EU Medical Device Regulation 2017/745

Laboratorio di Tecnologie Biomediche A.A 2018/2019

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WHAT THEY HAVE IN COMMON?




European Medical Device Legislation

Directive 90/385/EEC on Active Implantable Medical Devices
Directive 93/42/EEC on Medical Devices

Regulation on medical devices: **Regulation (EU) 2017/745**
http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0745&from=EN

Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Regulation on in vitro diagnostic medical devices: **Regulation (EU) 2017/746**
http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0746&from=EN

The Medical Device Regulation is a law that regulates the marketing of Medical Devices in the EU

What is a Medical Device?

MDR 2017/745 – Article 2 (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,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

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.

EU Regulation 2017/745

- 101 Whereas…= WHY
- 10 Chapters of 123 Articles = WHAT
- XVII Annexes = HOW

- Chapter I – Scope and Definitions
- Chapter II – CE Marking, Economic Operators, Reprocessing
- Chapter III – Identification and Traceability of Devices
- Chapter IV – Notified Bodies
- Chapter V – Classification and Conformity Assessment
- Chapter VI – Clinical Evaluation and Investigation
- Chapter VII – Vigilance and Market Surveillance
- Chapter VIII – Cooperation between Member States
- Chapter IX – Confidentiality, Data Protection, Funding, Penalties
- Chapter X – Final Provisions

EU Regulation 2017/745

- 101 Whereas…= WHY
- 10 Chapters of 123 Articles = WHAT
- XVII Annexes = HOW

- Annex I – General safety and performance requirements
- Annex II – Technical Documentation
- Annex III – Technical Documentation on PMS
- Annex IV – EU Declaration of Conformity
- Annex V – CE Marking of Conformity
- Annex VI – European UDI System
- Annex VII – Requirements to be met by Notified Bodies
- Annex VIII – Classification Criteria
- Annex IX – Conformity Assessment – QMS and Technical Documentation
- Annex X – Conformity Assessment – Type Examination
- Annex XI – Conformity Assessment – Product Conformity Verification
- Annex XII – Procedure for Custom-made Devices
- Annex XIII – Certificates issued by a Notified Body
- Annex XIV – Clinical Evaluation and Post-market clinical follow-up
- Annex XV – Clinical Investigations
- Annex XVI – Products without an intended medical purpose
- Annex XVII – Correlation Table 90/385, 93/42 and Regulation

ACTORS - WHO ARE THEY?

European Commission

European Commission, Parliament, Council

Member States EU, EEA, EFTA, Customs Union, MRA

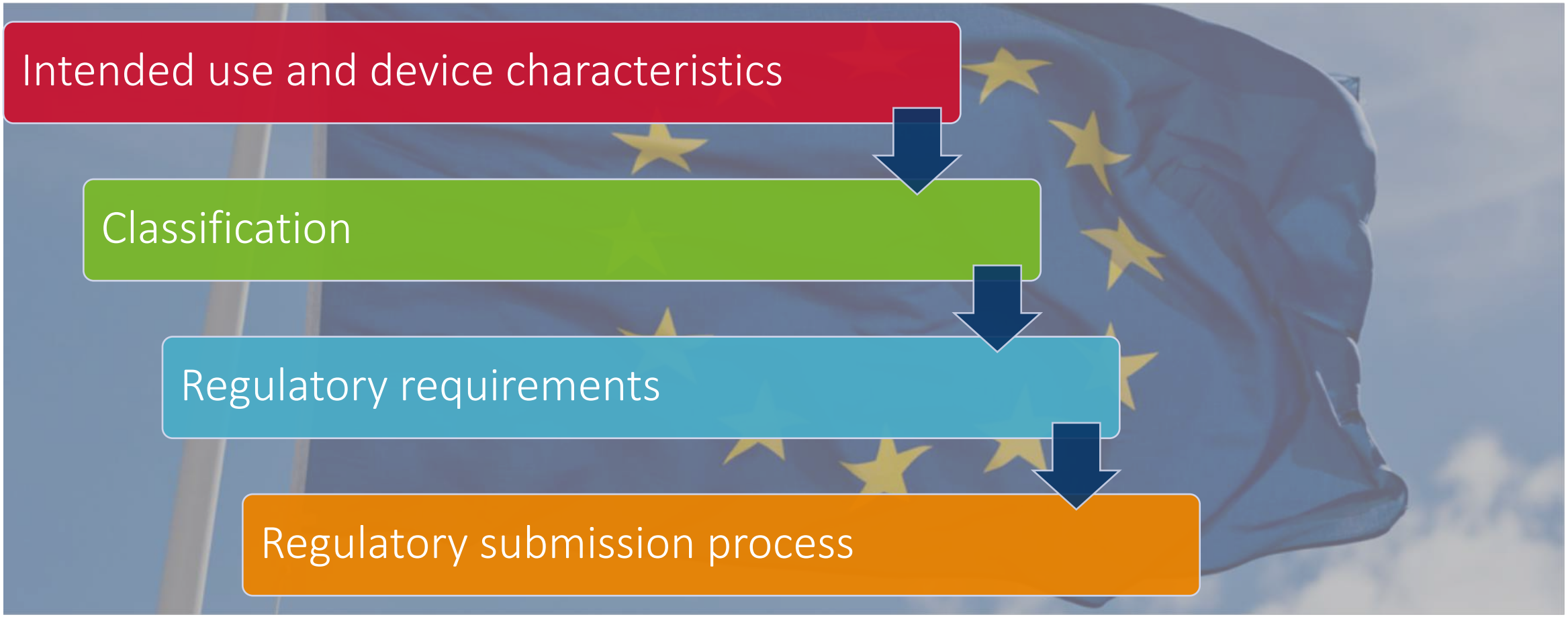
Notified Bodies

Manufacturer
Suppliers
Subcontractors
EU Authorised Representative

New Legislative Framework

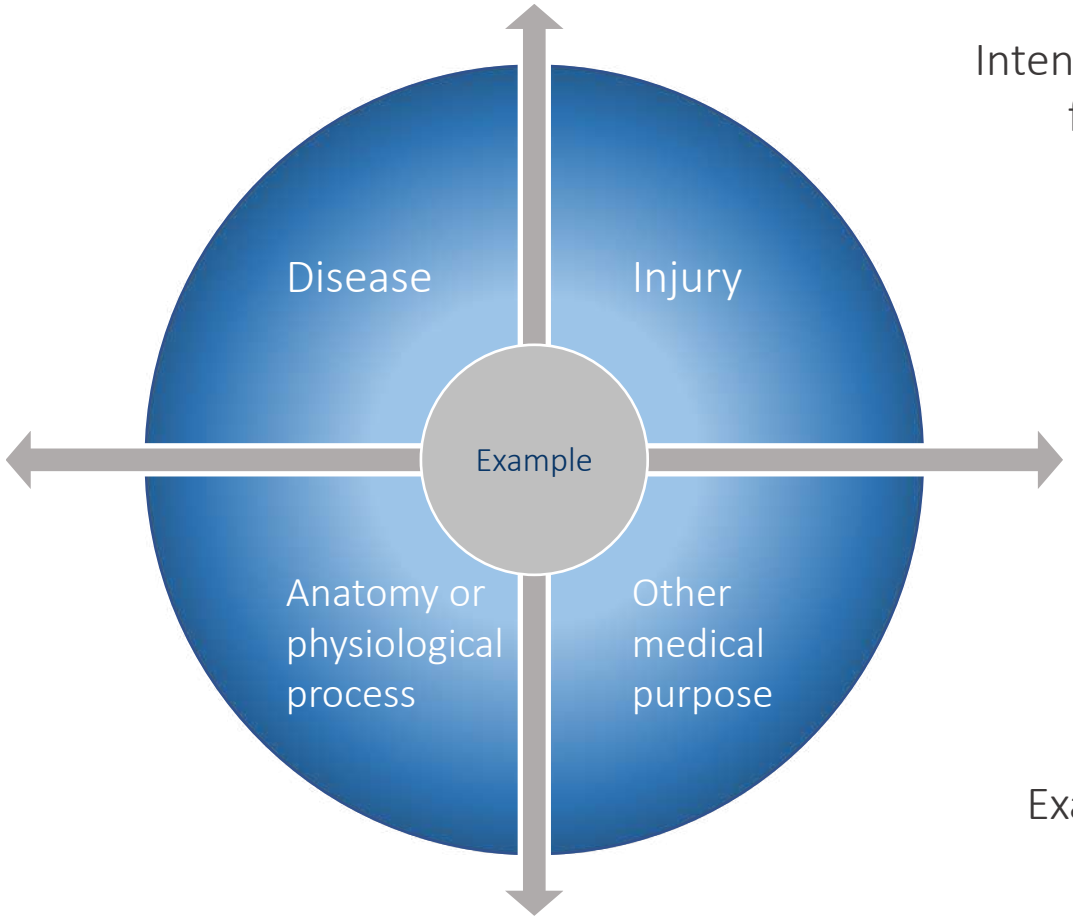
CE

Overview of Regulatory Framework

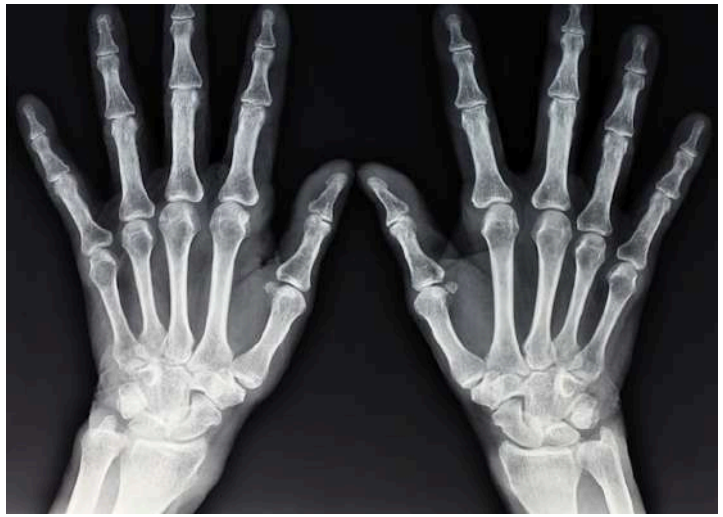


MDR 2017/745
INTENDED USE

MDR 2017/745 – INTENDED USE



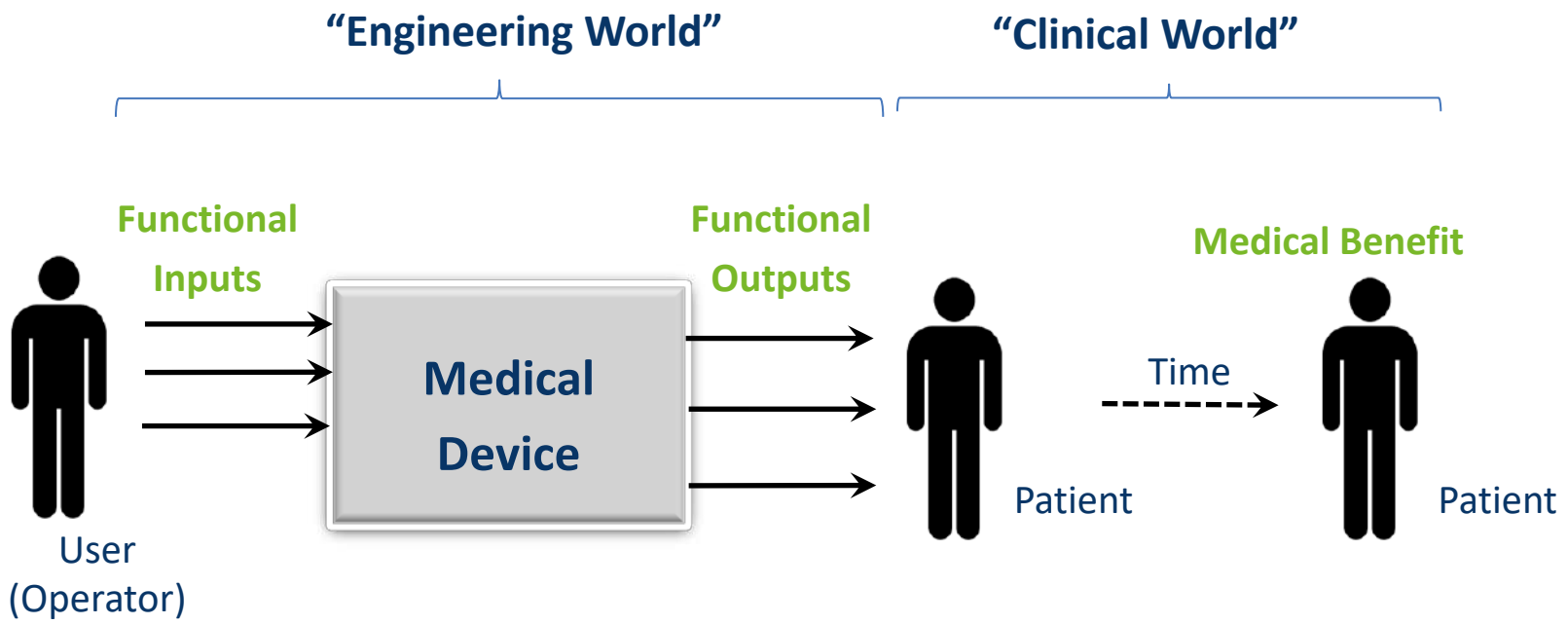
Intended use The general purpose of the medical device or its function (what you "claim" the medical device does)



Example: …. is a diagnostic x-ray system for generation of x-rays for examination of various anatomical regions

Intended use – Focus on Patients

The intended use of a medical device can be depicted using an idealized functional input/output diagram



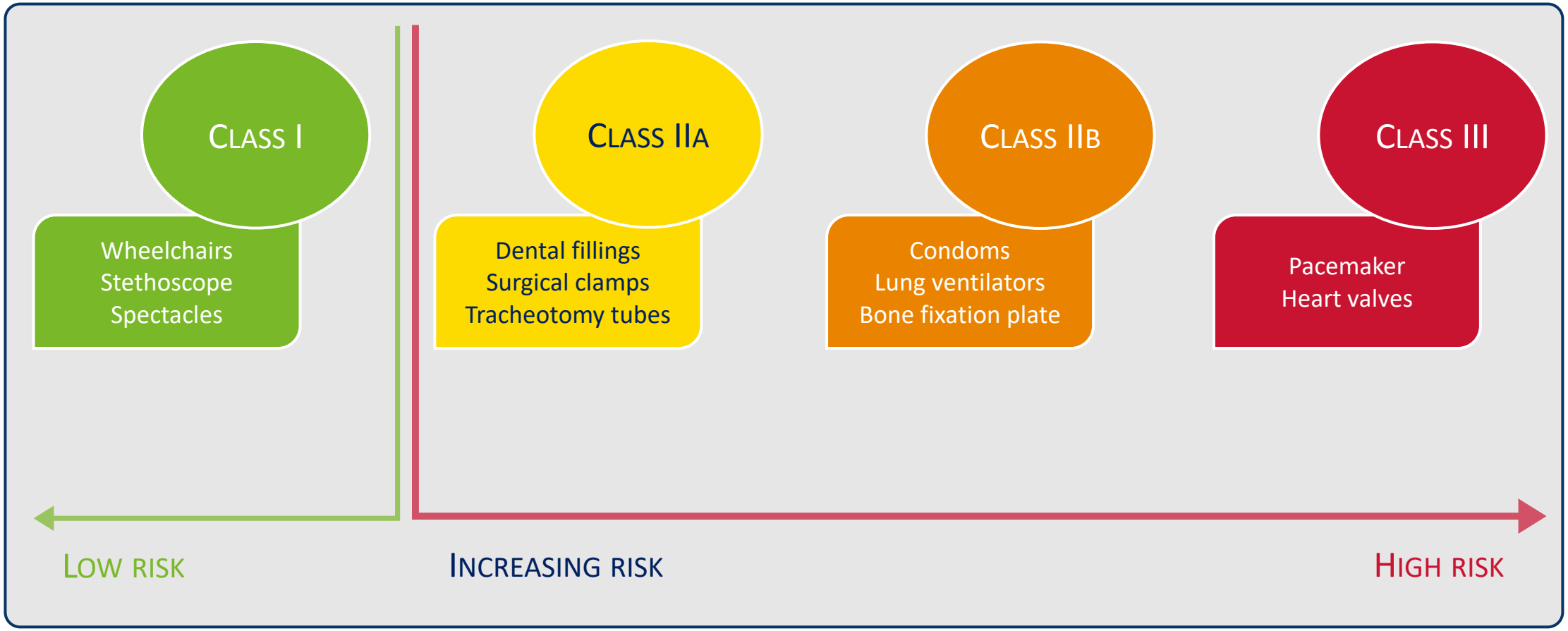
MDR 2017/745
CLASSIFICATION

MDR 2017/745 - CLASSIFICATION

- 1- 4 – Non-Invasive MD
- 5 –Invasive MD
- 9-13 – Active MD
- 14-22 – Special Rules

ANNEX VIII
22 CLASSIFICATION RULES

MDR 2017/745 – CLASS RISK



REGULATORY REQUIREMENTS –CONFORMITY ASSESSMENT PROCEDURE–

BASED ON THE CLASSIFICATION, WE CAN DETERMINE THE APPROPRIATE CONFORMITY ASSESSMENT PROCEDURE...

PRODUCT ON EUROPEAN MARKET

Many products require CE marking before they can be sold in the EEA. CE marking proves that your product has been assessed and meets EU safety, health and environmental protection requirements. It is valid for products manufactured both inside and outside the EEA, that are then marketed inside the EEA.

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

MDR 2017/745, Annex I

- General Requirements
  - Manufacturers shall establish, implement, document and maintain a risk management system
- Requirements regarding design and manufacture
  - E.g. chemical, physical and biological properties
- Requirements regarding the information supplied with the device
  - E.g. label and instruction use

CE

23 REQUIREMENTS

HARMONISED STANDARDS

Article 8 – MDR 2017/745

*"Devices that are in conformity with the relevant **harmonised standards**, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof." (1)*

International Standards Organization

ISO International Organization for Standardization

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

European Standards Organization

CEN CENELEC

Official Journal of the European Union

L 117

English edition

Legislation

Volume 60

5 May 2017

Contents

I Legislative acts

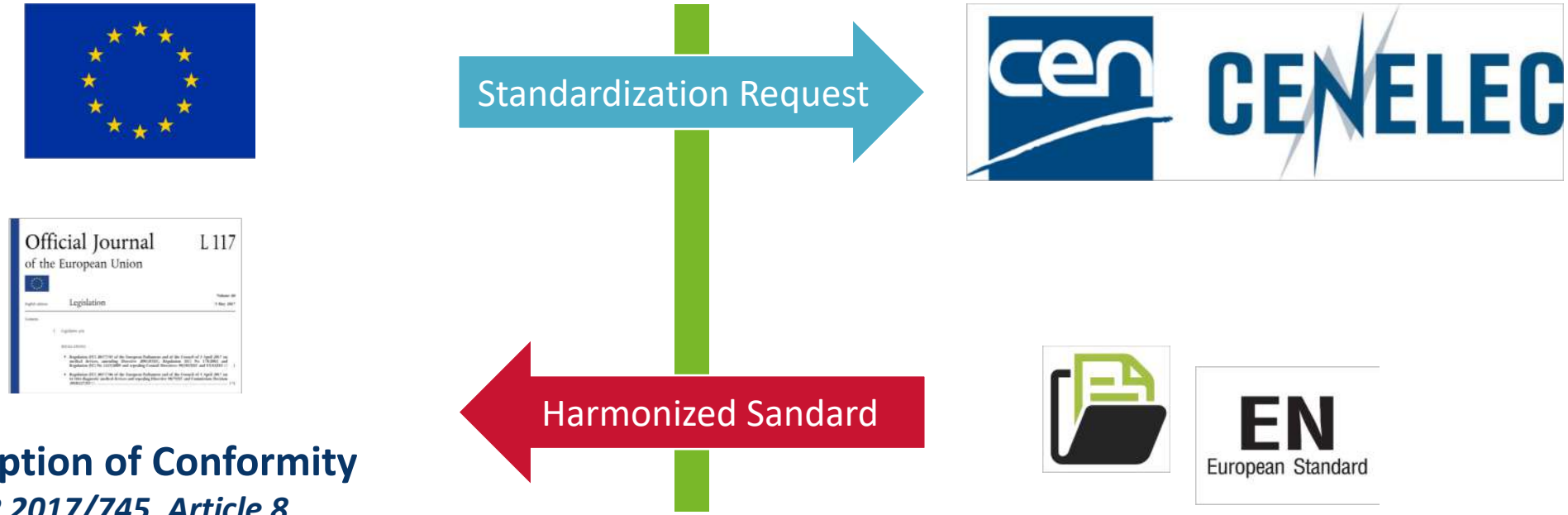
REGULATIONS

- 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 (1) 1
- 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 (1) 176

HARMONISED STANDARDS

WHAT IS AN HARMONISED STANDARD?

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.



Presumption of Conformity

MDR 2017/745, Article 8

Some Key Standards

- EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes

  specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements

- EN ISO 14971:2016 –Medical devices – Application of risk management to medical devices

  specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

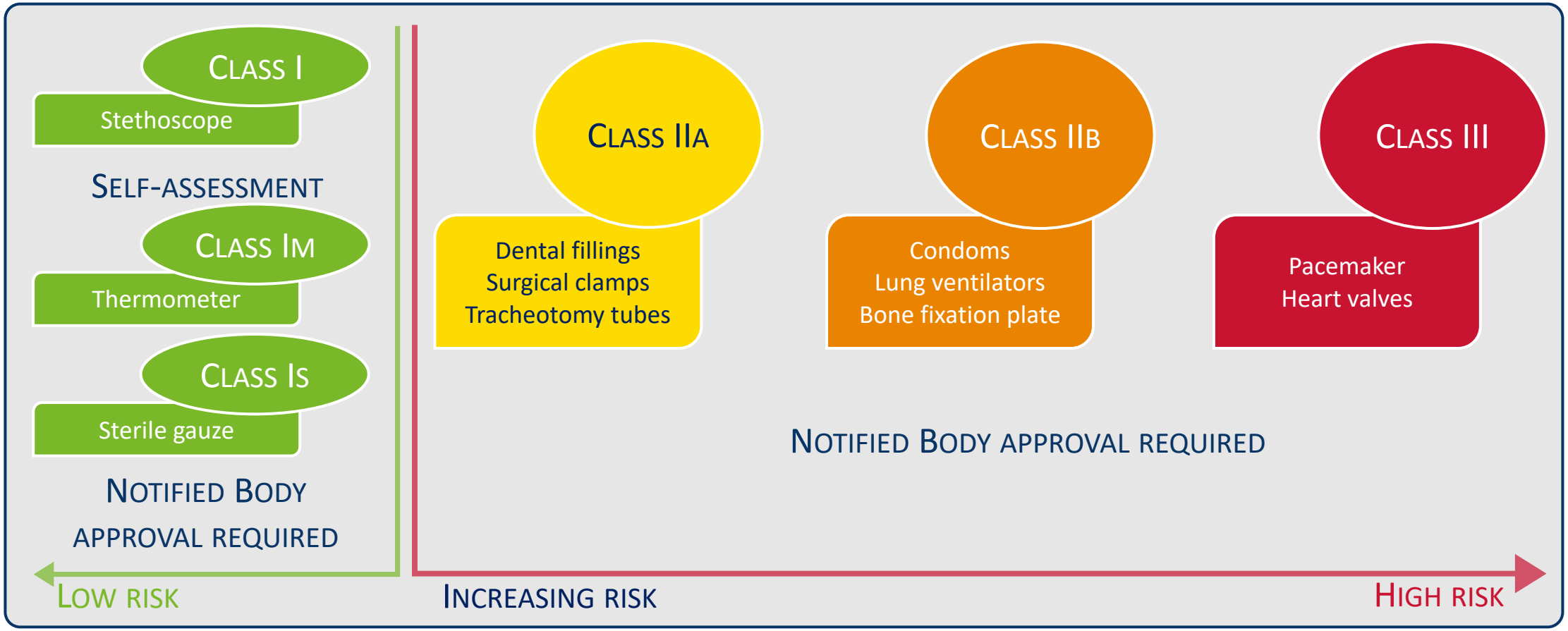
  identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document.

- EN ISO 10993-1:2009Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

- IEC 60601-1:2018 Medical Electrical Equipment -- Part 1: General requirements for basic safety and essential performance

  contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment.

MDR 2017/745 – CLASS RISK

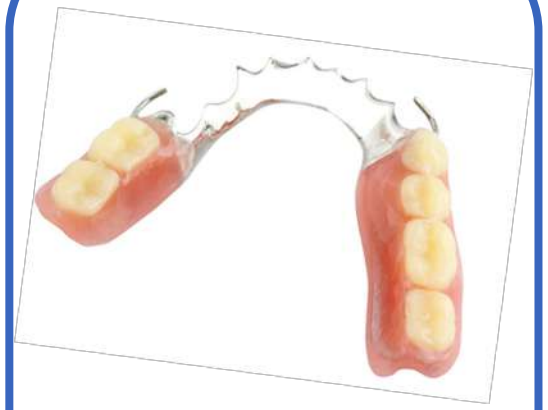


MDR 2017/745 – CUSTOM-MADE MD

"custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs." MDR 2017/745 Article 2 (3)

Mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices.

Example of Custom-Made MDs



Dentures

Maxillofacial implants

Custom insole

CUSTOM-MADE MD NOT INCLUDE…

"CUSTOMIZED" DOES NOT EQUAL A CUSTOM-MADE MEDICAL DEVICE

An existing medical device that is adapted, altered, fashioned, modified or 'customised' to fit a patient is NOT a custom-made medical device (e.g. contact lenses, orthodontic braces)

KNEE REPLACEMENT

LUMBAR INTERBODY CAGES

PROSTHETIC LEGS

STANDARDS ON MEDICAL DEVICES

WHAT IS A STANDARD? (1/2)

European Directive 98/34/CE 1998 :

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0034&from=en

- 'standard', a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:
  - **international standard**: a standard adopted by an international standardisation organisation and made available to the public,
  - **European standard**: a standard adopted by a European standardisation body and made available to the public,
  - **national standard**: a standard adopted by a national standardisation body and made available to the public;

WHAT IS A STANDARD? (2/2)

Principal characteristics of Standards:

- are volunteers;
- are based on the consensus and on the transparency;
- are re-examined every 5 years;
- are made by standardization bodies.

Some standards have regulatory effect

- Harmonised standards in EU
- Recommended standards in USA

WHERE DO STANDARDS COME FROM?

There are particular institutions, national and international, all non-profit, which constantly develop and update this regulatory activity.

- UNI – Ente Nazionale Italiano di Unificazione
- CEN – Comité Européen de Normalisation
- ISO – International Organization of Standardization
- IEC – International Electrotechnical Commission
- CENLEC – Comité Européen de Normalisation Électrotechnique
- CEI – Comitato Elettrotecnico Italiano

WHO ARE ISO AND IEC?

- The *International Organization for Standardization (ISO)* is a worldwide federation of national standards bodies.
- The *International Electrotechnical Commission (IEC)* is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

- The official purpose for the issuance of ISO/IEC Standards is to facilitate world trade through standardization

STANDARDIZATION BODIES

ISO	CEN	UNI
ISO	EN	UNI
	EN ISO	UNI EN
		UNI ISO
		UNI EN ISO

STANDARDIZATION BODIES

IEC

CENLEC

CEI

- IEC
- CENLEC
- CEI
- CEI CENLEC
- CEI IEC
- CEI CENLEC IEC

Standards and Medical Devices

- Device lifecycle is regulated by:
  - ISO 13485 for Quality System
  - ISO 14971 for Risk Management
- Each product category is than regulated by technical norms
  - For electro medical devices IEC 60601-1
  - For sterile device ISO 11137
  - For devices in contact with the body ISO 10993

Standards and Medical Devices

IEC standards have numbers in the range 60000–79999

The IEC cooperates closely with the International Organization for Standardization (ISO)

Other standards developed in cooperation between IEC and ISO are assigned numbers in the 80000 series

IEC 60601 EXAMPLE

IEC 60601 Medical Electrical Equipment

IEC 60601-x-xx

- The IEC 60601-1-xx series of collateral standards for MEDICAL DEVICE ELECTRICAL EQUIPEMENT
- The IEC 60601-2-xx series od particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT
- The IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPEMNT

IEC 60601 EXAMPLE

Collateral Standards

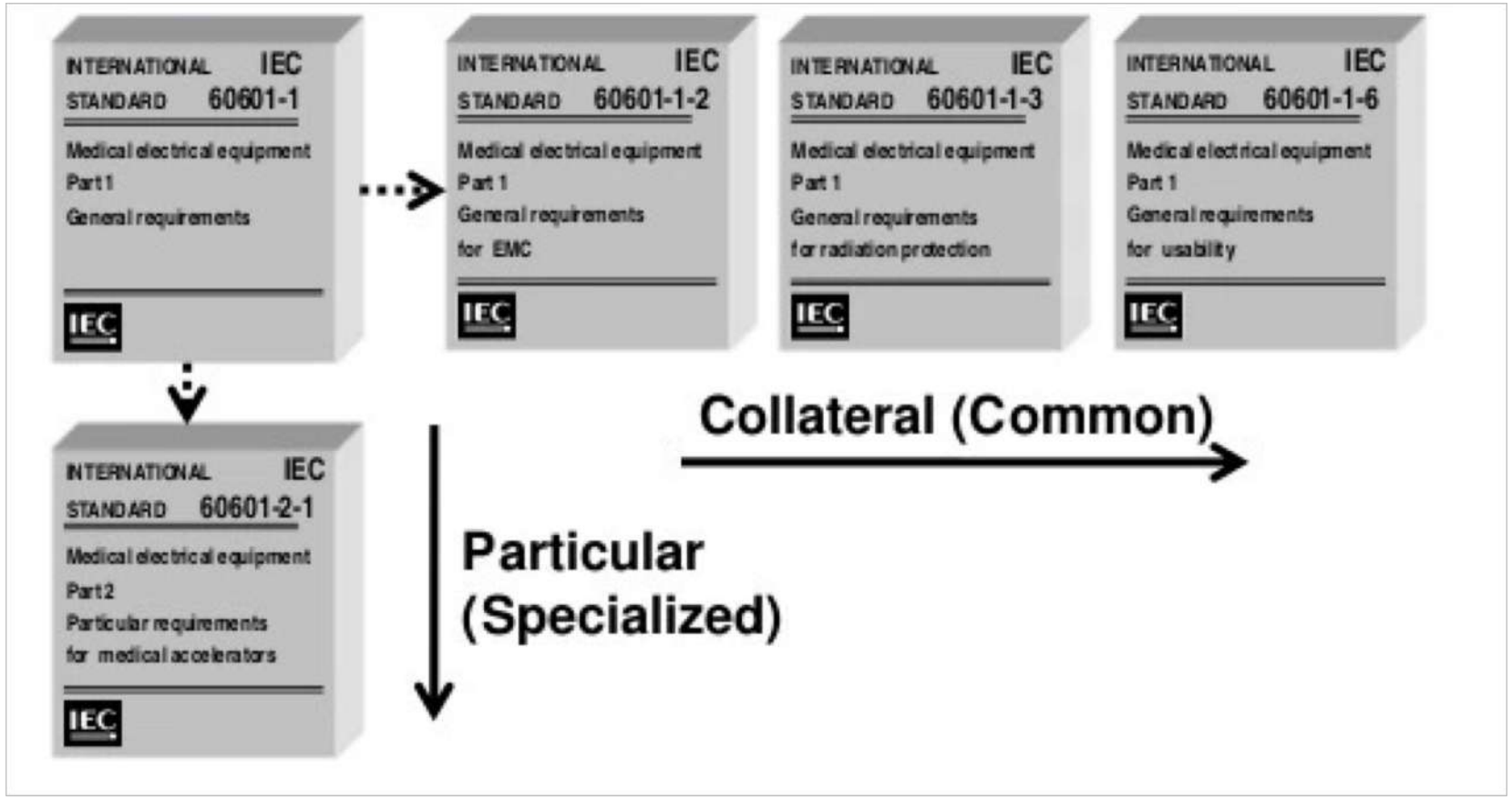
- IEC 60601-1-2, Medical electrical equipment – *Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests*
- IEC 60601-1-3, Medical electrical equipment – *Part 1-3: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*
- IEC 60601-1-6, Medical electrical equipment – *Part 1-6: General requirements for safety - Collateral standard: Usability*

IEC 60601 EXAMPLE

Particular Standards

- IEC 60601-2-1 Medical electrical equipment - *Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
- IEC 60601-2-2, Medical electrical equipment - *Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
- IEC 60601-2-4, Medical electrical equipment - *Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

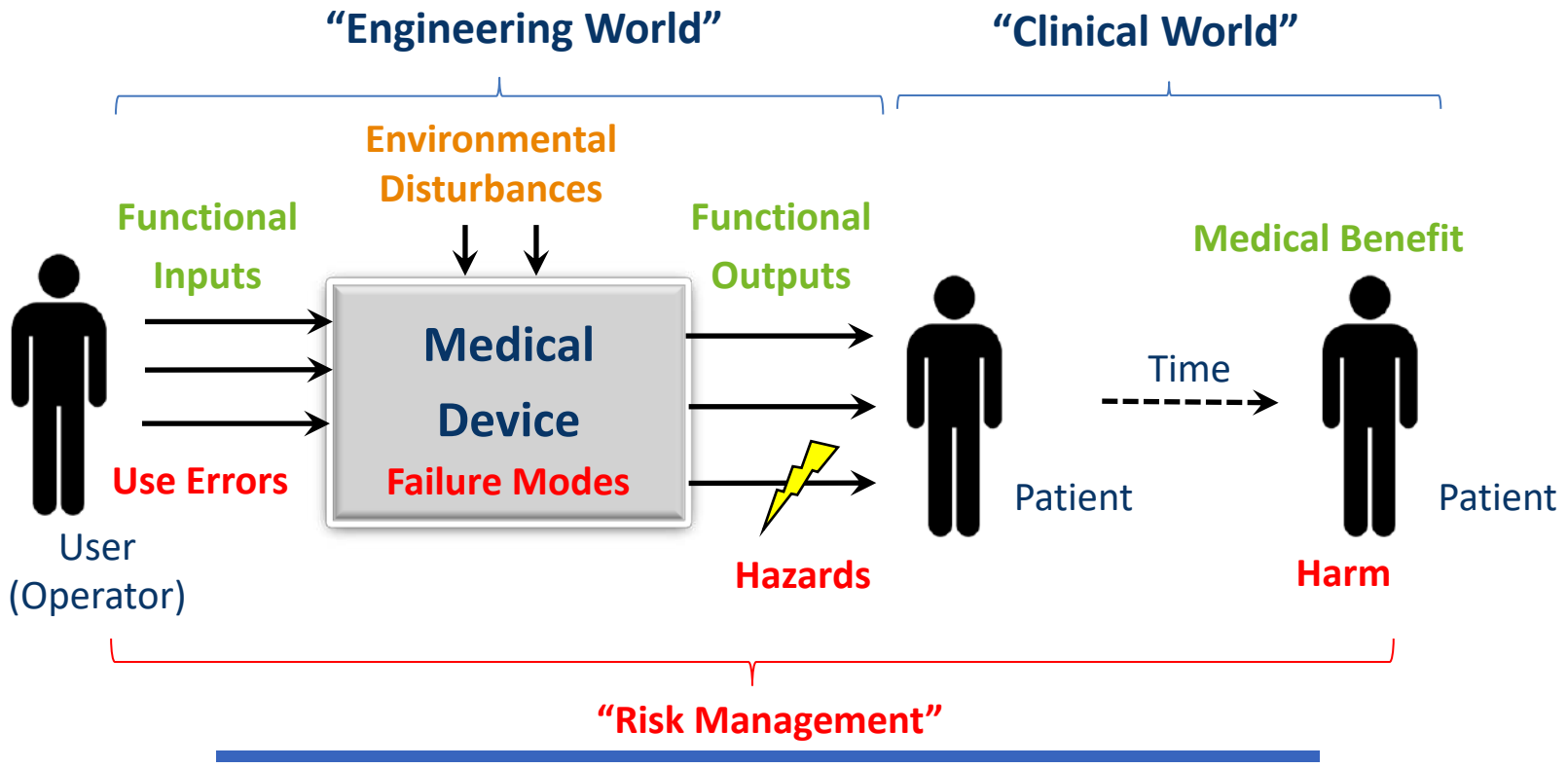
IEC 60601 EXAMPLE



ISO 14971 – Application of Risk Management on Medical Device

People exposed to Hazards

Risk management takes the idealized functional input/output diagram and identifies potential problems. In addition to the patient, Risk management also focuses on medical device users and other people who are exposed to hazards



Two Factors of Risk

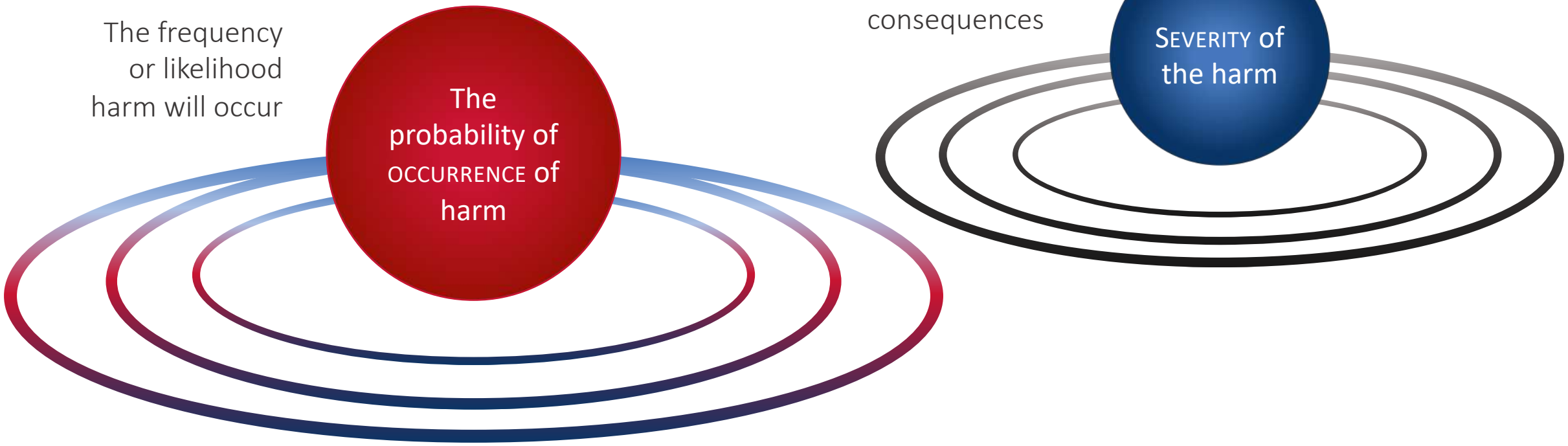
Risk is defined as the combination of....

The frequency or likelihood harm will occur

The probability of OCCURRENCE of harm

The extent of its impact or consequences

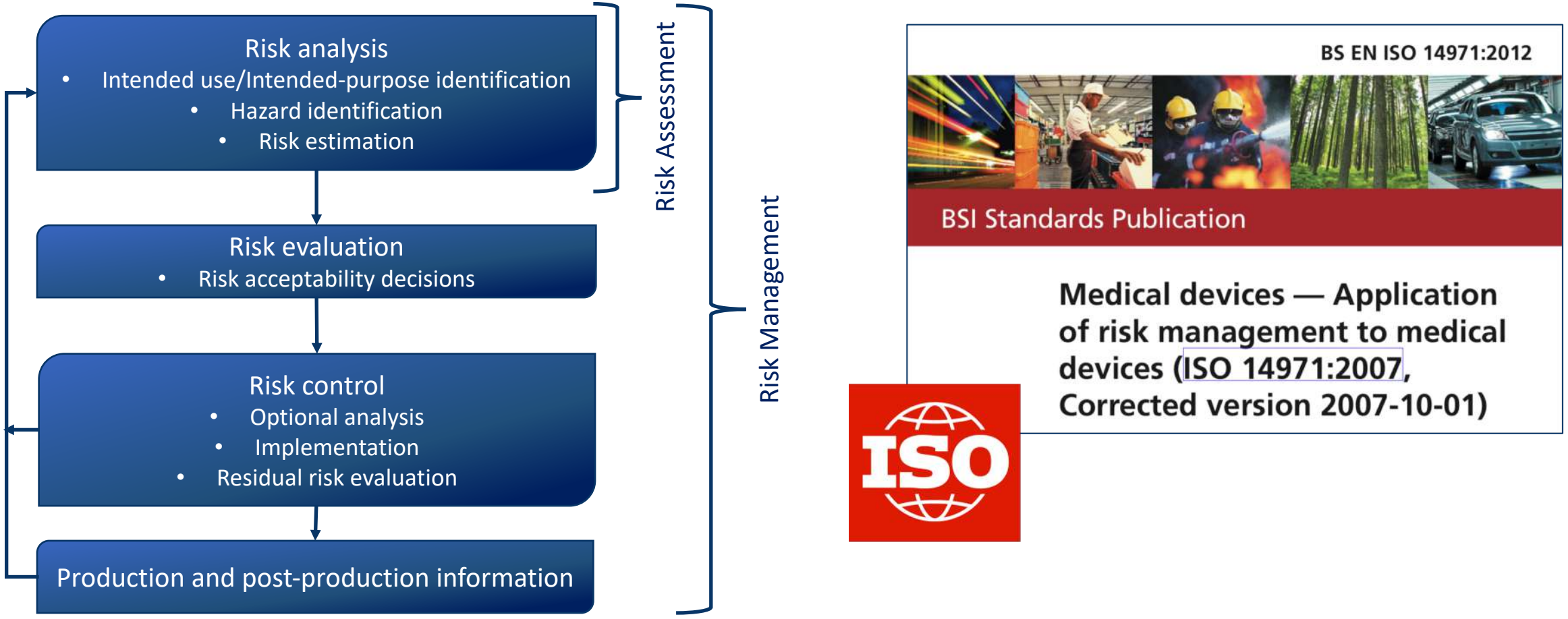
SEVERITY of the harm



ISO 14971 – KEY DEFINITIONS

Harm	Physiological injury or damage to the health of people, or damage to property or the environment
Hazard	Potential source of harm
Hazard situation	Circumstance in which people, property, or the environment are exposed to one or more hazard(s)
Severity	Measure of the possible consequences or impact of a hazard. Severity is one component of risk.

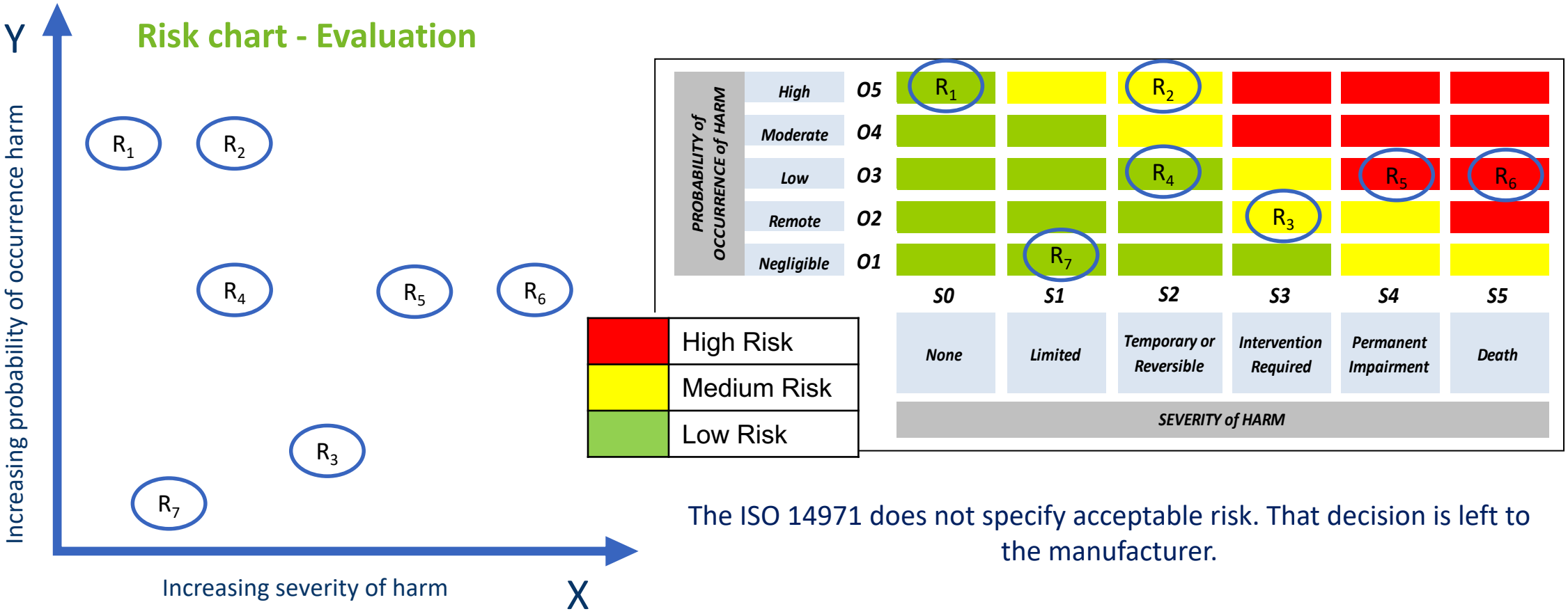
RISK MANAGEMENT PROCESS



From Hazard to Control

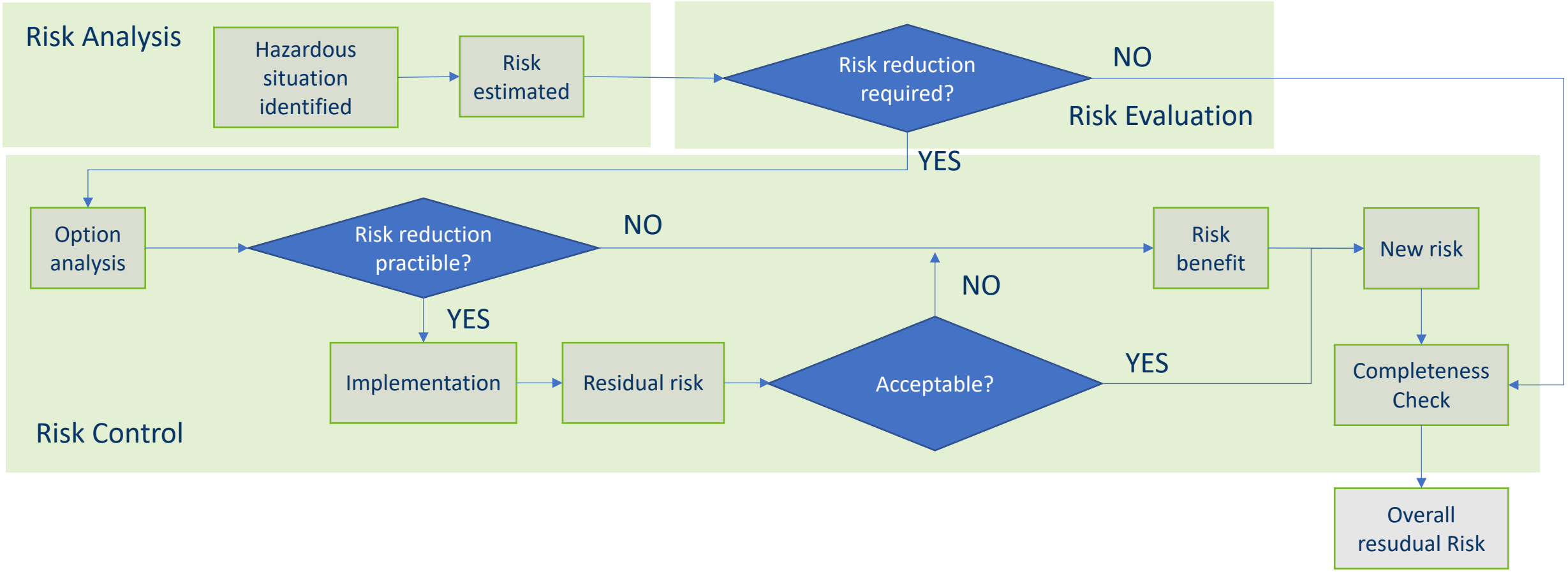
P_1 is the probability of a hazardous situation occuring
P_2 is the probability of a hazardous situation leading to harm

Risk analysis for Medical Devices



The ISO 14971 does not specify acceptable risk. That decision is left to the manufacturer.

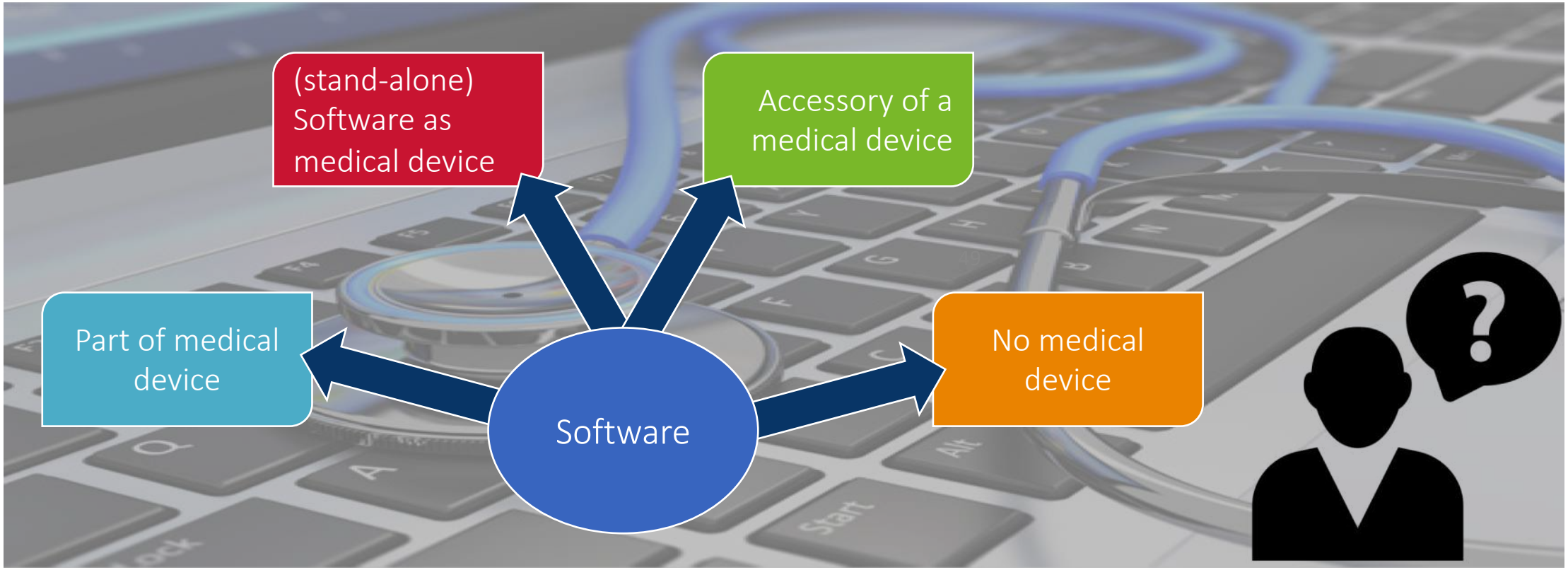
RISK ANALYSIS, RISK EVALUATION,RISK CONTROL



IEC 62304 – MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

MEDICAL SOFTWARE

Software in medical product field are classified as:



QUALIFICATION CRITERIA AS MEDICAL DEVICE

Stand alone software MUST HAVE a medical purpose to be qualified as medical devices

MDR 2017/745 (19)

BLOOD GLUCOSE METERS

RADIOTHERAPY TREATMENT

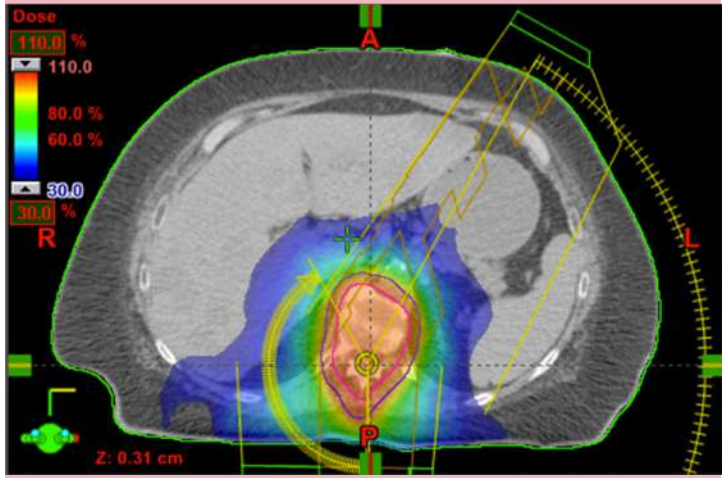
ECG INTERPRETATION

Stand-Alone Software – Classification

Stand-alone software shall also be deemed to be an ACTIVE device.

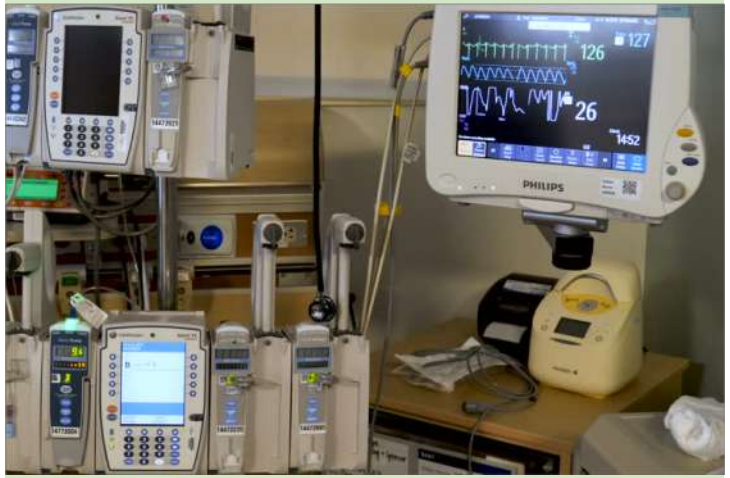
MDR 2017/745, Chapter I, Article 2 (4)

Radiotherapy Planning System



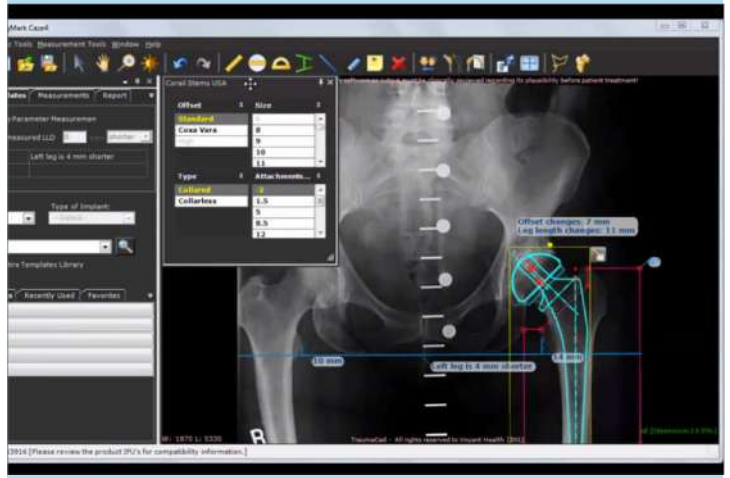
Class III

Software for Intensive care monitoring



Class IIb

Orthopaedic planning software



Class I

SAFETY CLASS FOR SOFTWARE

Three safety class for software:

CLASS A NO INJURY OR DAMAGE TO HEALTH IS POSSIBLE	CLASS B NON-SERIUS INJURY IS POSSIBLE	CLASS C DEATH OR SERIUS INJURY IS POSSIBLE
If the thermometer gives a wrong value, then the nurse is going to touch the forehead of the patient, or redo the measurement with another thermometer to confirm the fever. No damage is possible.	If the thermometer gives a wrong value, then the nurse may give a wrong treatment to the patient. However there is no chance that this may endanger the patient.	If the thermometer gives a wrong value, then the nurse is going to give a medicine to treat the fever. The wrong medicine may endanger the patient, and eventually cause death.
NO DESIGN DOCUMENTATION, POOR TESTING	DESIGN DOCUMENTATION AND TESTING	DEEP DESIGN DOCUMENTATION AND DEEP TESTING

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