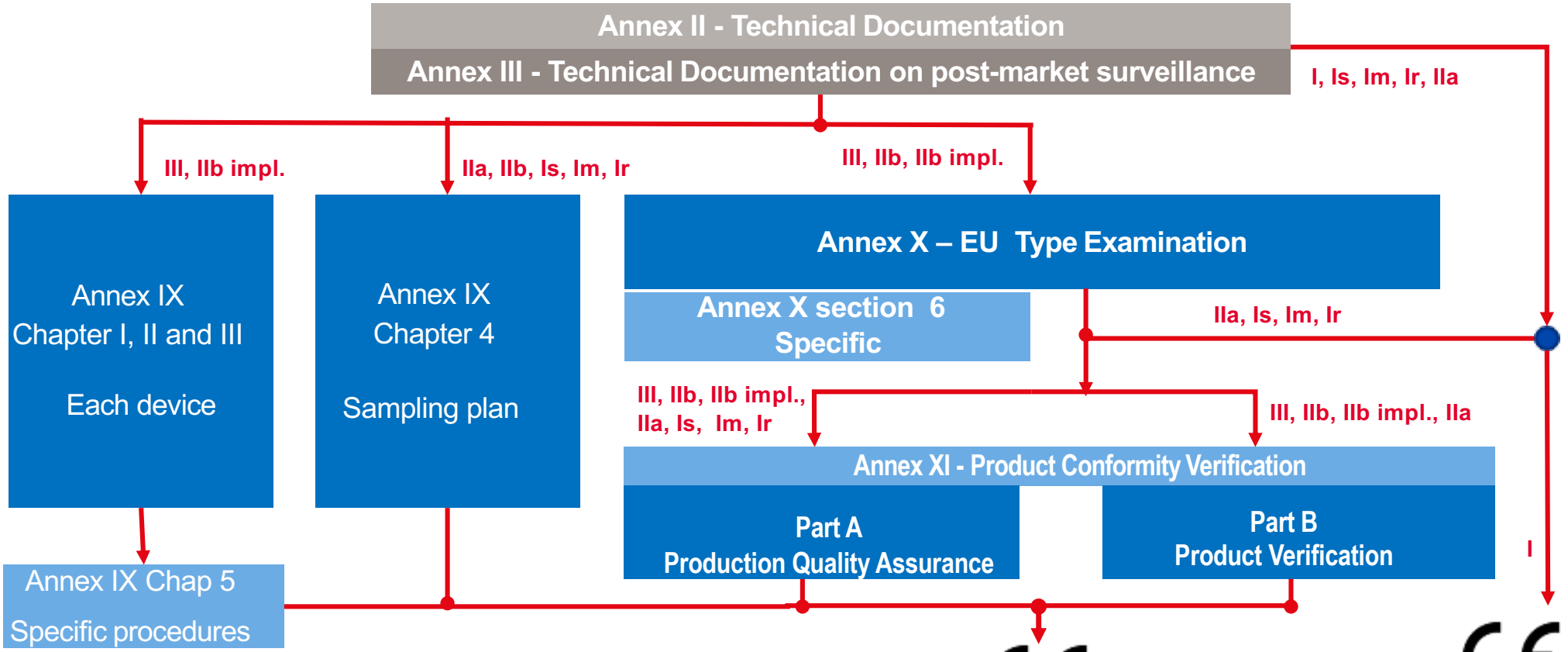
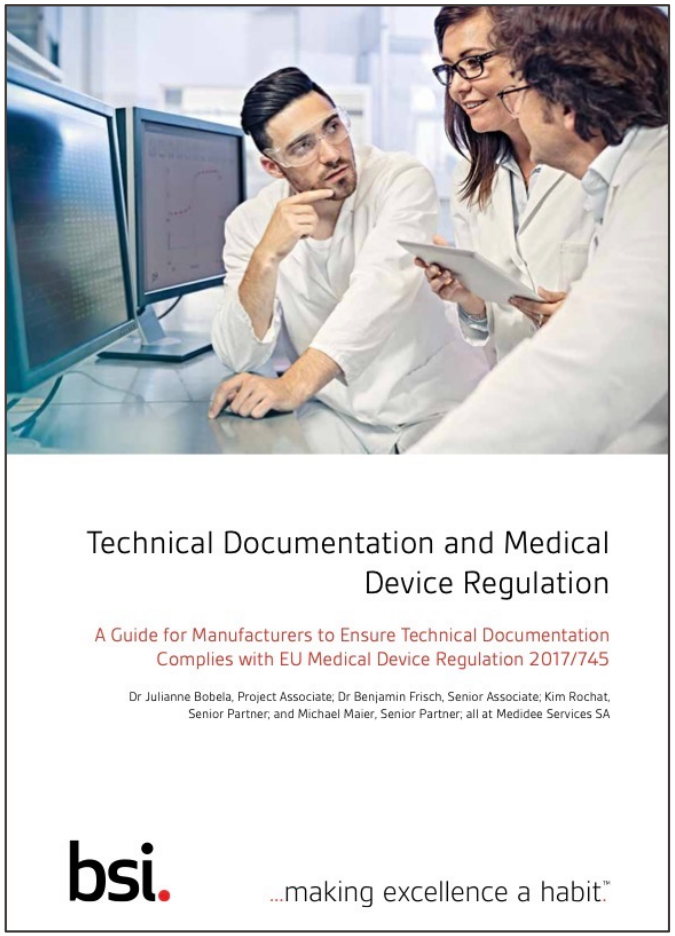
MDR Annex IX, X & X – Conformity assessment

"Conformity assessment" means the process demonstrating whether the requirements of the Regulation relating to a device have been fulfilled; (Art 1, MDR)



*Class III implantable devices, class III with incorporated medicinal product, class III utilising tissues or cells of human or animal origin, class IIb active devices intended to administer and/or remove a medicinal product

MDR Annex I, II, III, IX, X & X



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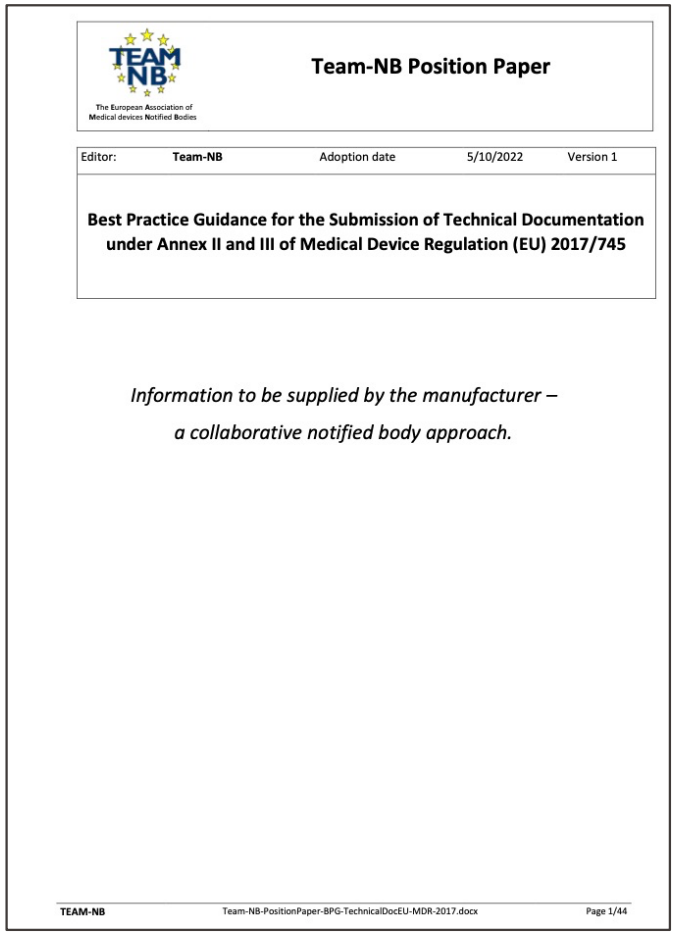

https://www.team-nb.org/wp-content/uploads/2022/10/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V1-20221005.pdf

Q&A