Journée croisée des *GDR*

B2I et *Réparer l'Humain*

13ème journée thématique

30 septembre 2024

Les dispositifs médicaux : de l'aspect réglementaire à la mise sur le marché

PARIS - Campus Pierre et Marie Curie

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A medical device:

… what is it ?

Classic baby bootle

No

Hip prosthesis

Yes

Bandage

Yes

Syringes

Yes

Condom

Yes

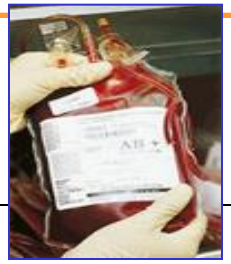
Pre-filled syringes

No

Needles container

No

Blood bag

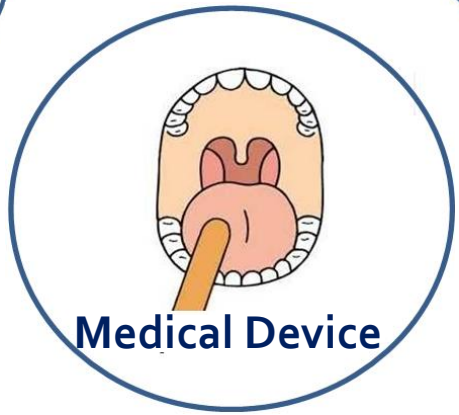


Yes

How do you know if a product is a medical device?

- How does it work? What is its intended use?
- What are the requirements, the performances?
- What "regulatory" definition does it meet?

For example :
wooden sticks



Not the same regulations, directives, standards

Medical device : MDR 2017/745 - definition

- means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
  - 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,
- …

Medical device : MDR 2017/745 – definition (cont.)

- 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.

- The following products shall also be deemed to be medical devices:
  - devices for the control or support of conception;
  - products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Two regulations: for **MD** and **IVD**

2017/745 and **2017/746**

- With effect from 26 May 2021, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on **medical devices** replaced Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.

HTML link : (EU) 2017/745

- With effect from 26 May 2022, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on **in vitro diagnostic medical devices** replaced Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

HTML link : (EU) 2017/746

Medical device regulations: What are they for?

- Reinforcing the safety of medical devices in the interests of patients

Including:

- Meet general safety and performance requirements (GSPR)
- Assess the risks
- Demonstrate the risk/benefit ratio

Medical device regulations: what are the consequences ? …

CE

- All medical devices must be certified according to a set of regulations
- In Europe, compliance with these regulations is reflected in the CE medical mark.
- This mark guarantees that the medical device meets requirements in terms of safety and clinical benefits.

These requirements apply to all medical devices

GSPR : Lien HTML : (EU) 2017/745 – ANNEX I

Medical device :
Many, many different devices…









But also … different levels of risk

Risk classification

- The general safety and performance requirements are identical for all products,

… but …

- The way in which compliance with the requirements is demonstrated depends on the risk class of the medical device.

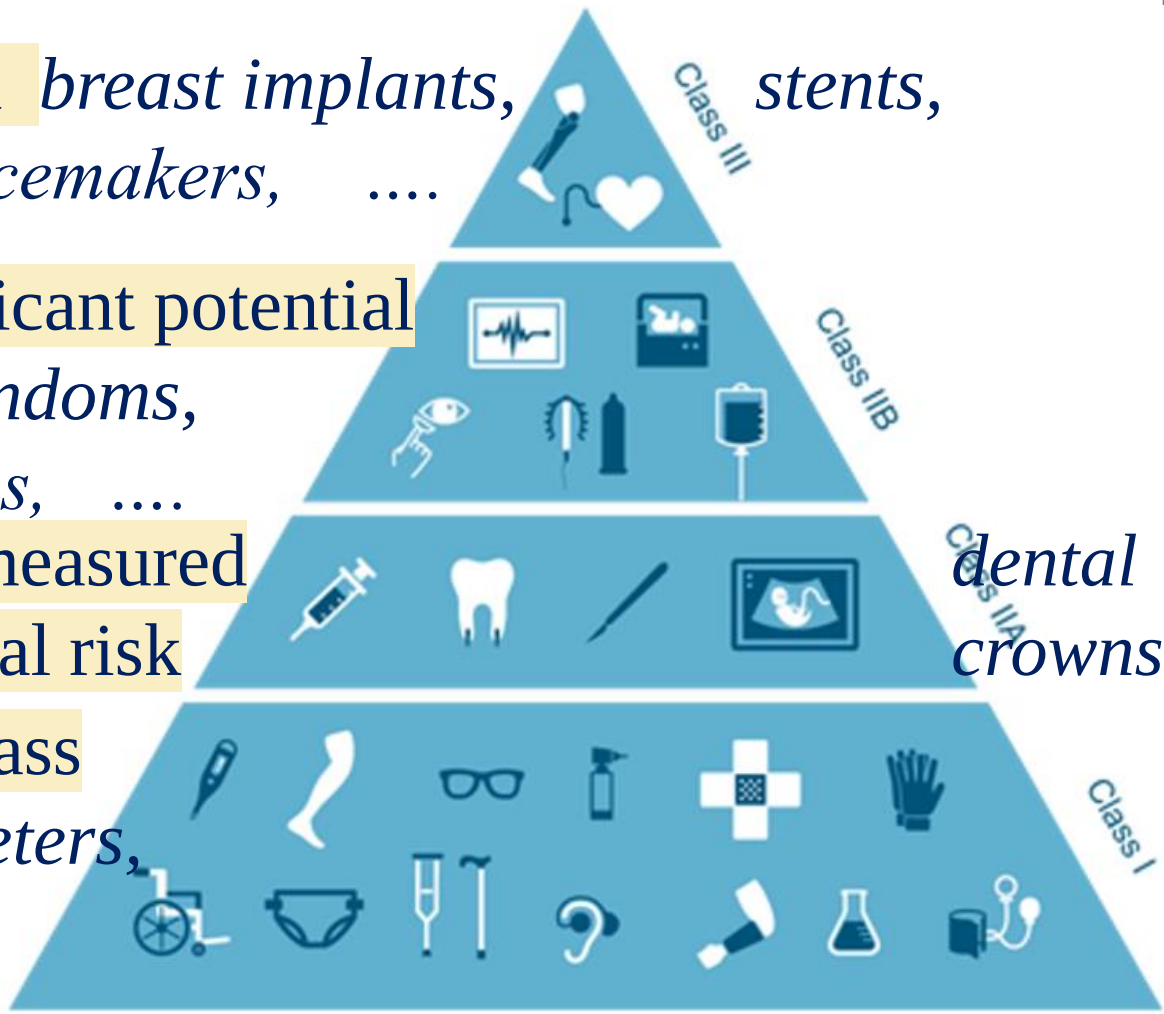
Risk classification : according to risk

Class III: highest risk *breast implants, stents, hip prostheses, pacemakers, ….*

Class IIb: high/significant potential risk *condoms, radiotherapy systems, ….*

Class IIa: moderate/measured potential risk *hearing aids, dental crowns*

Class I: lowest risk class *compresses, thermometers, medical beds, …*



Rules 1 to 22 : Lien HTML : (EU) 2017/745 – ANNEX VIII

CE Marking : need two approaches

CE

Description of the product

MDR 2017/745

Description of the organization

Regulatory Affairs (RA)

Quality Assurance (QA)

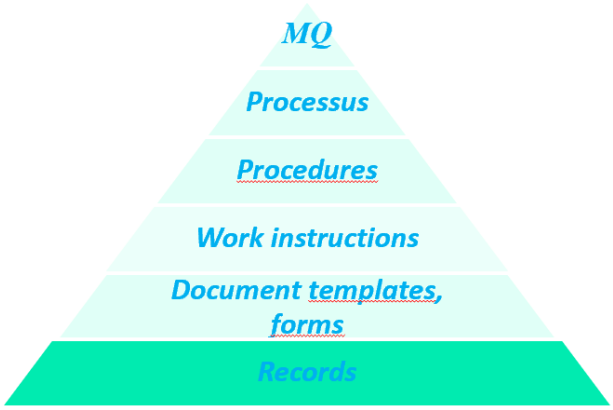
- **TECHNICAL FILE**
- For each range of medical devices

- **Quality Management System (QMS)**

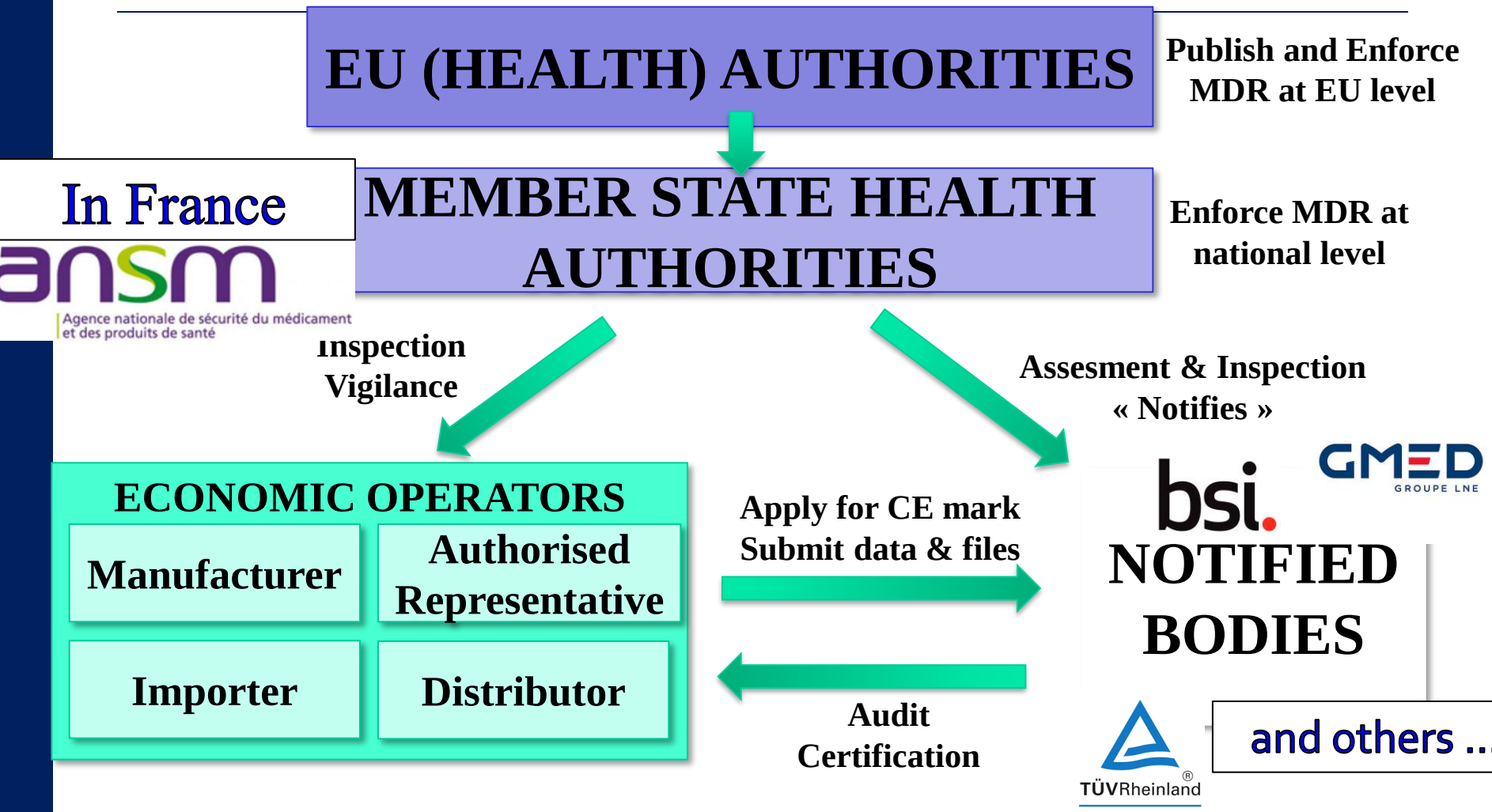
Notified Bodies (NB)

CE Certificates

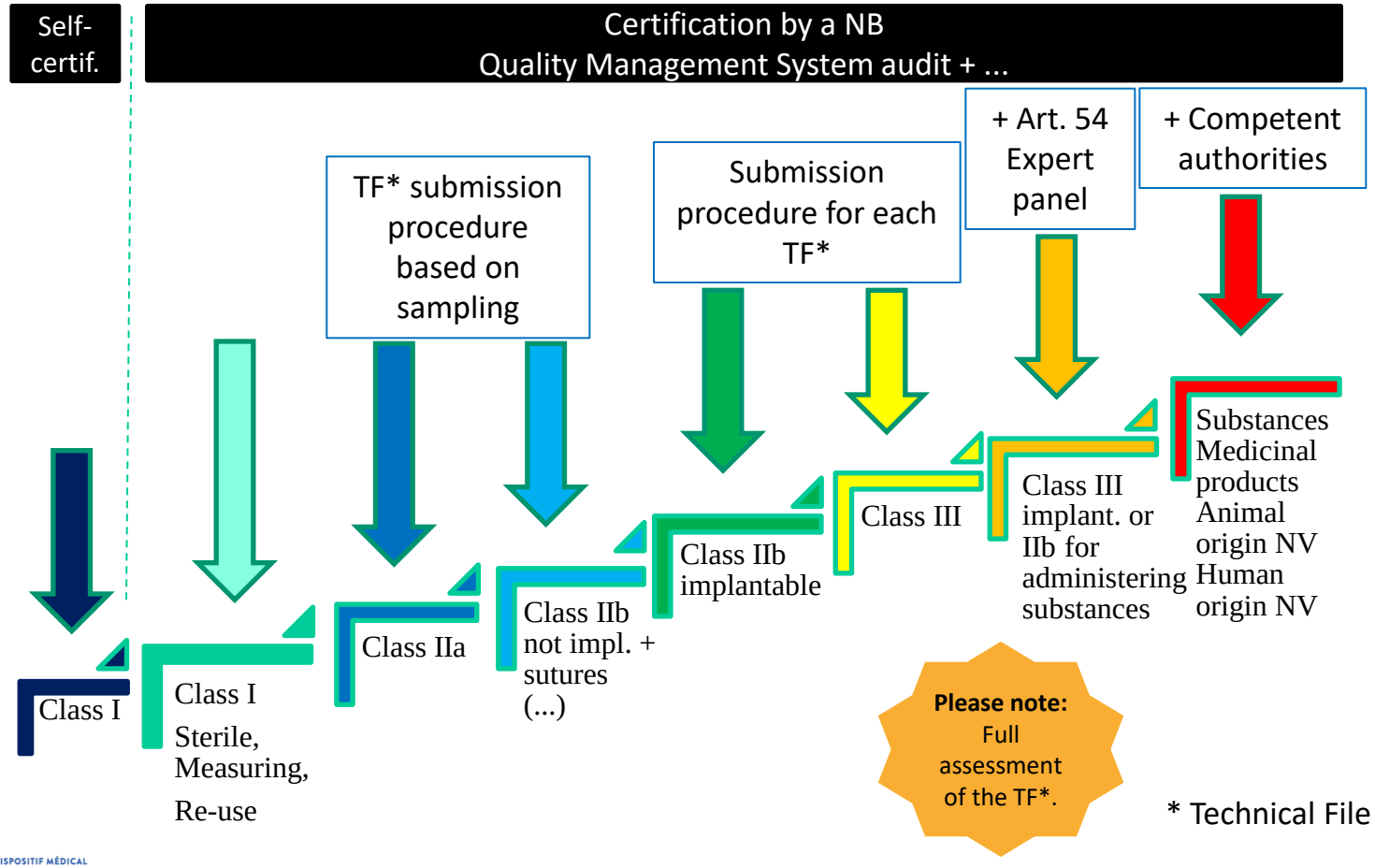
QMS Certificates



Economic Operators, Notified Bodies and Authorities



The assessment procedures (MDR 2017/745 - Art. 52)



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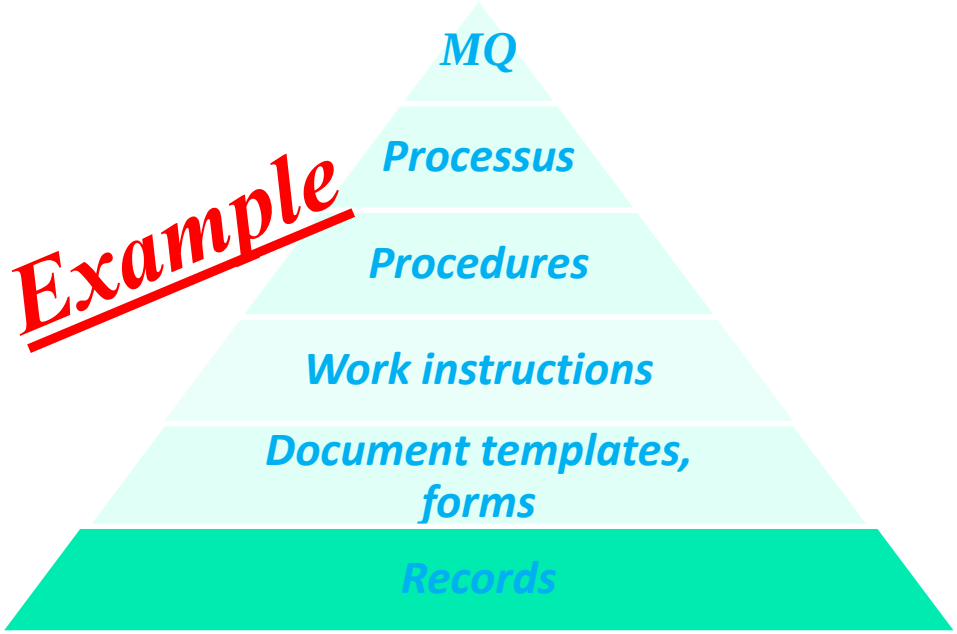
QMS : Quality Management System

- Documentary structure for the QMS



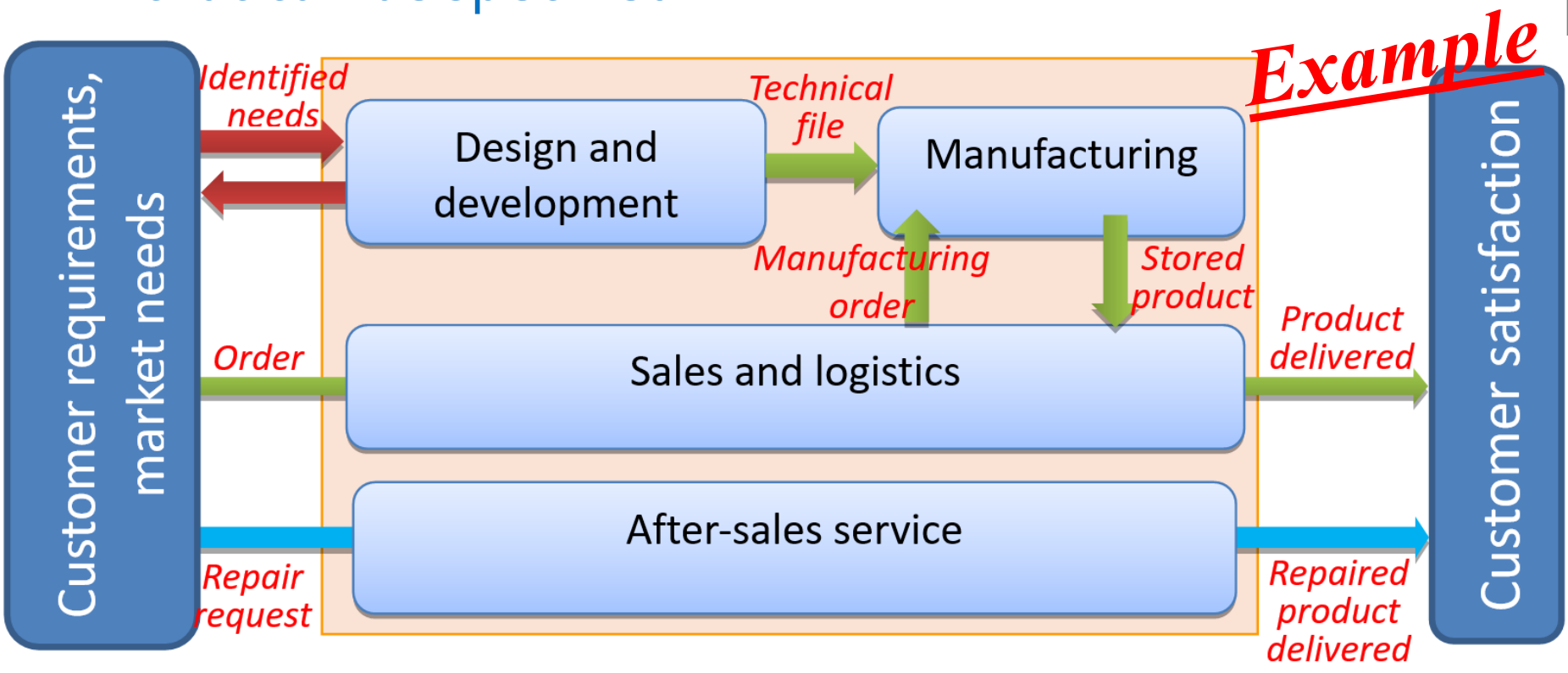
Documented procedures
required by the standards :

- Design and development
- Purchase
- Curtomer complaints
- Post market surveillance
- …

Records are proof of the activities carried out, to meet the requirements

QMS : Quality Management System

- Need to determine processes in the QMS
- A QMS process is a set of activities, with a result that can be specified



MDR 2015/745
Technical Documentation

- "The documentation for CE marking of medical devices, as well as the technical documentation for the PMS, shall describe the devices subject to CE marking."

- "The technical documentation to be drawn up by the manufacturer shall be presented in a clear, organized, easily consultable and unambiguous manner and shall include in particular the elements listed in this Annex."

MDR 2015/745 Annex II and III: Technical Documentation

ANNEX II - TECHNICAL DOCUMENTATION

- DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
- INFORMATION TO BE SUPPLIED BY THE MANUFACTURER
- DESIGN AND MANUFACTURING INFORMATION
- GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
- BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
- PRODUCT VERIFICATION AND VALIDATION
  - Pre-clinical and clinical data
  - Additional information required in specific cases

ANNEX III - TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

MDR 2015/745 Annex II : Technical Documentation

- DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
  - Device description and specifications
  - Reference to previous and similar generations of the device
- INFORMATION TO BE SUPPLIED BY THE MANUFACTURER
  - Labels (complete set)
  - Instruction for use
- DESIGN AND MANUFACTURING INFORMATION
  - Design stage of the devices
  - Specification, manufacturing process, validations, testing, monitoring
  - All production / sub-contractor sites listed
- GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
  - Requirements set out in Annex I
  - Applicability / Demonstration of conformity / Harmonized standards / evidence documentation (table)

… / ….

MDR 2015/745 Annex II : Technical Documentation

…. / …

- BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
  - Benefit-Risk refered to in section 1 and 8 of Annex I
  - Solutions adopted and result of the risk management refered to in secion 3 of Annex I
- PRODUCT VERIFICATION AND VALIDATION
  - Pre-clinical and clinical data
    - Biocompatibility, identification of all material in contact direct or indirect with patient
    - Physical, chemical, microbological characterization
    - Electrical safety and electromagnetic compatibility;
    - Software validation and verification
    - Stability testing , including shelf life
    - Clinical Evaluaton Report
    - Post-Market Clinical Follow-up (PMCF) plan
  - Additional information required in specific cases
    - Medicinal products
    - Device utilising tissues of human or animal origin, or their derivatives
    - Substance abosrbed or locally dispersed in the body
    - Device containing CMR or Endocrin-disrupting substances
    - Sterile devices : manufacturing environnement, cleaning and sterilsation validations report…
    - …

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Thank you for your attention

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