Regulatory, quality and clinical affairs

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

Session 2

Kim Rochat

last update 2025-03-03

EU Medical Devices Legislation – Players

Manufacturer

The manufacturer is the legal responsible body for the medical device. It has the responsibility to ensure the device is safe and performs as expected. Among this, the manufacturer is responsible to ensure the device is placed on the market only once the adequate conformity assessment has been performed and ensures necessary post market surveillance activities.

Notified Body (NoBo / NB)

In the EU, the Notified Body is an organization that has been designated by a Member State to assess whether a product meets defined requirements. Assessment can include inspection and examination of a product, its design and manufacturing process, as well as Technical Documentation and Quality Management System.

EU Medical Devices Legislation – Players

Competent Authority

For medical devices, the Competent Authority has the responsibility to monitor the market, to ensure that the players respect the rules. The competent authority collects vigilance reports and perform manufacturers or clinical investigations inspections for cause or for continuous surveillance.

The Competent Authority manages the class I / Class A notifications from manufacturer and authorize clinical investigations on medical devices.

Ethics Committees

They ensure oversight of clinical trials involving medical devices to ensure the protection of participants' rights, safety, and well-being. These committees review clinical investigation proposals for medical devices, assessing potential risks and benefits, ensuring compliance with ethical standards, and verifying that the informed consent process is properly conducted. They ensure that studies are scientifically sound and comply with ethical guidelines, including safeguarding vulnerable populations.

EU Medical Devices Legislation – Players

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Drug process

Marketing Autorisation Application (MAA) evaluation. →

← **Autorisation**

← **Surveillance**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

swissmedic

Medical Device process

Request for conformity assessment →

← **Approval**

← **Surveillance**

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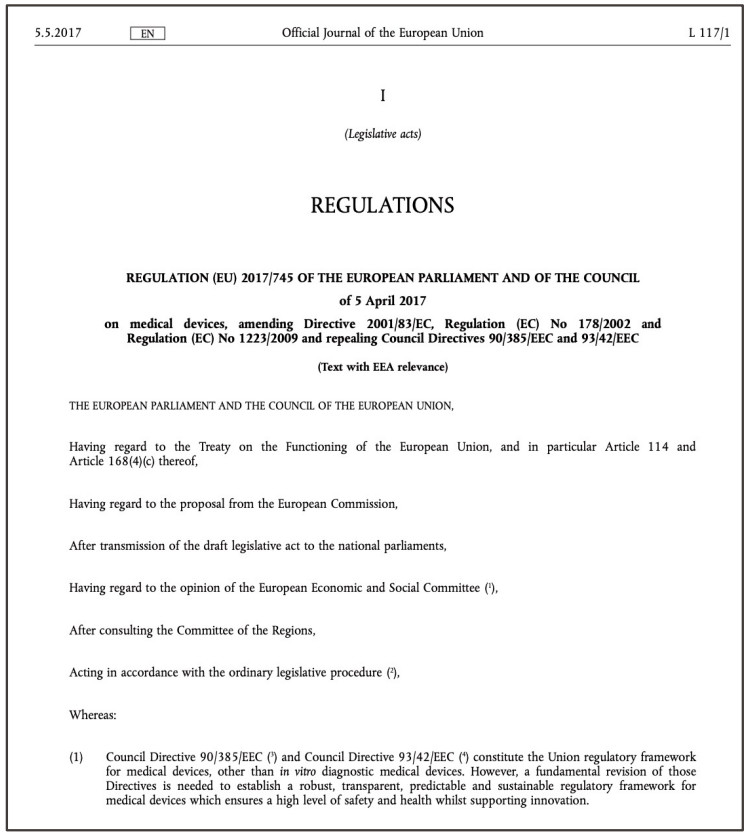
Medical Devices Regulations

Medical Device Regulation (MDR)



5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

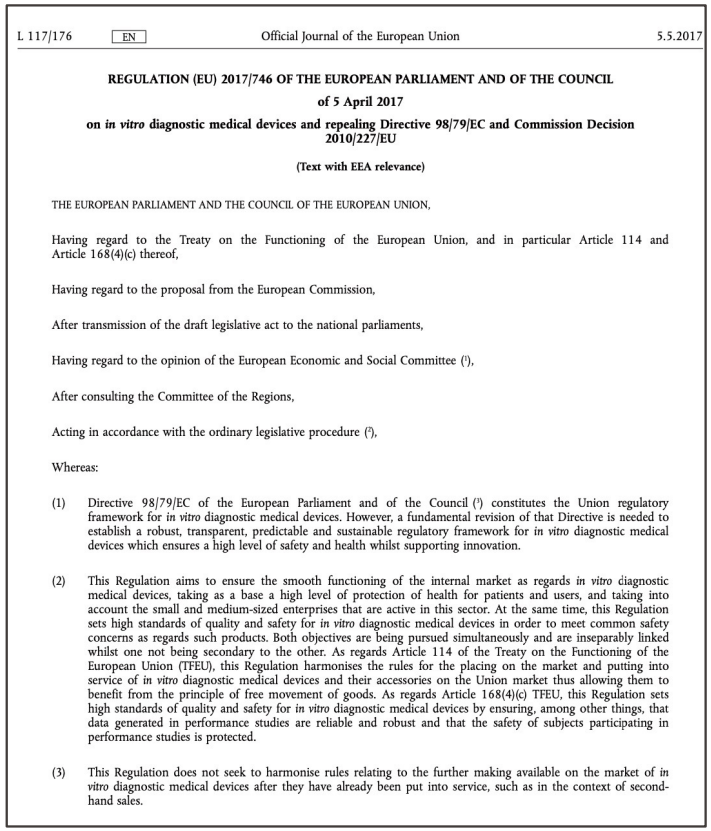
Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Council Directive 90/385/EEC [3] and Council Directive 93/42/EEC [4] constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

In Vitro Diagnostic Regulation (IVDR)



L 117/176 EN Official Journal of the European Union 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Directive 98/79/EC of the European Parliament and of the Council [3] constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of *in vitro* diagnostic medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices by ensuring, among other things, that data generated in performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of *in vitro* diagnostic medical devices after they have already been put into service, such as in the context of second-hand sales.

https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng

Regulatory compliance - Medical Device Regulation

EU 2017/745

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

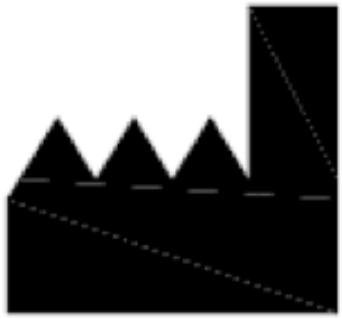
The European Medical Device Regulation:

- 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

MDR - Manufacturer obligations (MDR Art.10)

Manufacturers shall:

- Ensure compliance with EU MDR (in particular GSPRs as stated in Annex I)
- Implement Quality Management System incl.
  - a system for risk management
  - a system for post market surveillance
- Establish and retain technical documentation incl. clinical evaluation
- Select applicable conformity assessment process
- Apply UDI for the devices they are responsible for
- Establish sufficient financial coverage

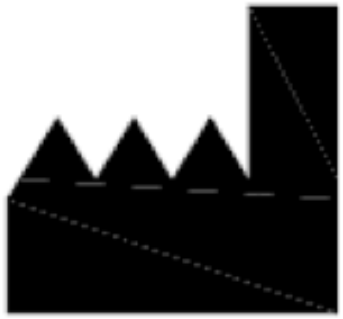


Note: Paraphrased from MDR. Art. 10. To view the requirements as is, kindly refer to MDR Art. 10

MDR - Manufacturer obligations (MDR Art.10)

Art 10.4 specifically address the obligation to establish a technical documentation

*Manufacturers […] shall draw up and keep **up to date technical documentation** […] to allow the conformity assessment of the device with the requirements of this Regulation"*



In other words, the Technical Documentation must provide **sufficient evidence** for fulfilling the **General Safety And Performance Requirements.**

Note: Paraphrased from MDR. Art. 10. To view the requirements as is, kindly refer to MDR Art. 10

MDR – Claims (MDR Art.7)

Prohibited Misleading Claims in Medical Device Labeling & Advertising

- No False Claims – Devices must not be advertised with functions or properties they do not have.
- No Misleading Impressions – Information must not create a false sense of effectiveness for treatment or diagnosis.
- Full Risk Disclosure – Users and patients must be informed of any likely risks associated with the device.
- No Unauthorized Uses – The device must only be marketed for its approved intended purpose as assessed during conformity evaluation.

⇒This strives to ensure honest, transparent, and patient-safe communication regarding medical devices.

⇒ Clinical data shall be available to support claims.

MDR – Person responsible for regulatory compliance (MDR Art.15)

Mandatory PRRC Role – Manufacturers must have at least one qualified person responsible for regulatory compliance within their organization.

- Key Responsibilities of PRRC:
  - Ensure device conformity before release.
  - Maintain technical documentation & EU declaration of conformity.
  - Oversee post-market surveillance.
  - Fulfill reporting obligations (Articles 87-91).
  - Issue statements for investigational devices.
- Multiple PRRCs Allowed – If multiple persons share the role, responsibilities must be clearly defined in writing.
- Independence & Protection – The PRRC must not face disadvantages within the company for performing their duties, ensuring independent regulatory oversight.

MDR – Notified Bodies (MDR Chap. IV – Art.35 – 49)

- Designation & Monitoring – Notified Bodies (NBs) are designated by national authorities and must meet strict competency, impartiality, and independence requirements.
- Oversight & Reassessment – Competent authorities regularly monitor and reassess NBs to ensure they comply with MDR standards.
- Scope of Activities – Each NB is approved for specific device categories based on their expertise.
- Conformity Assessment Role – NBs assess medical devices for compliance with MDR through audits, inspections, and technical reviews.
- Reporting & Transparency – NBs must report assessments, decisions, and any non-conformities to competent authorities and maintain transparency.
- Joint Assessments & Cooperation – The EU Commission and national authorities conduct joint assessments to ensure harmonized and high-quality certification standards across the EU.

MDR – Clinical Evaluation and clinical investigations (MDR Chap. VI – Art.61 – 82)

- Clinical Evaluation Requirement – Manufacturers must conduct a clinical evaluation to demonstrate safety, performance, and benefit-risk balance of a device.
- Use of Clinical Data – Clinical evaluations rely on existing clinical data or require new clinical investigations if data is insufficient.
- Clinical Investigations – Required for high-risk devices or when existing data is inadequate. Must follow ethical and regulatory standards.
- Approval & Oversight – Clinical investigations must be approved by national authorities and ethics committees before starting.
- Post-Market Clinical Follow-Up (PMCF) – Manufacturers must continuously gather real-world clinical data to monitor device performance and safety.
- Adverse Event Reporting – Any serious adverse events or safety issues during investigations must be reported to authorities.
- EU-Wide Coordination – Clinical investigation processes are harmonized across the EU to ensure consistent patient safety and data reliability.

MDR – Post-Market Surveillance, Vigilance, and Market Surveillance (MDR Chap. VII – Art.83 – 92)

- Post-Market Surveillance (PMS) – Manufacturers must implement a PMS system to continuously collect and analyze real-world data on device safety and performance.
- Periodic Safety Reporting – High-risk devices require a Periodic Safety Update Report (PSUR), while lower-risk devices need regular PMS reports.
- Vigilance & Incident Reporting – Manufacturers must report serious incidents and safety issues (Articles 87–91) to authorities within strict timeframes.
- Field Safety Corrective Actions (FSCA) – If risks are identified, manufacturers must take corrective actions, including recalls or safety notices.
- Market Surveillance by Authorities – Competent authorities actively monitor devices, conduct inspections, and enforce compliance across the EU.
- Cooperation & Information Sharing – EU countries and the European Commission share safety data and market surveillance findings to ensure harmonized enforcement.

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 states the requirements a medical device must achieve:

- General Requirements
  - i.e. Security, safety, usability, etc.
- Requirements Regarding Design and Manufacture
  - Biocompatibility, protection against radiation, information security, protection against mechanical and thermal risk, etc.
- Requirements regarding the information supplied with the devices
  - Information to be provided, languages, etc.

MDR Annex I – General Safety & Performance Requirements

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

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.

First of 79

Medical Device – Definition (MDR)

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' 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,

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.

Intended Purpose – Definition

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"**intended purpose**" means the use for which a device is intended according to the …

- label
- instructions for use; and
- promotional or sales materials / statements
- online publication / web site

and

- as specified by the manufacturer in the **clinical evaluation**
- based on the **claims made** for the device

Intended Purpose – Example

- Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy(contraception) or planning a pregnancy (conception)[1]
- Aktiia Bracelet G1 is a non-invasive blood pressure (BP) monitor intended to measure optical Photoplethysmography (PPG) signals on the user's wrist and to calculate blood pressure values using a Pulse Wave Analysis (PWA) technique, following a calibration process using an oscillometric blood pressure monitor[2]
- The AIRFLOW STATION+ is intended to be used only for the retention of the EMS AIRFLOW Prophylaxis Master or the EMS AIRFLOW One.The AIRFLOW STATION+ is intended to supply water to the EMS AIRFLOW Prophylaxis Master or the EMS AIRFLOW One unit via the WATER Bottle Shelf System.[3]
- The eyeWatch system is indicated for patients suffering from glaucoma where medical and/or conventional surgical treatments have failed. The eyeWatch system is intended to drain aqueous humor from the anterior chamber to the subconjunctival space and to regulate non-surgically the intraocular pressure during the early post-operative period[4]

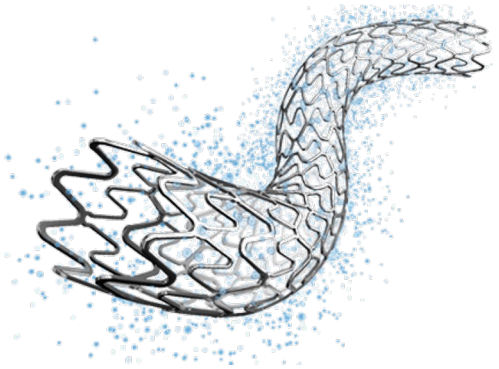
[1] https://www.datocms-assets.com/21281/1734432981-1019-2-22-instructions_en_us.pdf
[2] https://aktiia.com/ch/wp-content/uploads/sites/5/2023/11/Aktiia_Bracelet_G1_User_Manual_v4.0_WEB_EN.pdf
[3] https://s3-qrd-prd-docs.s3.eu-west-1.amazonaws.com/ems/documents/4752cfa3-9c8f-4318-8ef4-c4d3aa02f760.pdf
[4] https://rheonmedical.com/products-information/

Medical Device – Intended Action

Principle intended action:

- *Physical means* => ***Device Regulation***
- *Pharmacological, immunological, or metabolic means* => ***Drug Regulation***

Medical Device ?



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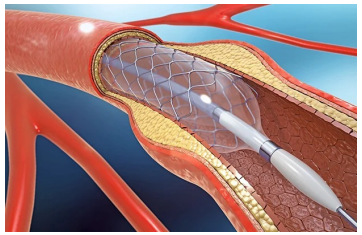
Intended Action - Example



Stents

- Mode of Action: A stent is a small, expandable metal tube inserted into narrowed or blocked blood vessels.
- Physical Effect: It physically keeps the vessel open, restoring blood flow.

Hip Implant

- Mode of Action: Restores joint function by replacing the damaged hip joint with an artificial prosthesis.
- Physical Effect: Provides mechanical support for weight-bearing and movement to allow smooth mobility.

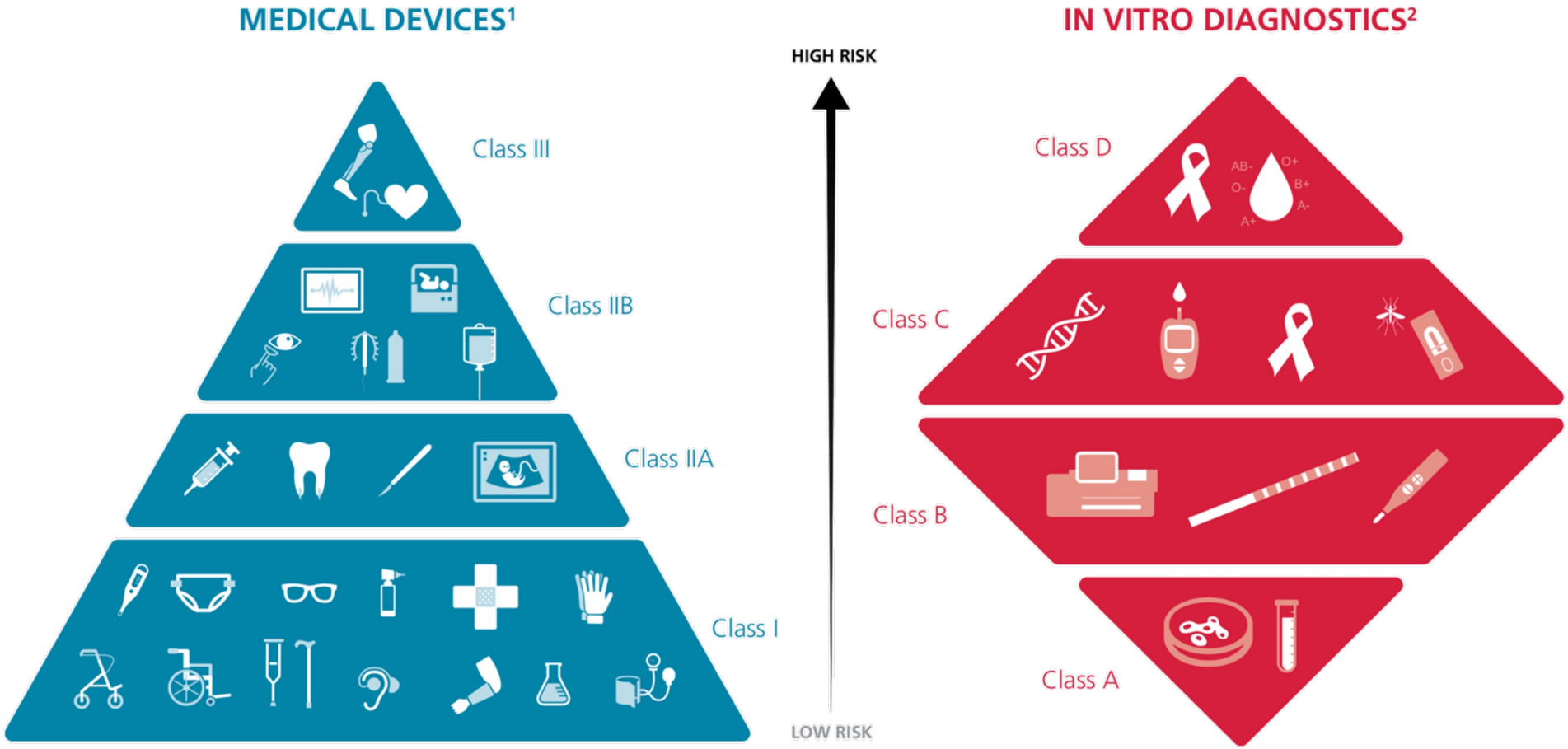
Penicillin

- Mode of Action: Inhibits bacterial cell wall synthesis, leading to cell lysis.Iodine (in Thyroid Function)
- Pharmacological Effect: Bactericidal (kills bacteria) by preventing peptidoglycan formation.

Iodine in Thyroid Function

- Mode of Action: Iodine is absorbed and used in the thyroid gland to produce thyroid hormones (T3 & T4).
- Metabolic Effect: Regulates metabolism by influencing energy production, growth, and body temperature.

Device Classification – Risk Based



Source: Eucomed

Device Classification - Purpose of classification

- Determination of Conformity Assessment Pathway
- Adjusting the level of scrutiny / identification of devices with higher risks
- Defining Post-Market Surveillance (PMS) and Vigilance Requirements
- Determining Clinical Evidence Requirements

Device Classification – MDR Rules

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

The methodology to adopt is to review all the rules and to justify why they are not applicable until:

- Only **one rule** is left
- Few rules are left, and the **highest classification** is chosen

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Device Classification – MDR Rules
Example

Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:

— class I if they are intended for transient use;

— class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and

— class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

Product Classification – MDR Definitions

Duration of Contact

Transient	< 60 minutes
Short Term	< 30 days
Long Term	over 30 days

Invasiveness

Body Orifice	Natural opening or stoma
Surgically Invasive	Penetrating body surface
Implantable	Remains in body after intervention

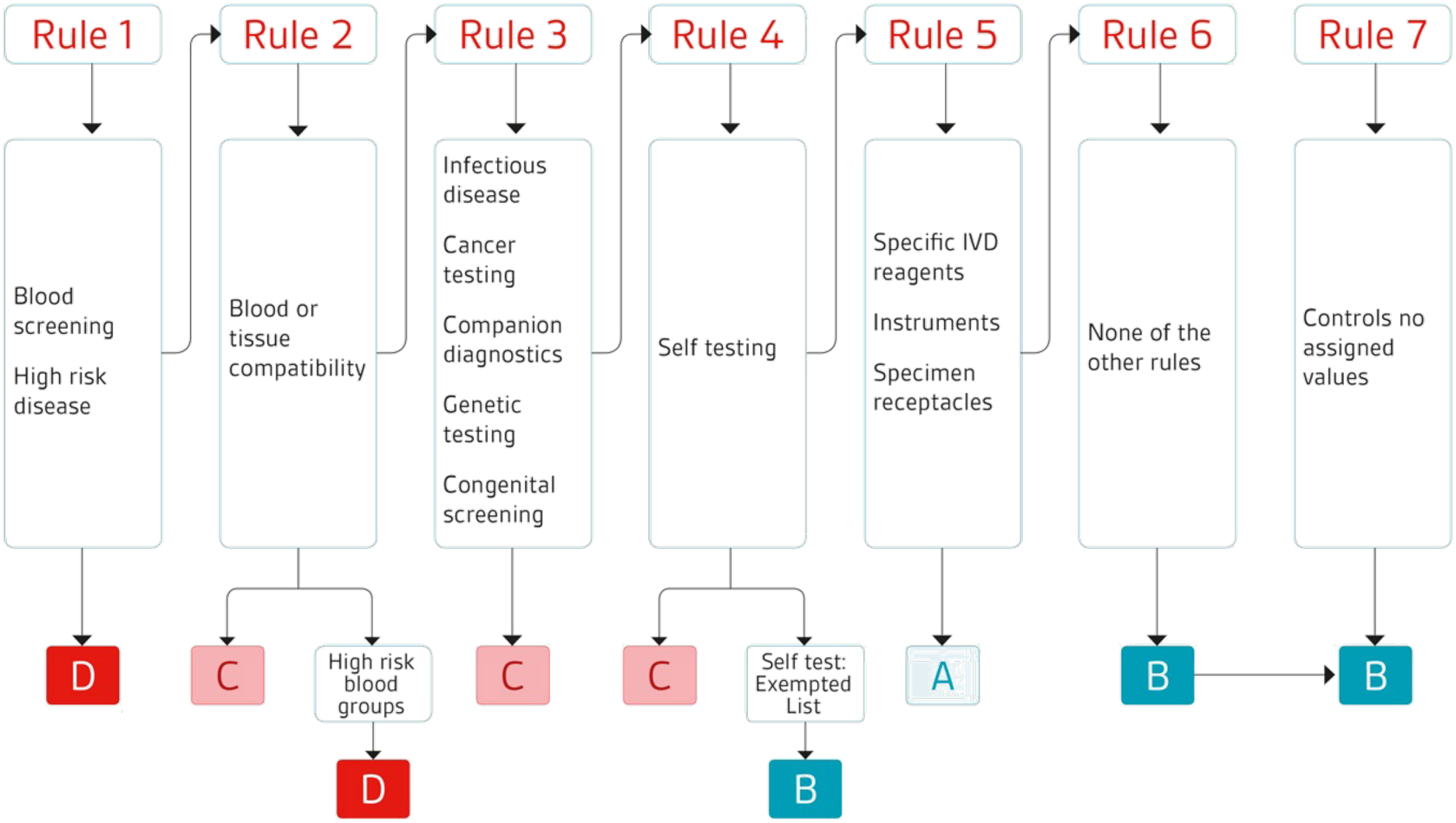
Active

Any source of power other than that generated directly by the human body or gravity; also **software**

Special Rules

Product specific, mode of action specific or exposure specific rules

Product Classification – IVDR Rules



Source: BSI

Q&A