Medical device regulations

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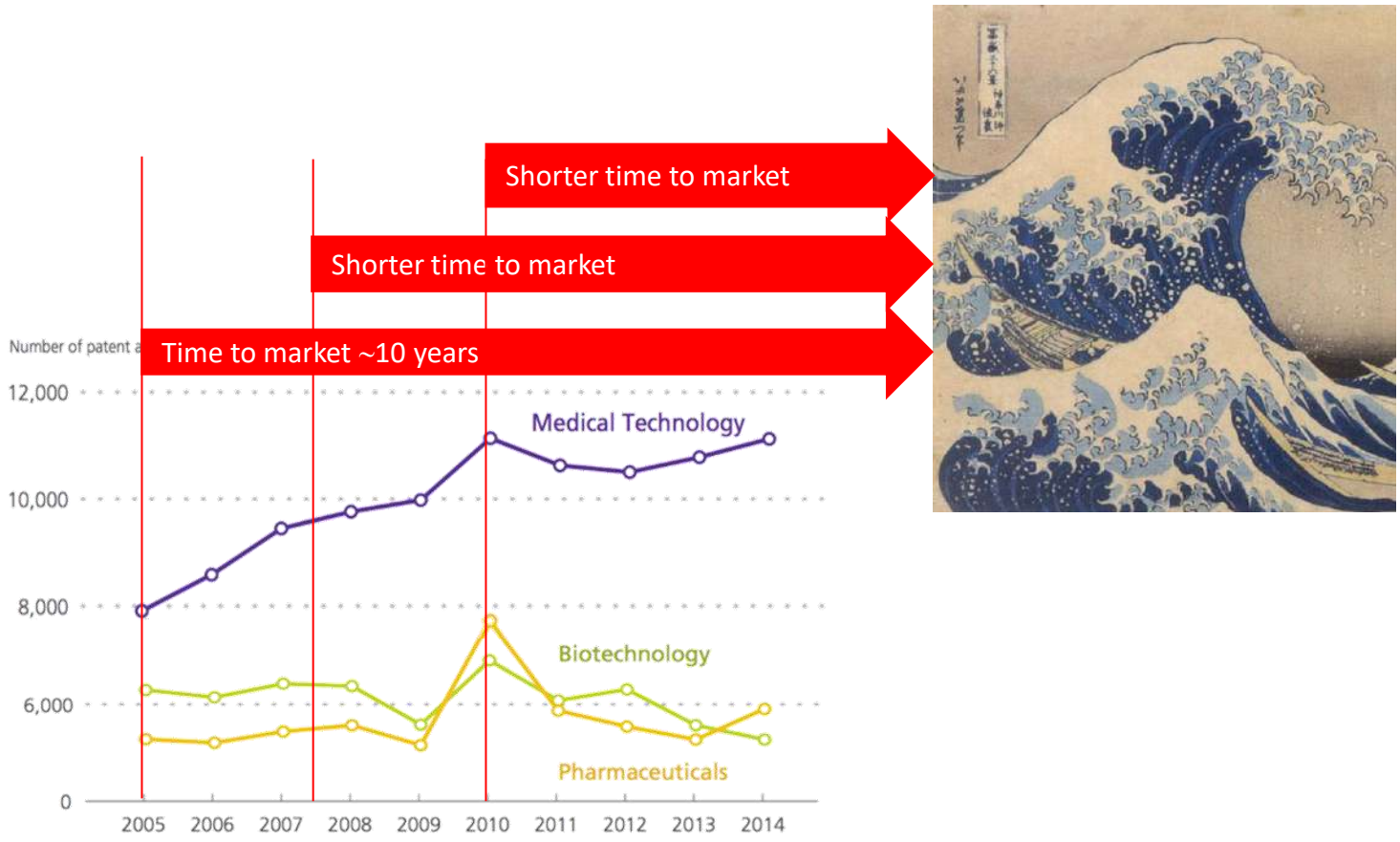
President, *EAMBES* (2021-23)
Secretary General, *IUPESM* (2018-2022)
Treasurer, *IFMBE CED* (2018-21)

…present: more than 600000 MDs in EU

…a tsunami of medical devices!



…future?

Real need for good regulation and (more) **Biomedical (and Clinical) Engineers**

*MedTech Europe, *The European Medical Technology Industry. In Figures. Brussels, 2015.*

World Health Organization (WHO) and BMEs

centre | Publications | Countries | **Programmes** | Governance | About WHO

Medical devices

Biomedical engineering global resources

Trained and qualified biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in health systems around the world.

WHO has conducted surveys and studies to have information on the academic programs, professional societies and status of biomedical engineers worldwide, which will further enhance their involvement to increase access to safe, quality medical devices globally in order to provide better health care.

Therefore, in 2015 WHO invited representatives of biomedical engineering institutions or programs, technical schools, professional societies, government institutions, and those responsible for country labour statistics, to complete the a survey on Biomedical Engineering professionals, in order to have information available.

World Health Organization

European Economic and Social Committee (EESC) and BME

4.9.2015 EN Official Journal of the European Union C 291/45

Opinion of the European Economic and Social Committee on Promoting the European single market combining biomedical engineering with the medical and care services industry

(2015/C 291/07)

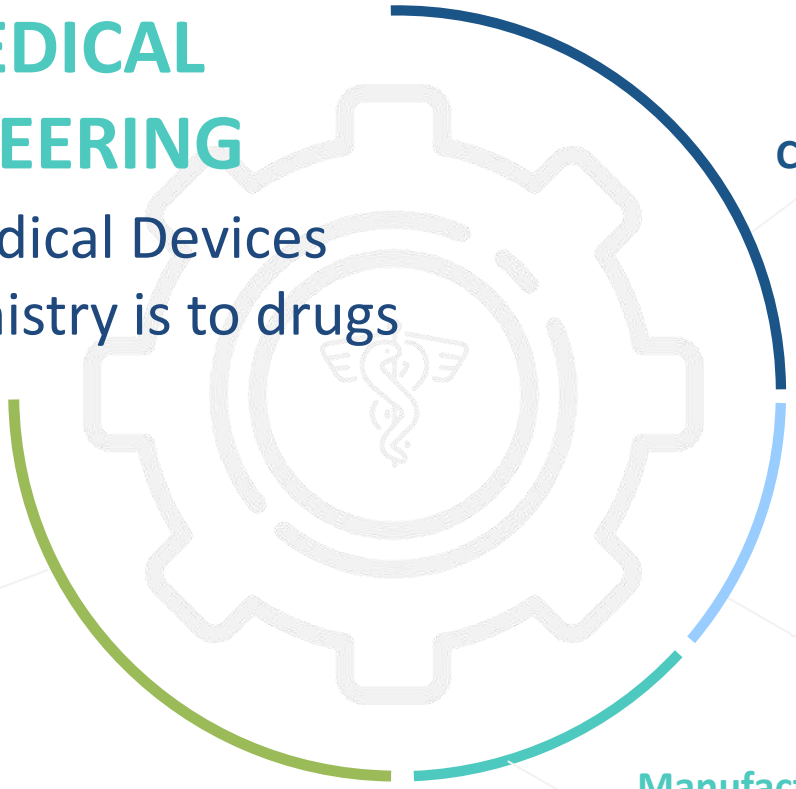
Rapporteur:
Edgardo Maria IOZIA

"*Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering*" (2015/C 291/07)

European Alliance for EAMBES Medical and Biological Engineering & Science

BIOMEDICAL ENGINEERING

is to Medical Devices
as Chemistry is to drugs



Conceptual and R&D phases

Testing & Approval

Manufacturing

Clinical Engineering

Medical Technology Management

Regulation(s)

- EU, USA, China & Japan account for >96% global market
- BME should be familiar with all these regulations. This lecture focuses on EU

The Legal Framework in Europe for Medical Devices

DIRECTIVES

AIMD 90/385/EEC
MD 93/42/EEC
IVDs 98/79/EC

Replaced by the

REGULATIONS

2017/745 on MDs &

2017/746 ON IVDs

GUIDELINES

MEDDEV Series

CE MARK

Competent Authorities
Notified Bodies

HARMONISED STANDARDS

EN SERIES

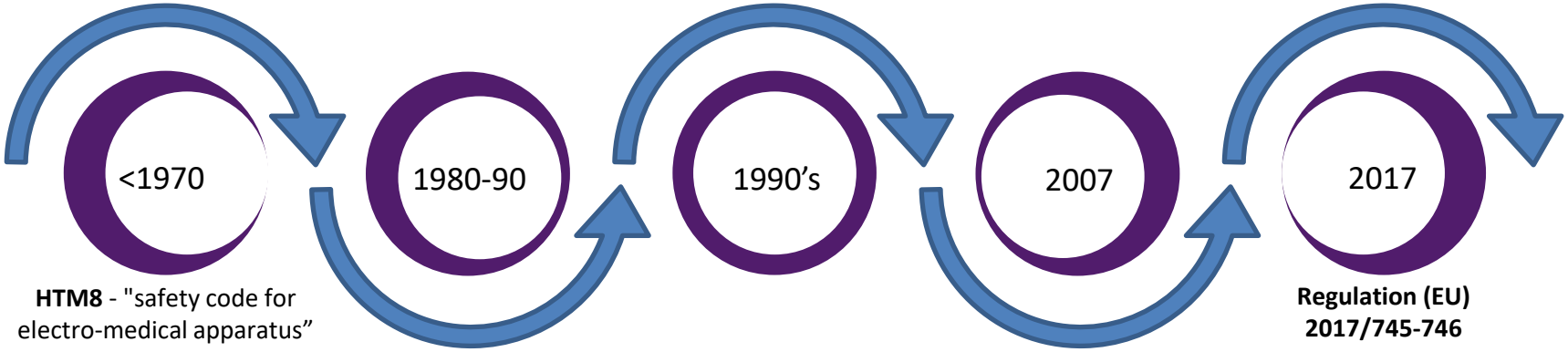
POST MARKET

Post Market surveillance
Vigilance

Medical Device regulation is a continuous process

IEC 60601 → BS 7524, that covers general requirements (I) and particular requirements for specific categories of MD (II);
Hospital Equipment Information 95

Directive 2007/47/EC,
Expands the previous one; it introduces **medical software.**

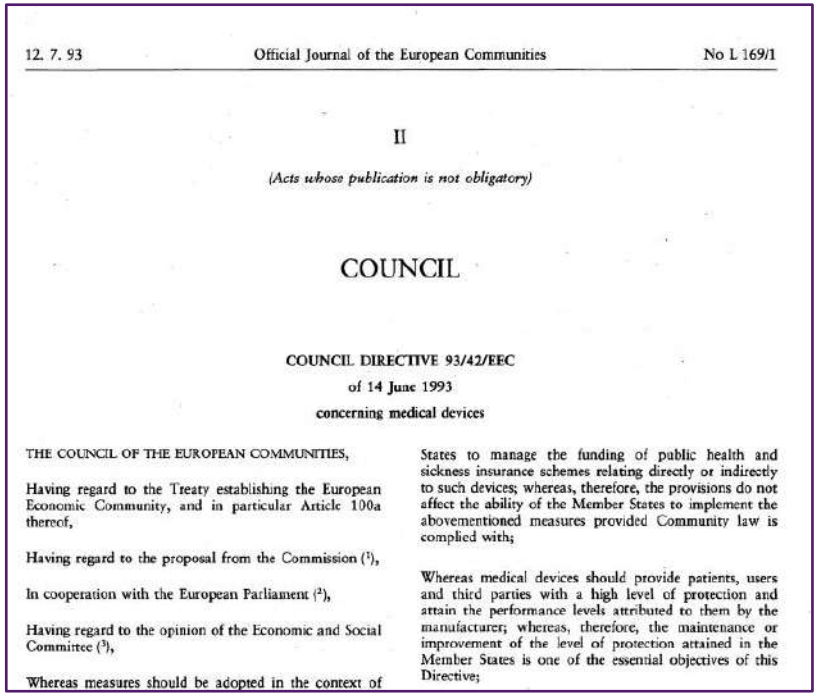


HTM8 - "safety code for electro-medical apparatus"

Regulation (EU) 2017/745-746

Directive 90/385/EEC on active implantable MD;
MD Directive 93/42/EEC
International validity; Does not substitute the general safety regulations; *prescriptive* trend → *more responsibility* given to the manufacturer;
Device Bulletin 9801p;
IVDD 98/79/EC on in vitro diagnostic medical devices

Medical device directive 93/42/EEC



12. 7. 93 Official Journal of the European Communities No L 169/1

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures should be adopted in the context of

States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

- It defines *medical device, accessory*, et cetera;
- It defines the essential requirements (safety);
- It imposes to report information regarding non-safe MDs or accidents cause by MDs to the national authorities;
- It defines the role of the national regulations;
- It defines the classification of the MDs in 4 classes (I, IIa, IIb, III);
- It defines the procedure of the declaration of conformity;
- It imposes the registration of the people who are responsible for the marketing;
- It imposes the CE mark and it defines the modalities on how to obtain it.

The MDD 93/42/EEC did not apply:

- In-vitro diagnostic medical devices (IVDD 98/79/EC);
- Active implantable devices Directive (90/385/EEC);

- Drugs;
- Cosmetics;
- Human blood and its derivatives;
- Organs, tissues, cells of human origin or products that contain them; personal protective equipment (depending on their specific purpose).

Now?

Directive
90/385/EEC on active implantable medical devices

Directive
93/42/EEC on medical devices

→ **Regulation (EU) 2017/745** on medical devices

Directive
98/79/EC on in vitro diagnostic medical devices

→ **Regulation (EU) 2017/746** on in vitro diagnostic medical devices

As other EU regulations, the MD and the IVD regulations are divided into:

- *Recitals* (101 each) [explanatory]
  {Chapters (10 each), [context]}
- *Articles* (123 for MDR, 113 for IVDR) [legally binding]
- *Annexes* (17 for MDR, 15 for IVDR) [technical details]

Transitional period

Entry into force takes place 20 days after their publication → 25th may 2017;

The transition periods are:

- 3 years for the medical devices regulation
- 5 years for the in vitro diagnostic medical devices regulation

05/05/2017

MEDICAL DEVICES

20 days

Application:
26/05/2020

05/05/2017

IN VITRO DIAGNOSTIC MEDICAL DEVICES

20 days

Application:
26/05/2022

Definitions - Regulation (EU) 2017/745

Medical devices 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:

a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

b) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;

c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

d) 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:

a) devices for the control or support of conception;

b) products specifically intended for the cleaning, disinfection or sterilisation of devices

Deepening: try to compare this definition with the old EU one, and with WHO/FDA ones…

Definitions - Regulation (EU) 2017/745

Accessory means an article which, whilst not being itself a medical device, is intended (…) to be used together with one or several particular medical device(s) (…)

Custom-made device means any device specifically made in accordance with a written prescription of any person authorised by national law (…) and it's for the sole use of a particular patient (…).

Active device means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. (…) Software shall also be deemed to be an active device;

Implantable device means any device, including those that are partially or wholly absorbed, which is intended: a) to be totally introduced into the human body, or b) 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 (…) partially introduced into the human body by clinical intervention and intended to remain in (…) for at least 30 days shall also be deemed to be an implantable device;

Definitions - Regulation (EU) 2017/745

Manufacturer means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials (…);

Placing on the market means the first making available of a device, (…) on the Union market; (29)

Putting into service means the stage at which a device (…) has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

From Regulation (EU) 2017/746

In vitro diagnostic medical device means any medical device which is a *reagent*, *reagent product*, *calibrator*, *control material*, *kit*, *instrument*, *apparatus*, *piece of equipment*, *software* or *system*, whether used alone or in combination, **intended by the manufacturer** to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of **providing information on** one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures.

Main innovations – 4 key points

1. Better protection of patients' <u>health</u> and safety;

E.g,

- Some ***aesthetic devices***, like coloured contact lenses, will be included in the regulations (**Annex XVI**)
- A ***new classification system for IVDD***, based on 4 risk classes, is given. This will allow notified bodies to control up to 80% of the IVDD (currently only 20% is controlled).
- A **reference code** based on **U**nique **D**evice **I**dentifier (**UDI**) will be introduced and will greatly affect the labels of medical devices → improved traceability of MDs
- More **focus on efficacy/effectivenss** requiring trials on MDs!

2. More legal certainty and innovation support;

E.g,

- The new **regulations** (<u>not directives</u>), are a fully-fledged legal instrument. They no longer require a national transposition, they are directly applicable
- New regulations regarding **medical software** and apps are specified. There is a new risk-based classification for medical software

3. More transparency and patients' responsability;

E.g,

- **Creation of EUDAMED**, European Database on Medical Devices. Most information is public.
- **New obligations for manufacturers** in order to protect damaged patients→guarantee an adequate financial support

4. A more European approach;

E.g,

- Creation of **EUDAMED**, European Database on Medical Devices. Most information is public.

Regulation EU 2017/745: Essential requirements for safety and efficacy

Annex I of the regulation describes the essential requirements. They can be divided into:

1) **General requirements;**
2) **Requirements regarding design and manufacture;**
3) **Requirements regarding the information supplied with the device**

A few examples of the general requirements

Requirement 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.

Requirement 4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable

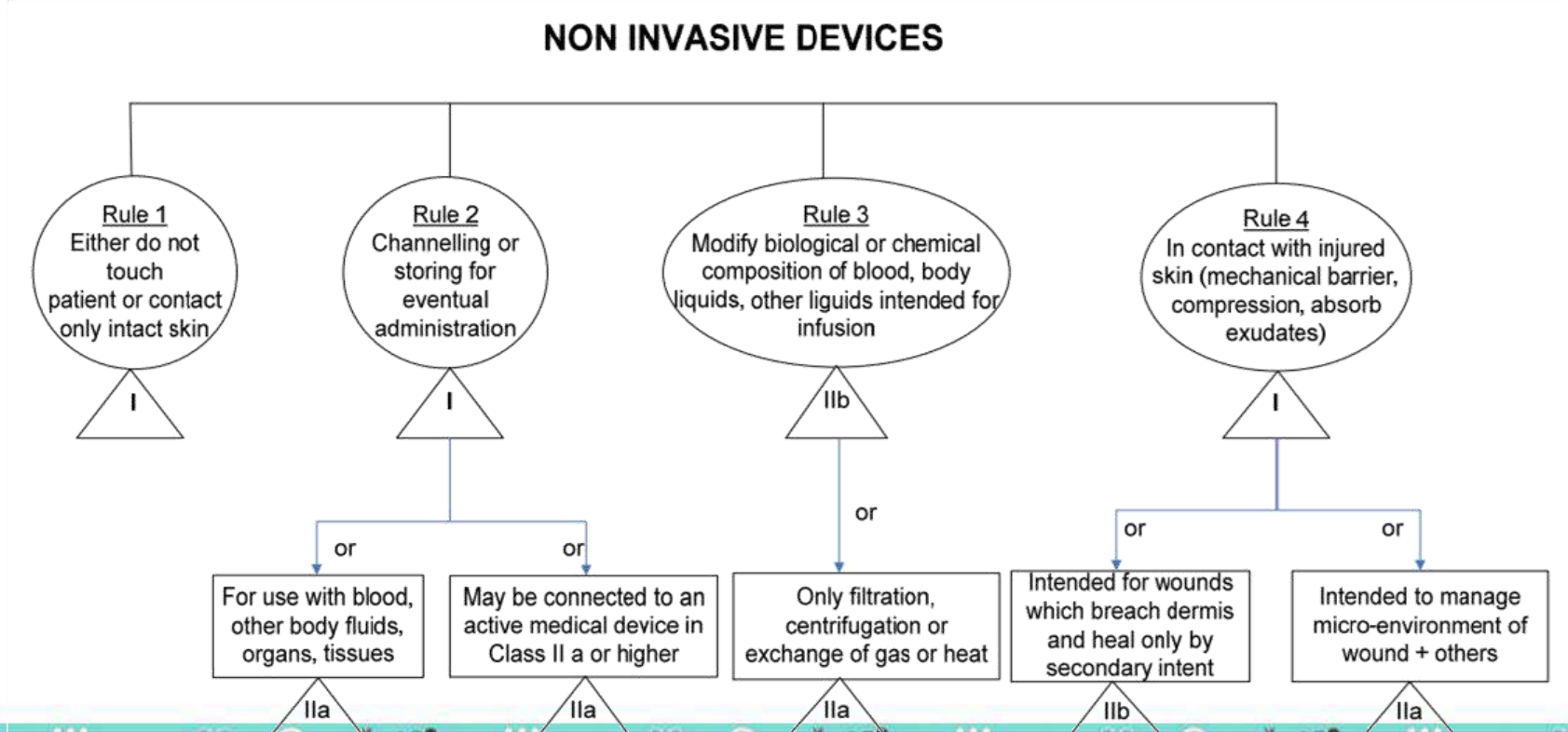
Requirement 7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

Requirement 23.1.d. Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions

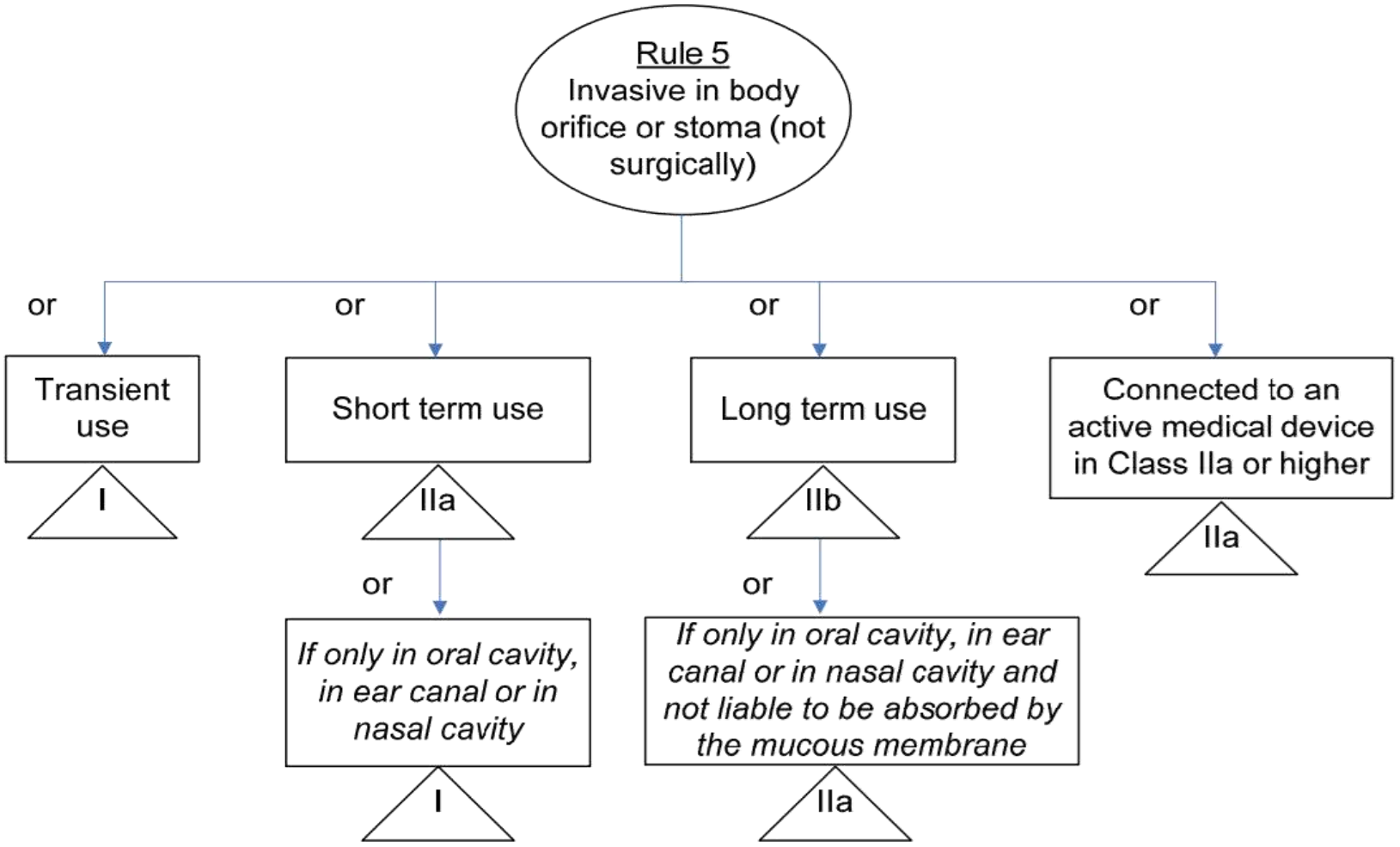
Classification rules– Annex VIII Chapter III

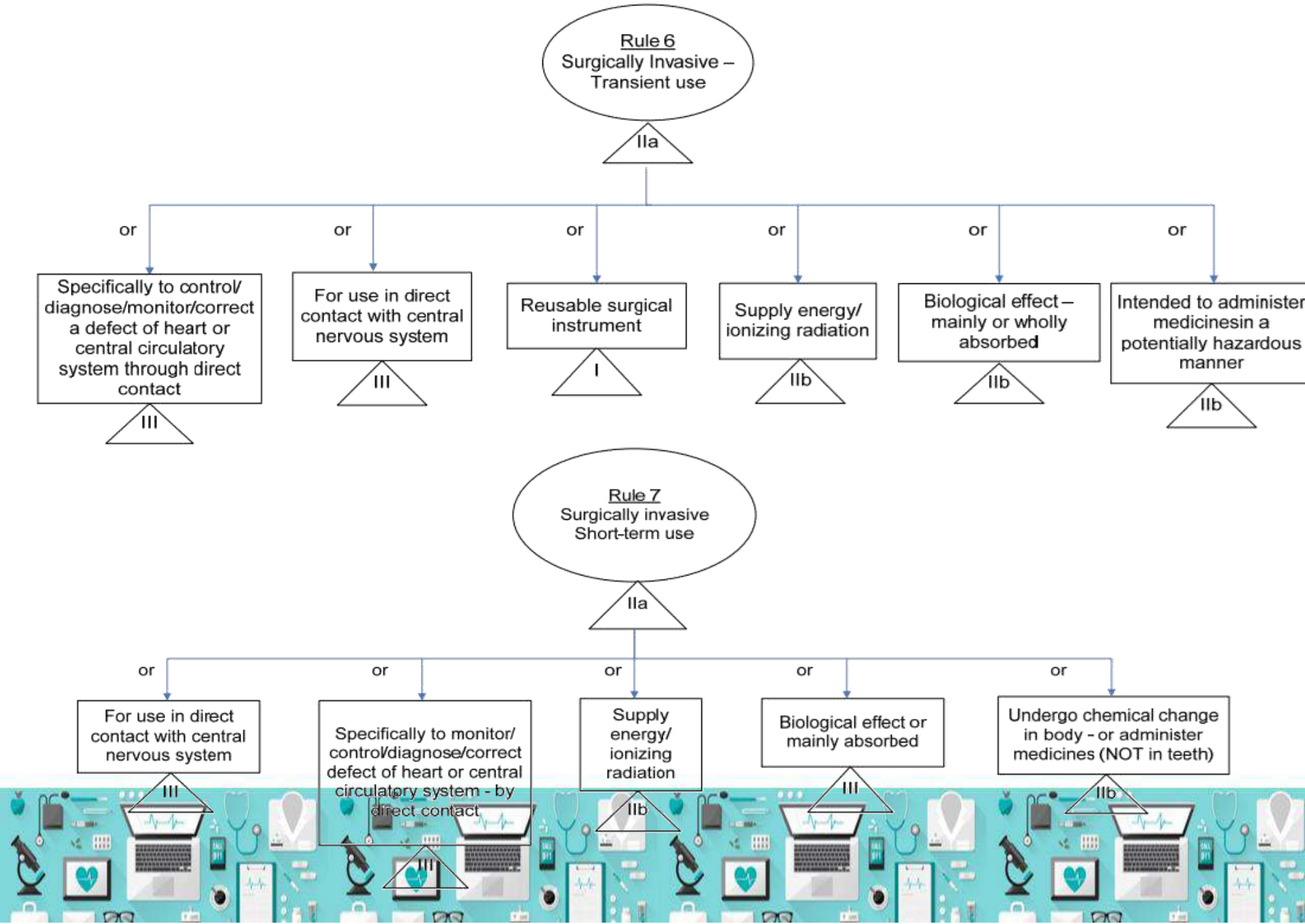
Medical devices are divided into 4 classes (I, IIa, IIb, III), according to the risk coming from their usage. The higher the risk, the higher the class. Risk depends upon:

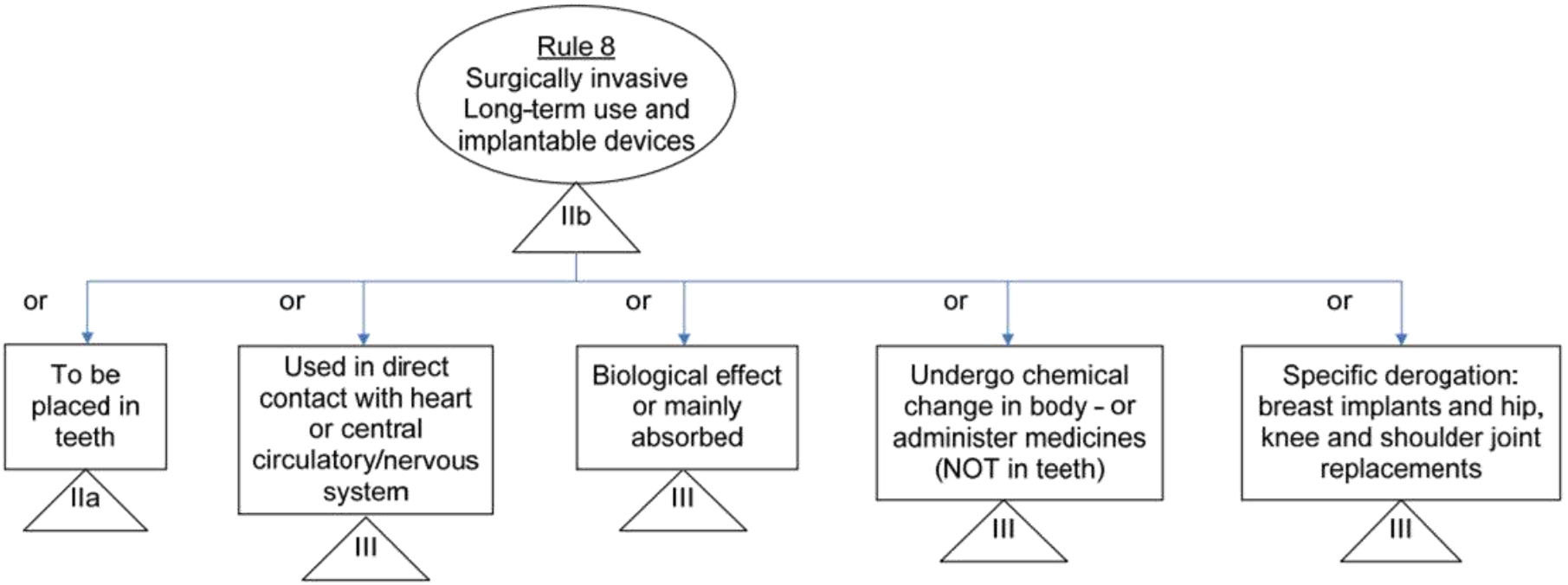
- **invasiveness**, and
- **length of use**: transient (<60min), short term (1h-30days, long term (>30 days)



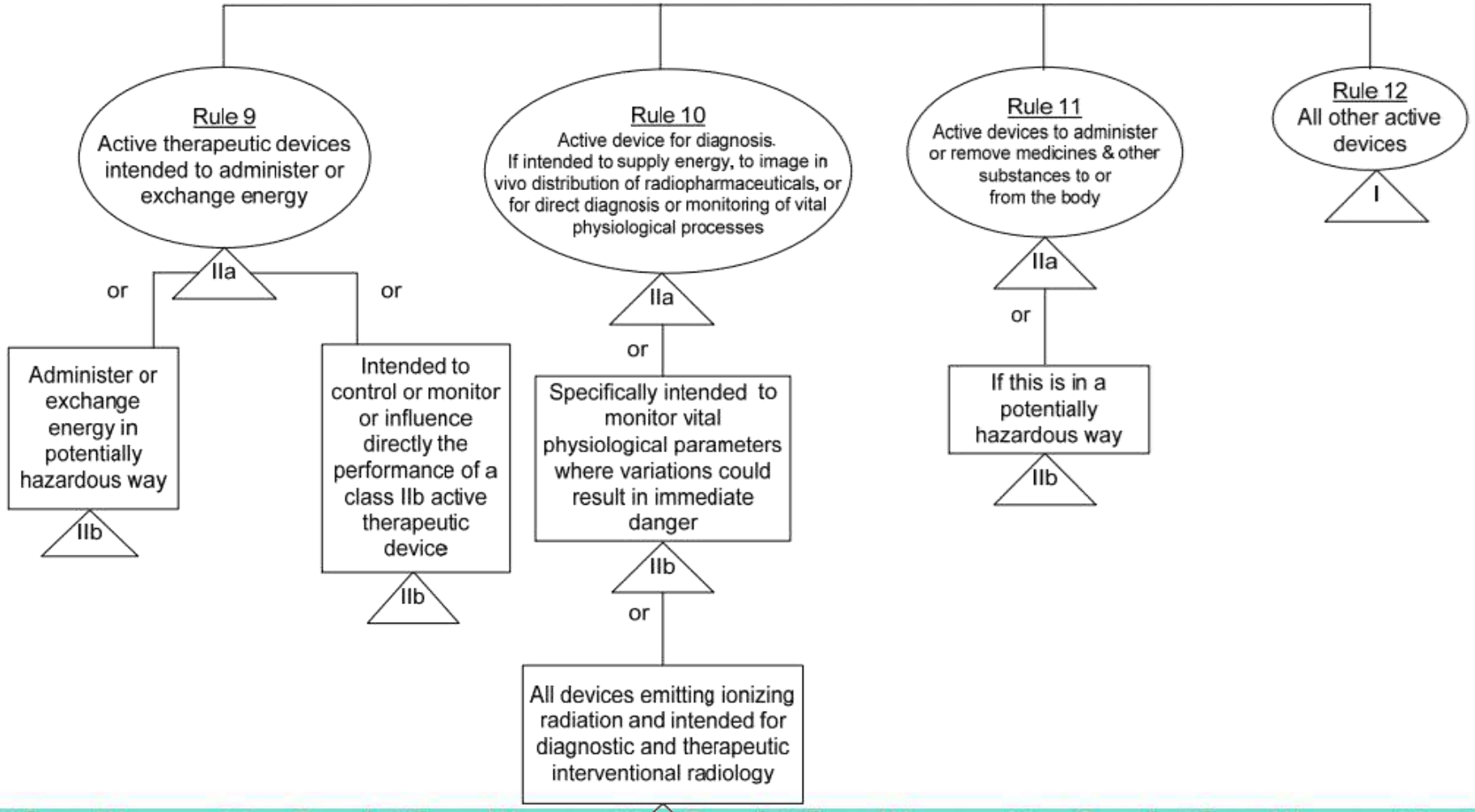
Click here for a link to the EU2017/745


Rule 5
Invasive in body orifice or stoma (not surgically)
or
Transient use
I
or
Short term use
IIa
or
If only in oral cavity, in ear canal or in nasal cavity
I
or
Long term use
IIb
or
If only in oral cavity, in ear canal or in nasal cavity and not liable to be absorbed by the mucous membrane
IIa
or
Connected to an active medical device in Class IIa or higher
IIa

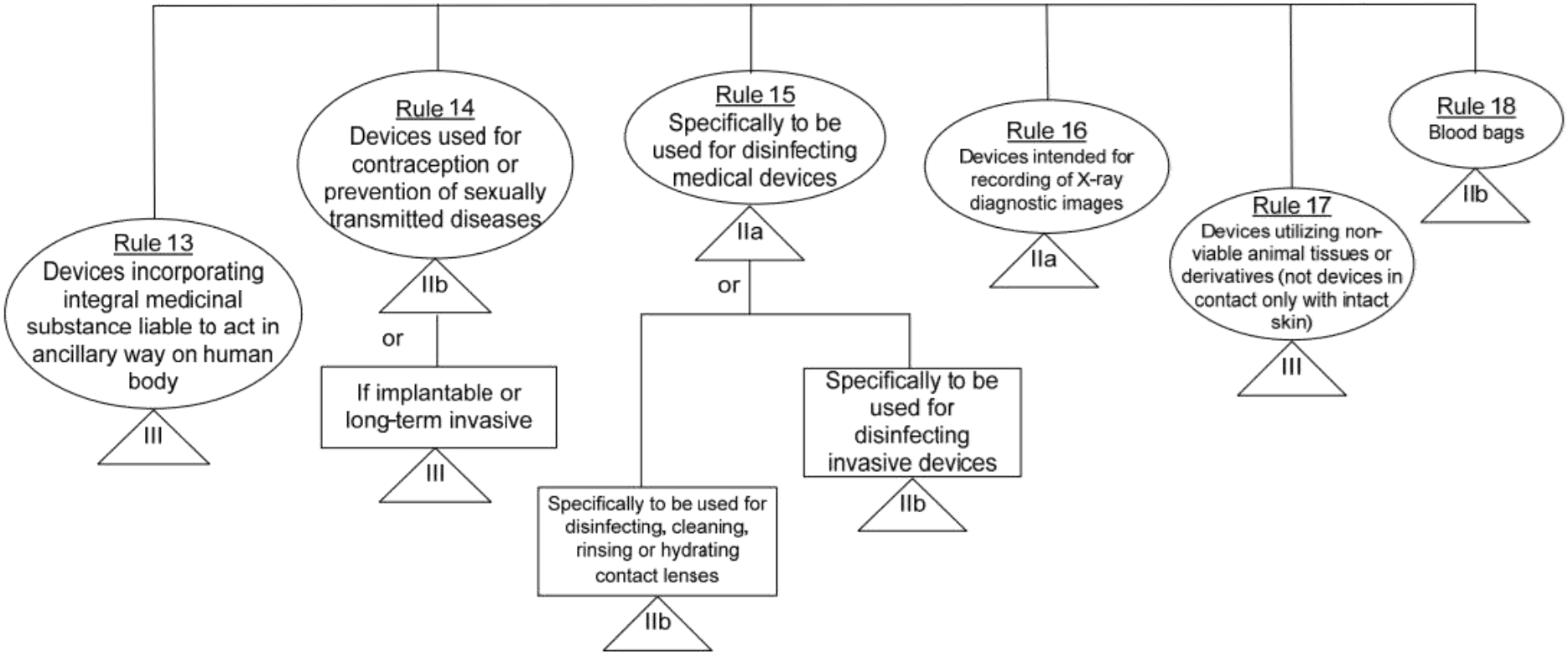

Rule 6
Surgically Invasive – Transient use
IIa
or
Specifically to control/ diagnose/monitor/correct a defect of heart or central circulatory system through direct contact
III
or
For use in direct contact with central nervous system
III
or
Reusable surgical instrument
I
or
Supply energy/ ionizing radiation
IIb
or
Biological effect – mainly or wholly absorbed
IIb
or
Intended to administer medicinesin a potentially hazardous manner
IIb
Rule 7
Surgically invasive Short-term use
IIa
or
For use in direct contact with central nervous system
III
or
Specifically to monitor/ control/diagnose/correct defect of heart or central circulatory system - by direct contact
III
or
Supply energy/ ionizing radiation
IIb
or
Biological effect or mainly absorbed
III
or
Undergo chemical change in body - or administer medicines (NOT in teeth)
IIb


Rule 8
Surgically invasive
Long-term use and
implantable devices
IIb
or
To be placed in teeth
IIa
or
Used in direct contact with heart or central circulatory/nervous system
III
or
Biological effect or mainly absorbed
III
or
Undergo chemical change in body - or administer medicines (NOT in teeth)
III
or
Specific derogation: breast implants and hip, knee and shoulder joint replacements
III

ACTIVE DEVICES

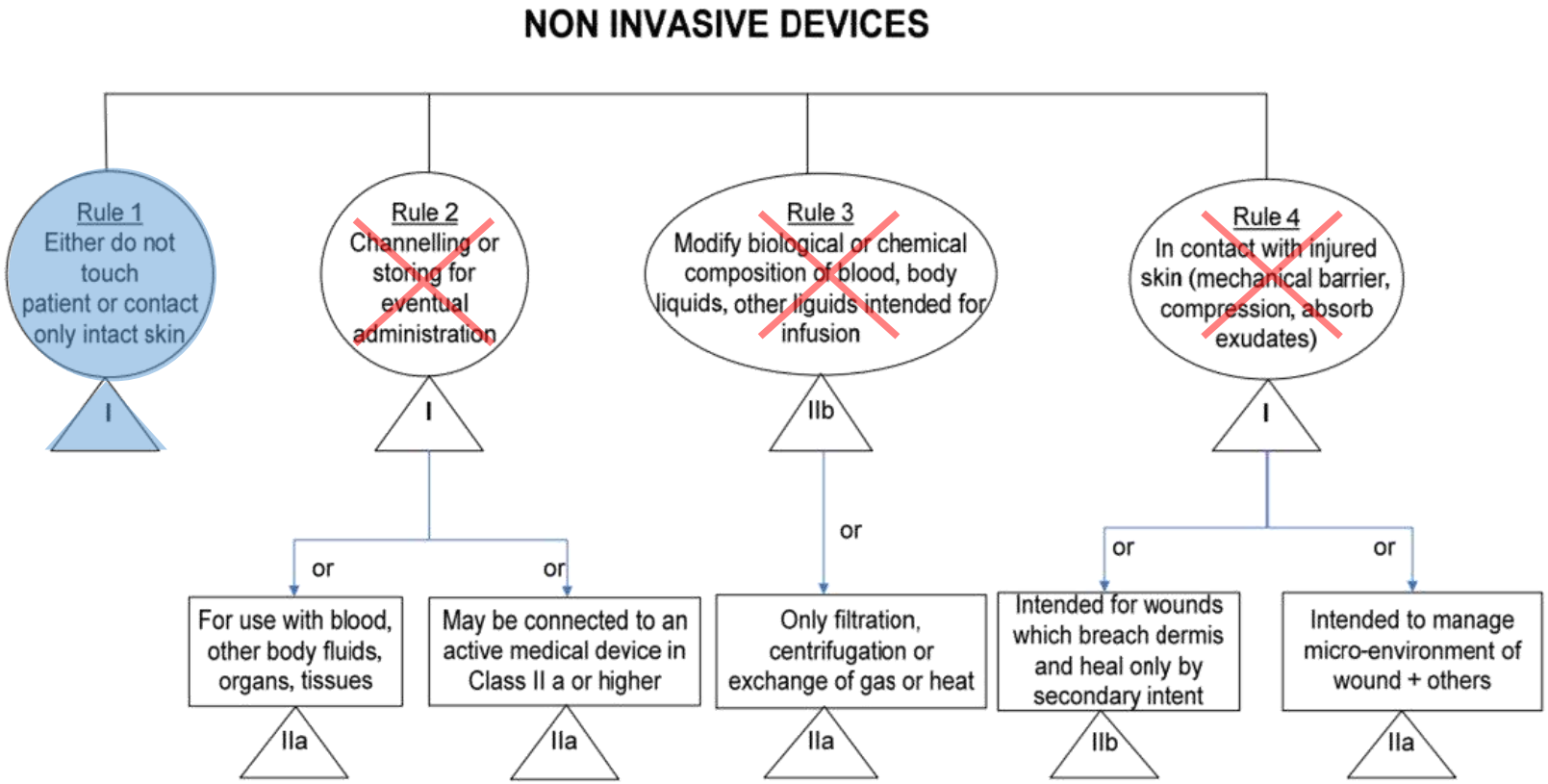


SPECIAL RULES



Examples

Stethoscope

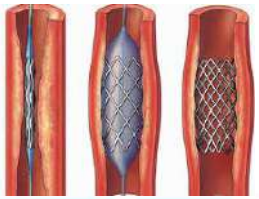


Examples

Contact Lenses → Invasive (Rules 5-8) → ~~Rule 6~~ ~~Rule 7~~ ~~Rule 8~~ → Rule 5 ✓ → **Class IIa**

*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 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…*

Cardiovascular Stent → Invasive (Rules 5-8) → ~~Rule 5~~ ~~Rule 6~~ ~~Rule 7~~ → Rule 8 ✓ → **Class IIb**



*All implantable devices and long-term surgically invasive devices are classified as **class IIb** unless they…*

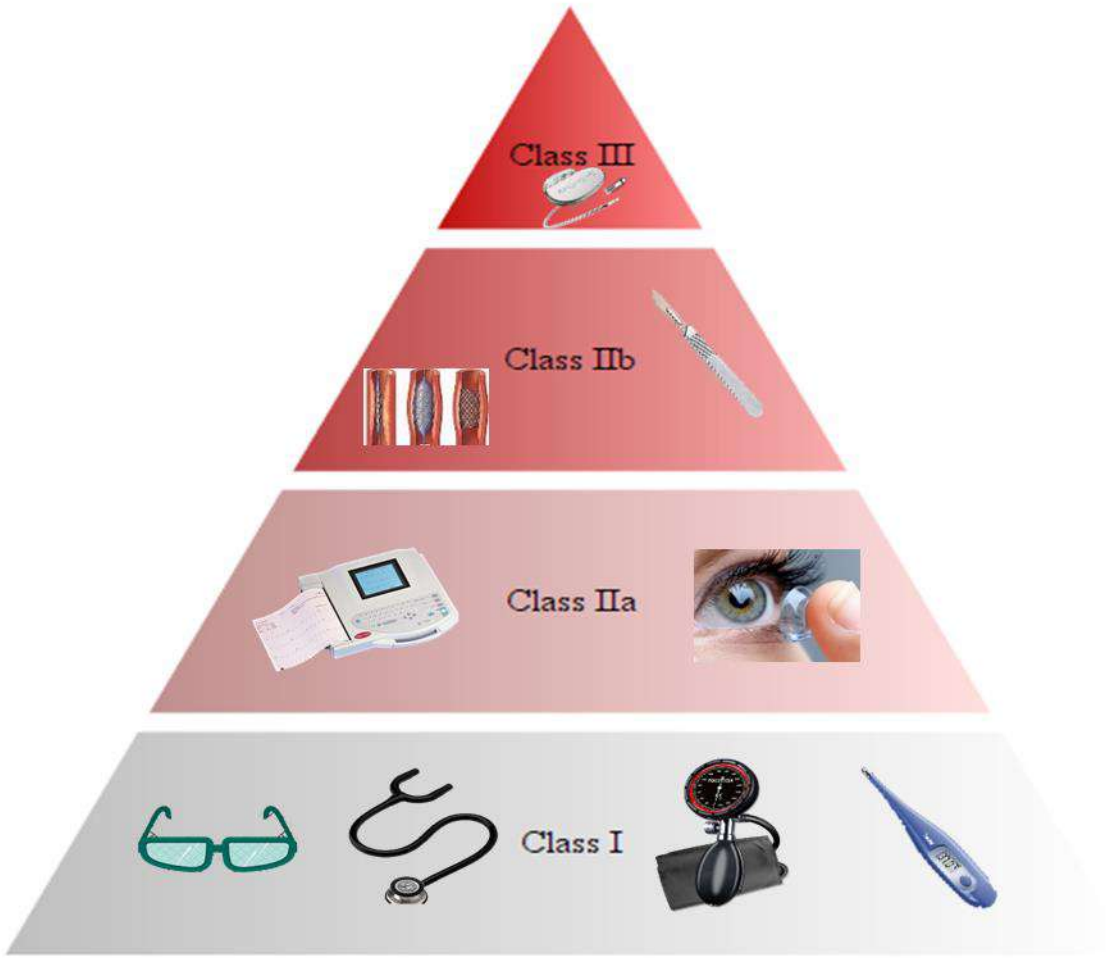
Pacemaker

→ Invasive (Rules 5-8) →

~~Rule 5~~
~~Rule 6~~
~~Rule 7~~

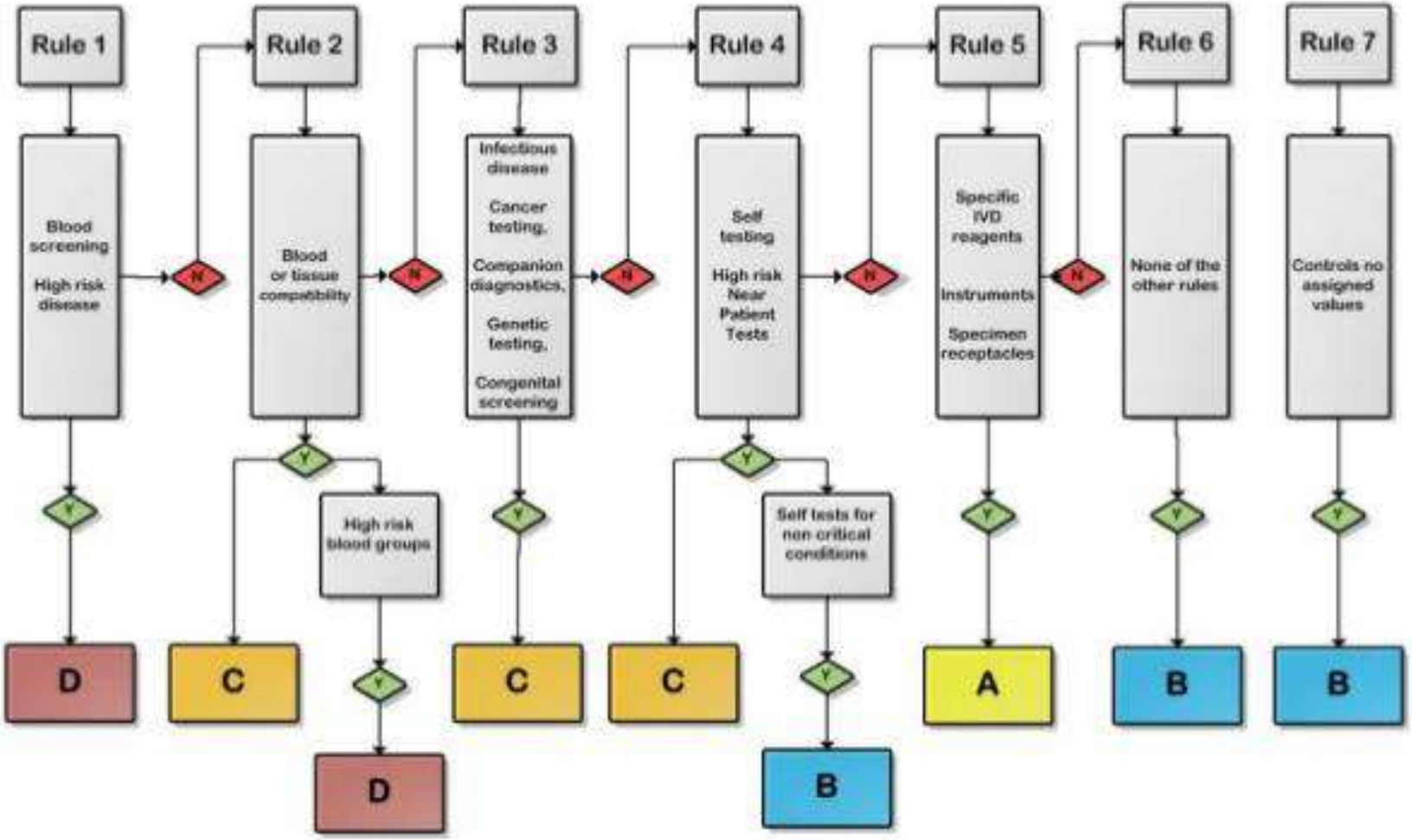
→ Rule 8 ✓ → **Class III**

*All implantable devices and long-term surgically invasive devices are classified as class IIb unless they…are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as **class III**…*



Increasing Risk

IVD Classification



CE marking and steps for obtaining it

CE marking is affixed to the device and accompanying documents; it demonstrates that the manufacturer has complied with the applicable directive(s)/regulation(s) and **is not** a quality sign.

1. Definition of medical device and intended use:
   Is the product a medical device according to the medical devices directives/regulations?
   What kind of medical device is the product (IVD, AIMD, MD)?

2. Classification of the medical device: *is it class I, IIa, IIb, III or A, B, C, D?*

3. Meet the directive requirements: ***To respect a certain harmonised standard*** *or some* ***common specifications*** *that can guarantee the respect of all, or part of, the essential requirements; If there is no harmonised standard of reference, the manufacturer has to prove how each essential requirement has been respected* ***(checklist)***.

Click here for a list of the EU harmonised standards

"Conformité Européenne"

4. Find and follow the right **C**onformity **A**ssessment **P**rocedures (**CAP**): CAPs allow manufacturers to demonstrate the conformity of their device with the regulation. The choice of the CAP depends on the classification of the device. In particular, low-risk products generally allow **self-certification.** Higher risk products will **require the services of a third party**, namely a **EU notified body**. The latter is an accredited test laboratory based in the EU. Its intervention is compulsory for all AIMD, some IVD and MD. A **quality management system (QMS)** is required for all devices (except Class I non sterile/non measuring). Most companies apply **EN ISO 13485** to comply with QMS requirements.

5. Assemble the **technical documentation**: it contains all the Important information to support the claims of compliance with the directive requirements. Must be available to national surveillance authorities.

6. Affix **CE Mark**: it is affixed to the device and any document. When a notified body intervenes, its ID number Must appear below or next to the CE mark.

7. Draw up a declaration of conformity: it is a one-page document in which the manufacturer declares the conformity of his product with the essential requirements and the safety and performance requirements. All devices must have it.

Conformity Assessment Procedures (CAP) Medical Devices

MANIFACTURER
INTENDED PURPOSE OF THE DEVICE

CLASS I | CLASS IIA | CLASS IIB | CLASS III

STERILE CONDITION, MEASURING FUNCTION, REUSABLE SURGICAL INSTRUMENT?

NO IF *YES*

OR

OR

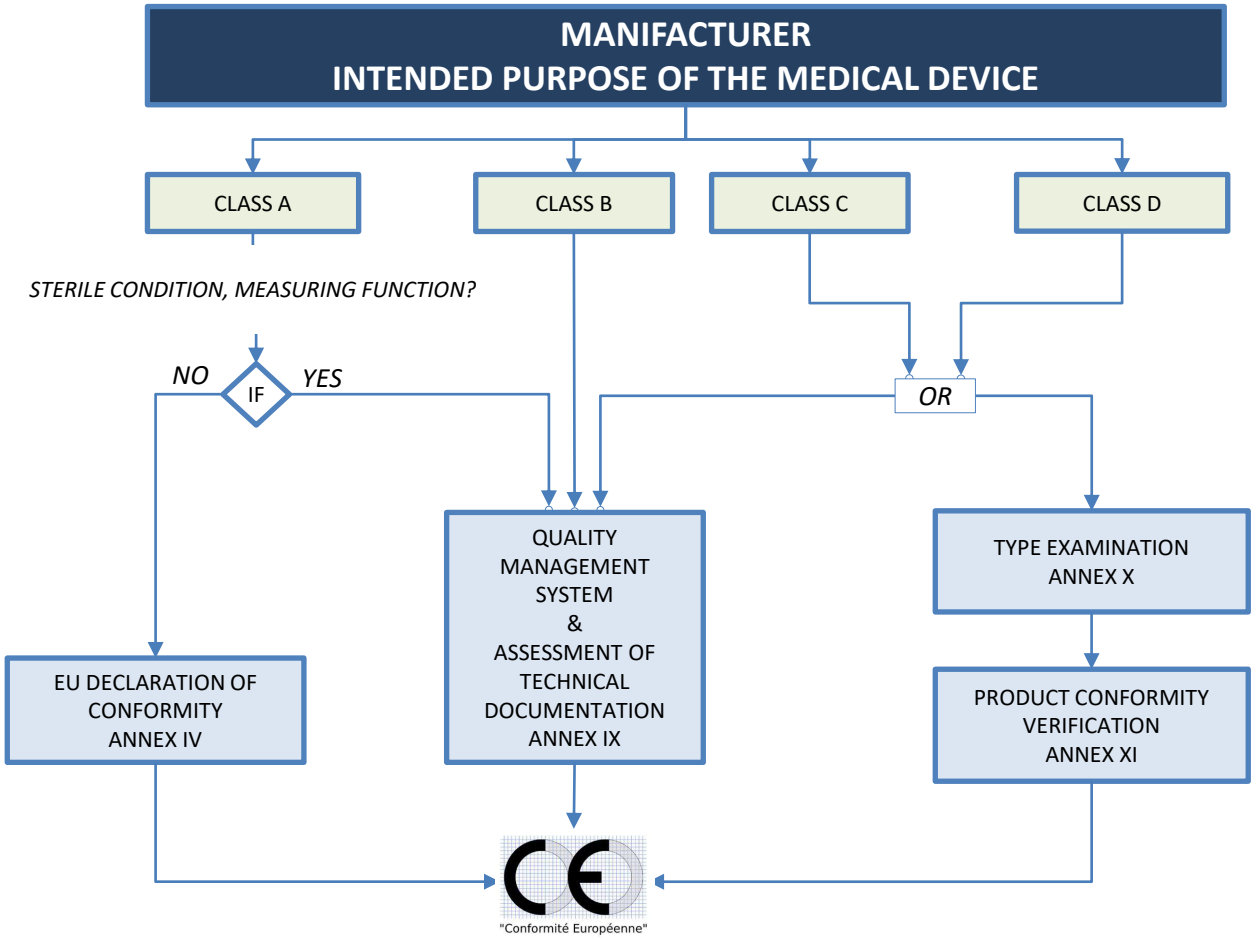
TYPE EXAMINATION
ANNEX X

QUALITY MANAGEMENT SYSTEM & ASSESSMENT OF TECHNICAL DOCUMENTATION
ANNEX IX

EU DECLARATION OF CONFORMITY
ANNEX IV

PRODUCT CONFORMITY VERIFICATION
ANNEX XI

Conformity Assessment Procedures (CAP) Invitro Diagnostic Medical Devices



Some evident criticisms (not exhaustive)

- Certifying MDs and IVDs in respect to the new MDRs *means de facto a new certification*.
- extension of MDs and IVDs definitions will *increase the # of devices requiring NB direct control* (e.g., from the current 20% to the 80%).
- A considerable *delay in Notified Bodies (NBs) designation*. Only 2 NBs and other 20 expected before the end of the year. This is a third of the actual number (i.e., 58) of Notified Bodies.
- Insufficient number of MD experts, compared to drugs ones, in public agencies. The same trend is dramatically evident also in international agencies, such as the WHO, where despite the tens of drug senior experts, only 1 MD expert is currently employed, and as senior consultant (i.e., not a permanent position).
- The new MDRs *introduce obligations for different economic operators* (importers, distributors) very distant from these requirements.
- Manufacturers likely underestimate the practical impact of the MDR on the MD design and development process due to the habits consolidated with the current certification.
- Clinical evidence before CE marking, but RCT fails to trial MDs (e.g., if parachutes were MDs, we could not use it! How can you 'control' its effectiveness in saving life?)

Devices	Drug
Principal action	
Other than principally drugs	Pharmaco./Immunologic/Metabolic
Mechanical/Electromagnetic/Materials	Chemical based
Product life cycle	
Short life cycle	Long life cycle
Constantly evolving components/parts	Unchanging compound
Clinical evaluation	
Difficult to blind (no placebo)	Easy to blind
Multiple end users	Usually one end users
Long learning curve	Short learning curve
Strongly dependent by settings/users	Less dependent by settings/users
Complex to standardize for RCT	Easy to standardize for RCT
Use issues	
User-dependent efficacy	Efficacy is less user-dependent
Often require intensive training	Usually do not require training
Complication decrease with use	Complication increase with use
Diversity	
Mainly small companies/few large co.	Mainly large multinationals
Diagnostic or therapeutic	Therapeutic
Costs	
Varying overheads/slow return	High overheads with quicker return
Higher distribution costs	Lower distribution costs
Higher maintenance/installation costs	No maintenance/installation

L Pecchia, MP Craven, "***Early stage Health Technology Assessment (HTA) of biomedical devices. The MATCH experience***". World Congress on Medical Physics and Biomedical 2012, 26-31 May 2012, Beijing, China.

Polisena, Julie, et al. "**Health technology assessment methods guidelines for medical devices: how can we address the gaps? The International Federation of Medical and Biological Engineering perspective**." International journal of technology assessment in health care 34.3 (2018): 276-289.

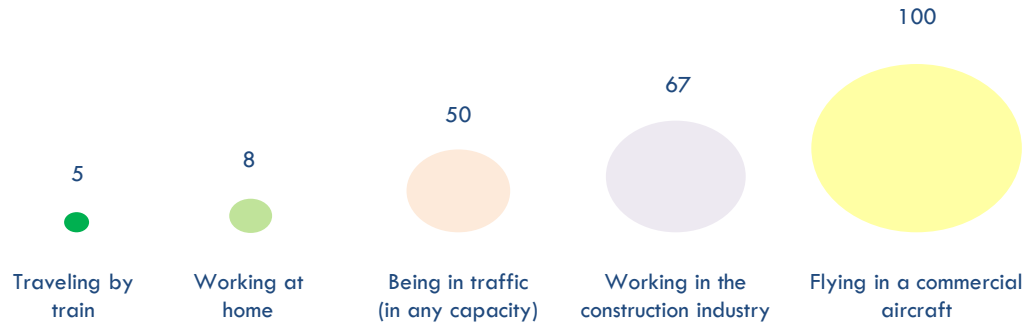
Deepening: is health a right or a duty?
Podcast: "HTA of Medical Device", an intro link

Why?

Because of RISKS (1/3)

Some estimations of Risks, in terms of

Deaths per 100 millions hours of activity associated with:



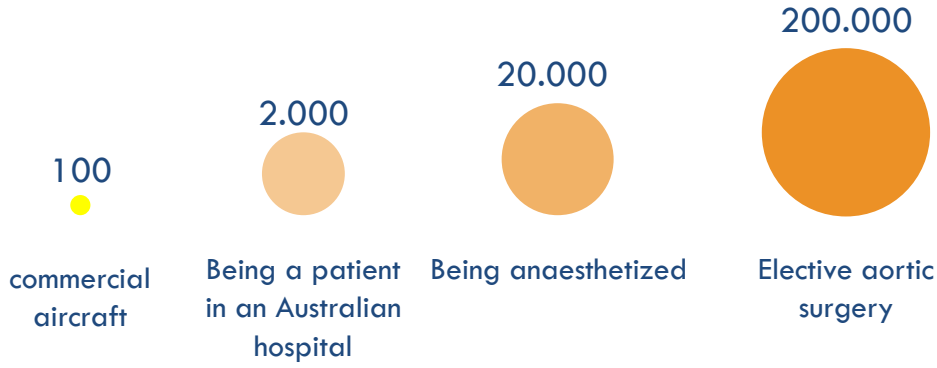
20.000

Parachute jumping

Ref. Bill Runciman
Australian Patient Safety Foundation
Australian Council for Safety and Quality in Healthcare

Because of RISKS (1/3)

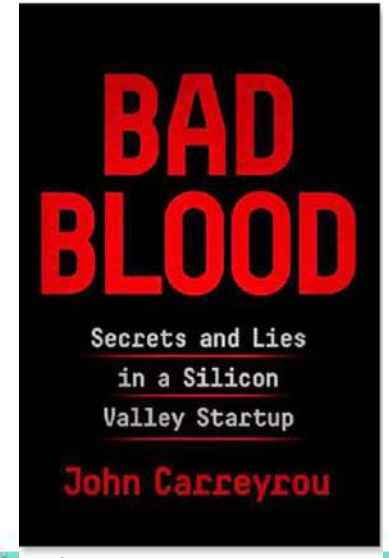
Risks in terms of Deaths per 100 millions hours associated with:



2.000.000
Emergency aortic surgery

Ref. Bill Runciman
Australian Patient Safety Foundation
Australian Council for Safety and Quality in Healthcare

Because of difficulty in proving EFFECTIVENESS (2/3)

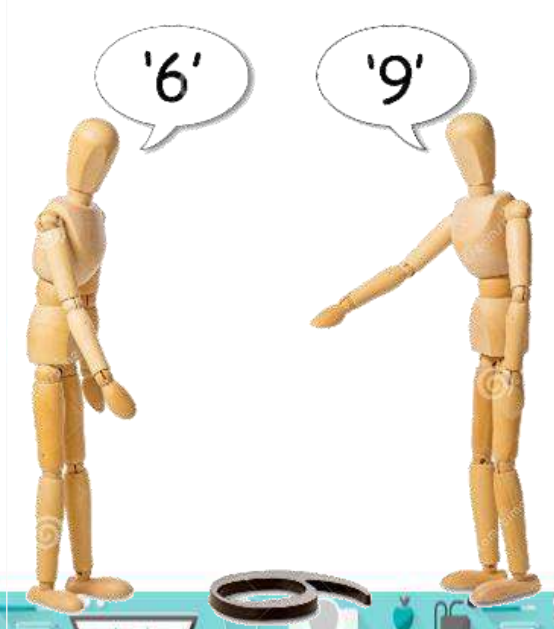


*Suggested reading…

The '*case Theranos*': all a BME should never do…

Because Medical Device ecosystem is complex and asymmetric (3/3)

- **R&D** -> biology and medicine engineers and scientists
- **Assessment** -> health economists, medical doctors, pharmacists, (recently) BMEs
- **Lead users** -> medical doctors, nurses
- **Lay users** -> patients
- **Payer** -> NHS (i.e., tax payers) or private insurance (i.e., groups of patients)



Deepening: is health a right or a duty?
Podcast: "HTA of Medical Device", an intro link

Health(care) technologies, medical devices & equipment

Health Technologies

The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life (WHO).

Medical Devices

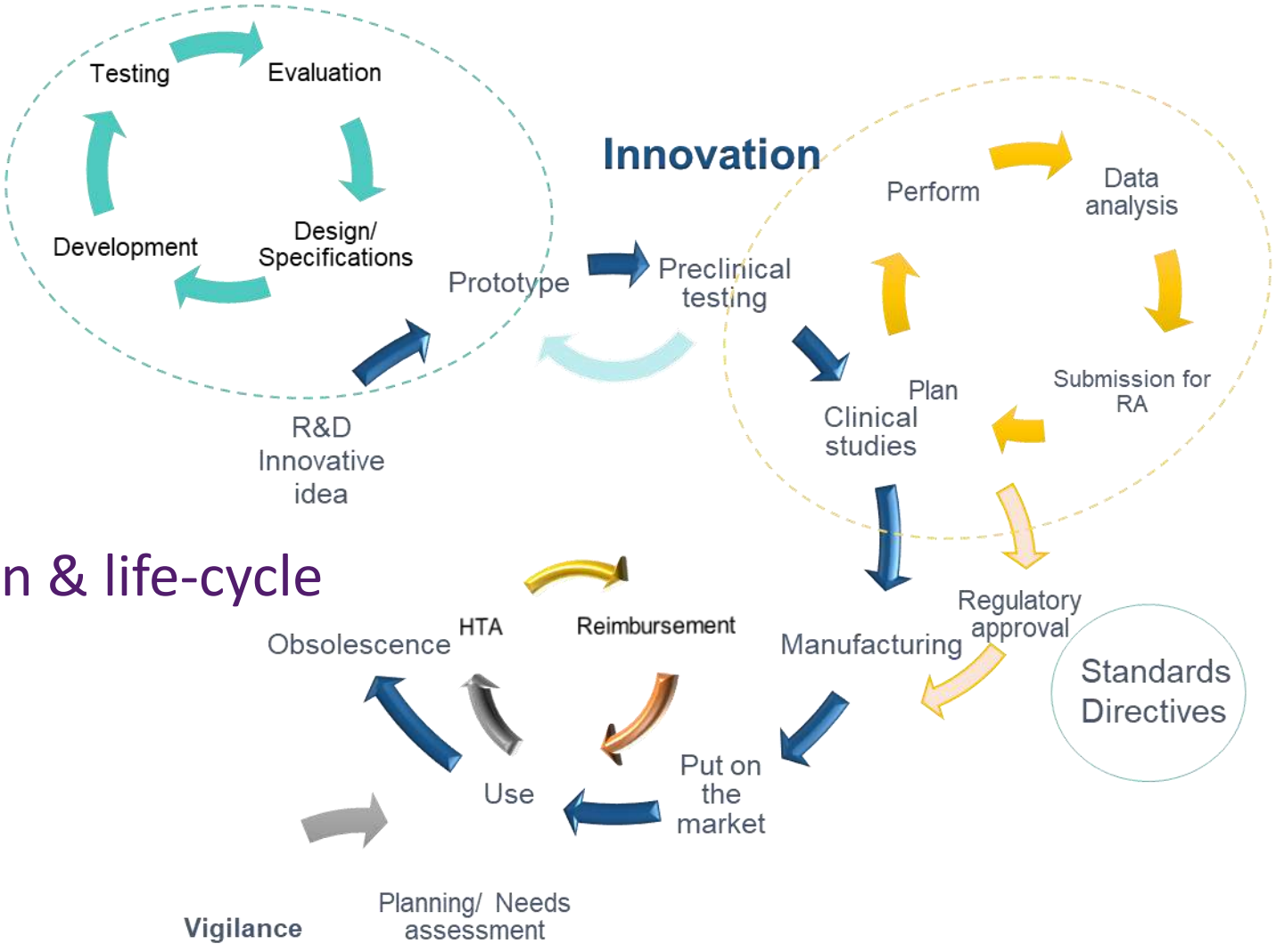
Medical Equipment

Take Home Message (THM1): Regulation into the context

- No-silos (i.e., overcome the Cartesian model, as I prefer to say…)
- According to the World Health Organization (WHO)

** From "Human resources for medical devices", WHO technical series:*

https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479-eng.pdf



THM2: Regulation & life-cycle

- Start ASAP!

*From N. Pallikarakis et al. (2017), *Hospital Technology Management,* in Miniati, Roberto, Ernesto Iadanza, and Fabrizio Dori. *Clinical Engineering: From Devices to Systems*. Academic Press, 2015.

Deepening

Podcast: "Medical Device lifecycle", an intro link

THM3: consider the HTA aspects (cost-utility)

Medical Engineering and Physics xxx (xxxx) xxx-xxx

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com

Health Technology Assessment and biomedical engineering: Global trends, gaps and opportunities

L. Pecchia [a, e, *], N. Pallikarakis [b, e], R. Magjarevic [c, e], E. Iadanza [d, e]

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[d] Department of Information Engineering, University of Florence, Florence, Italy
[e] International Federation of Medical and Biological Engineering (IFMBE), Brussels, Belgium

Deepening

Podcast: "IFMBE HTAD 2015-18" link

THM4: consider the Clinical Engineering and HTM prospectives

Contents lists available at ScienceDirect

Biomedical Signal Processing and Control

journal homepage: www.elsevier.com/locate/bspc

Evidence-based clinical engineering: Machine learning algorithms for prediction of defibrillator performance*

Almir Badnjević [a,b], Lejla Gurbeta Pokvić [a,b], Mehrija Hasičić [a], Lejla Bandić [a,*], Zerina Mašetić [a], Živorad Kovačević [a], Jasmin Kevrić [a], Leandro Pecchia [c]

Medical & Biological Engineering & Computing

ORIGINAL ARTICLE

Evidence-based medical equipment management: a convenient implementation

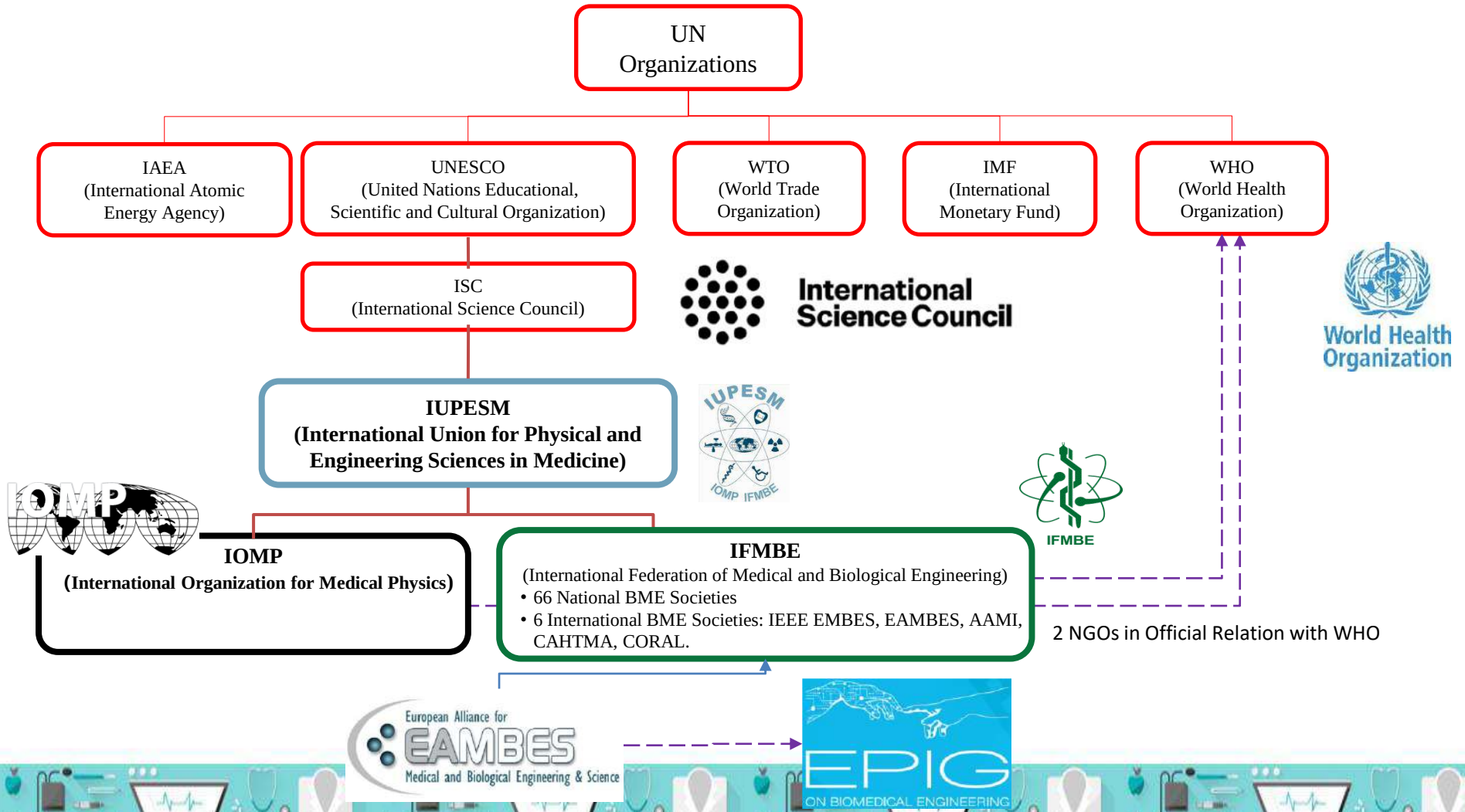
Ernesto Iadanza [1] · Valentina Gonnelli [1] · Francesca Satta [2] · Monica Gherardelli [1]

Received: 5 July 2018 / Accepted: 27 July 2019

Take home messages (THM):

- **BME relates** to medical devices as *chemistry to pharma*
- **The new regulations introduced essential innovations** this will make innovation more complex (i.e., costly, time consuming), but is also an opportunity for doing better
- **All BMEs should be educated to medical device regulation** (possibly considering EU and FDA regulatory frameworks), because MedTech are mainly microE/SME…
- **Medical device regulation**, should be considered in relation to medical device assessment (i.e., HTA) and management (i.e., HTM), as per WHO recommendation.
- **Medical device regulation** must be considered during R&D, when a small change can make huge difference. Do not leave this for the last phase…
- **Do not delegate this responsibility!** Be proactively involved into preparation of standards, norms, regulations… how?

BME ecosystem



…how? Be proactively involved as member of you national society and/or volunteer to join the *Early Career Chapter* of EAMBES and Europe)

III ICEHTMC

OCT 21st – 22nd | 2019
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Clinical Engineering Division

INTERNATIONAL CLINICAL ENGINEERING AND HEALTH TECHNOLOGY MANAGEMENT CONGRESS

Dr. Leandro Pecchia

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Secretary General, **IUPESM** (2018-21)

Elected President, **EAMBES** (2019-21)

Treasurer, **IFMBE CED** (2018-21)

European Alliance for EAMBES Medical and Biological Engineering & Science

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- # Errata Corrige: Table 2

	Perspective	Focus	Role
HTR	Jurisdiction (e.g. EU)	Safety, efficacy, quality	Mandatory. HTR aims at ensuring MD compliance with safety, health and environmental protection standards.
HTA	Policy-maker, Payer (e.g. NHS, sickness funds, …)	Effectiveness, cost-effectiveness and appropriateness	Inform policy-makers and decision-making. HTA aims at maximizing the benefits (mainly a combination of quantity and quality of life gains) per unitary cost.
HTM	Local (e.g., Hospital Trusts, Local Trust)	Operational	Support Trusts in planning, budgeting, selection, purchasing, Training, installation, operation, maintaining, servicing, decommissioning of MDs. HTM ensures affordable, effective and safe use of MD, in relation to local organization, asset, culture and budget.

L Pecchia, *D Piaggio*, *R Castaldo*, *L Radice*, *N Pallikarakis (2019)* Medical device regulation and assessment: new challenges for biomedical engineers in Elena De Momi, Arianna Menciassi, Alberto C L Redaelli *Advanced Bioengineering Methods, Technologies And Tools In Surgery And Therapy*, Patron Editore