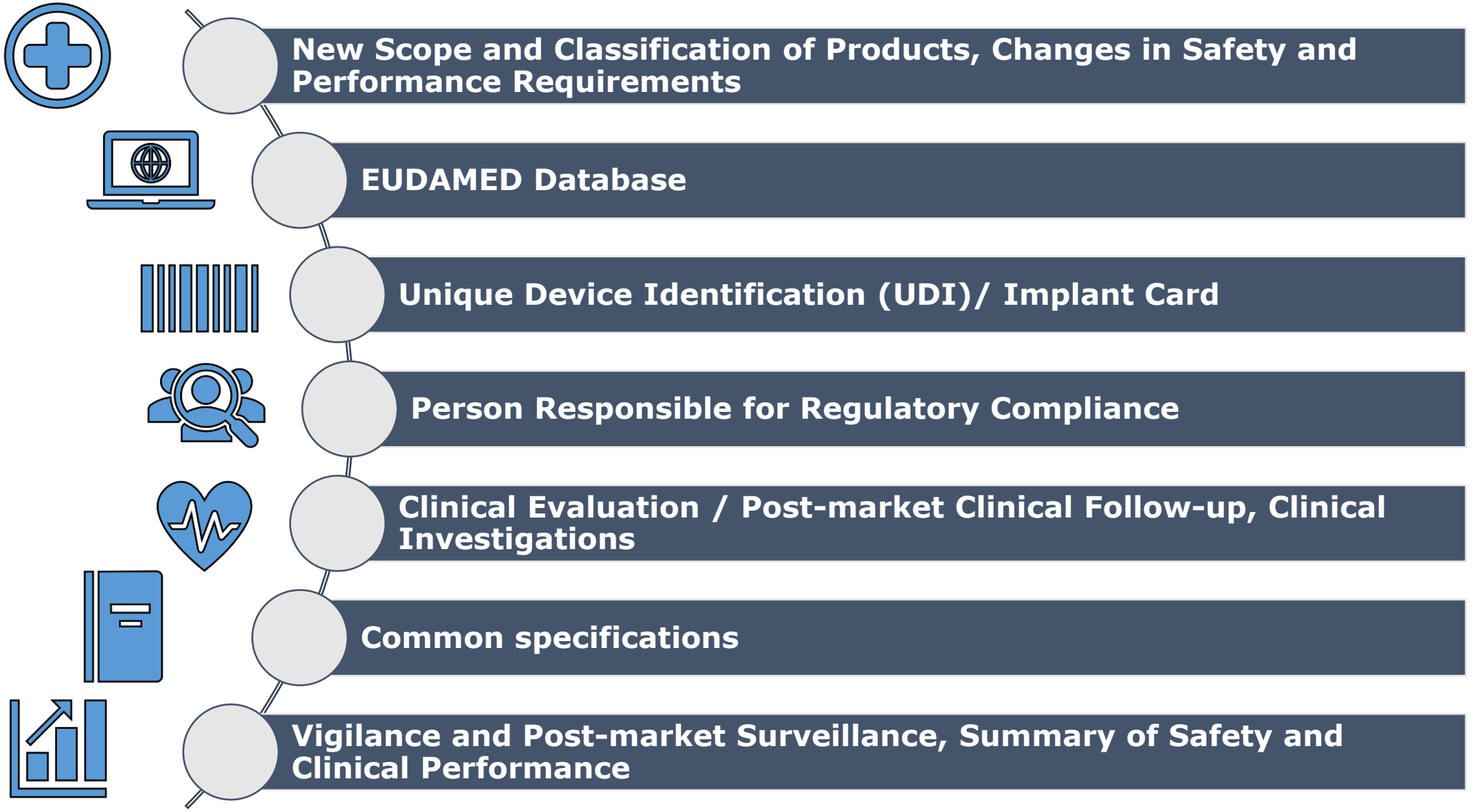
The requirements of the new Regulation 2017/745 for medical devices

Pilot Action

CHAIN REACTIONS – GAPR, CCIAA PD

Key points of MDR



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What does it mean „the **significant changes** in the design and intended purpose" ?

- ✓ Is there any change of the Intended Purpose?
- ✓ Is there any design change related to corrective actions?
- ✓ Is there any change of the design or performance specification?
- ✓ Is there any software change?
- ✓ Is there any change of a Material?
- ✓ Is there any change of terminal sterilization method of device or packaging design with impact to the sterilisation?

⇒ Detail guidelines:

MDCG 2020-3 **Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD -** March 2020

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General obligations of the manufacturer – Article 10

- General Safety & Performance Requirements
- Risk Management
- Clinical evaluation
- Technical documentation
- EU declaration of conformity
- CE marking
- UDI system
- Quality Management System
- Post market surveillance system
- Insurance

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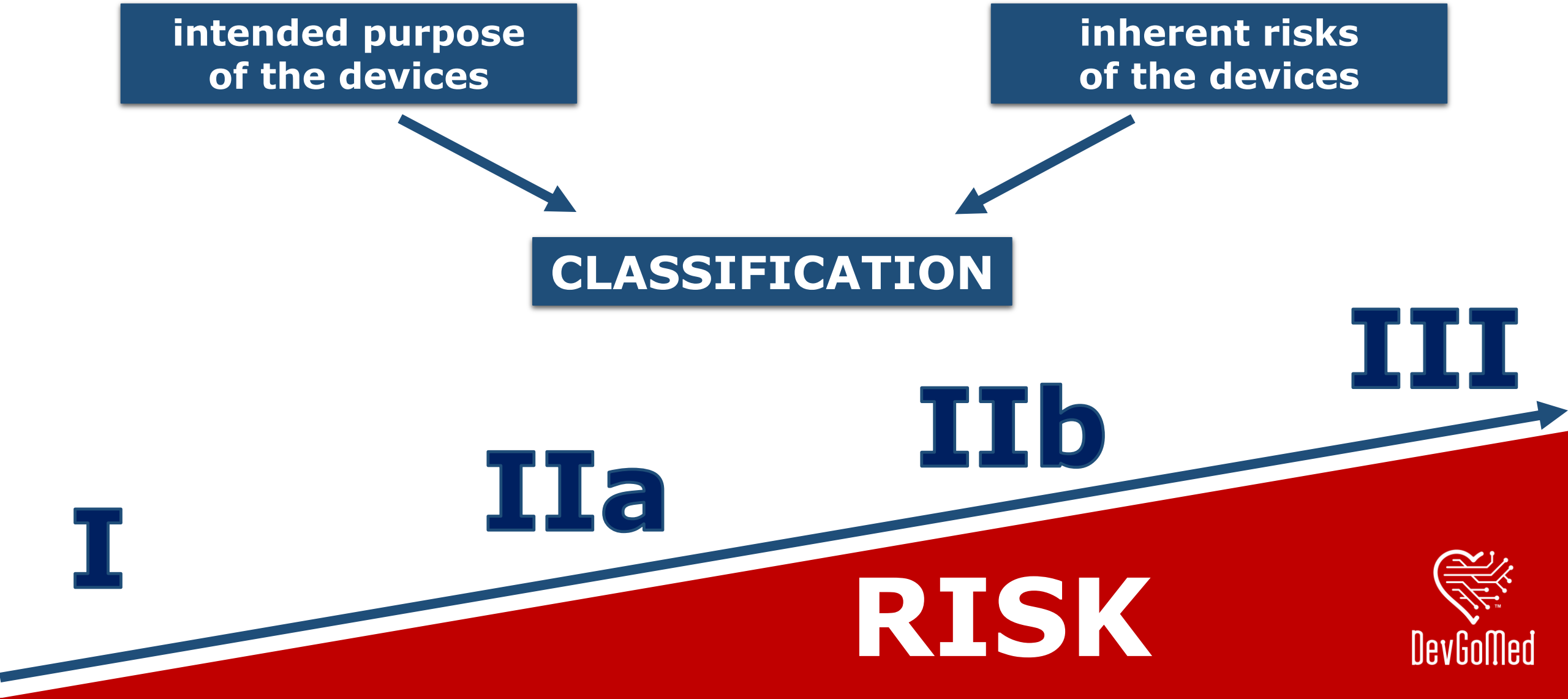
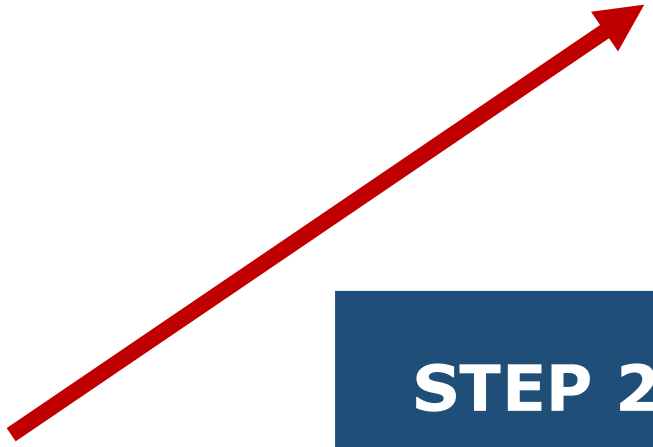
Classification of devices – Article 51



Classification rules – Annex VIII

Rules 1 - 4	• Non-invasive devices
Rules 5 - 8	• Invasive devices
Rules 9 - 13	• Active devices
Rules 14 – 22	• Special rules



STEP 3 – Choose the right classification rule for the device

STEP 2 – Characterize the medical device

invasive / non-invasive & active / non active

STEP 1 - Define the duration of use of medical device

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Classification rules – Duration of use

- the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device
- the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type

Transient	Short term	Long term
< 60 min	< 60 min < 30 days	> 30 days

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Technical Documentation

Annex II - TECHNICAL DOCUMENTATION

1) Device description and specification, including variants and accessories
2) Information to be supplied by the manufacturer
3) Design and manufacturing information
4) General safety and performance requirements
5) Benefit-risk analysis and risk management
6) Product verification and validation

Annex III - TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

1) Post-market Surveillance Plan
2) Periodic Safety Update Report
3) Post-market Surveillance Report

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Annexes of MDR

- I – General Safety & Performance Requirements
- II – Technical Documentation
- III – TD post market surveillance
- IV - EU declaration of conformity
- V – CE marking of conformity
- VI - Information to be submitted upon the registration
- VII - Requirements to be met by notified bodies
- VIII - Classification rules
- IX – CA based on a QMS and assessment of TD
- X – CA based on type examination
- XI – CA based on product conformity verification
- XII - Certificates issued by a notified body
- XIII - Procedure for custom-made devices
- XIV - Clinical evaluation and post-market clinical follow-up
- XV - Clinical investigations
- XVI - Products without an intended medical purpose
- XVII - Correlation table

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