DISPOSITIVI MEDICALI DIY: ORIENTARSI NELLE CERTIFICAZIONI

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UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education

Centro E. Piaggio
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UNIVERSITÀ DI PISA

WHO WE ARE

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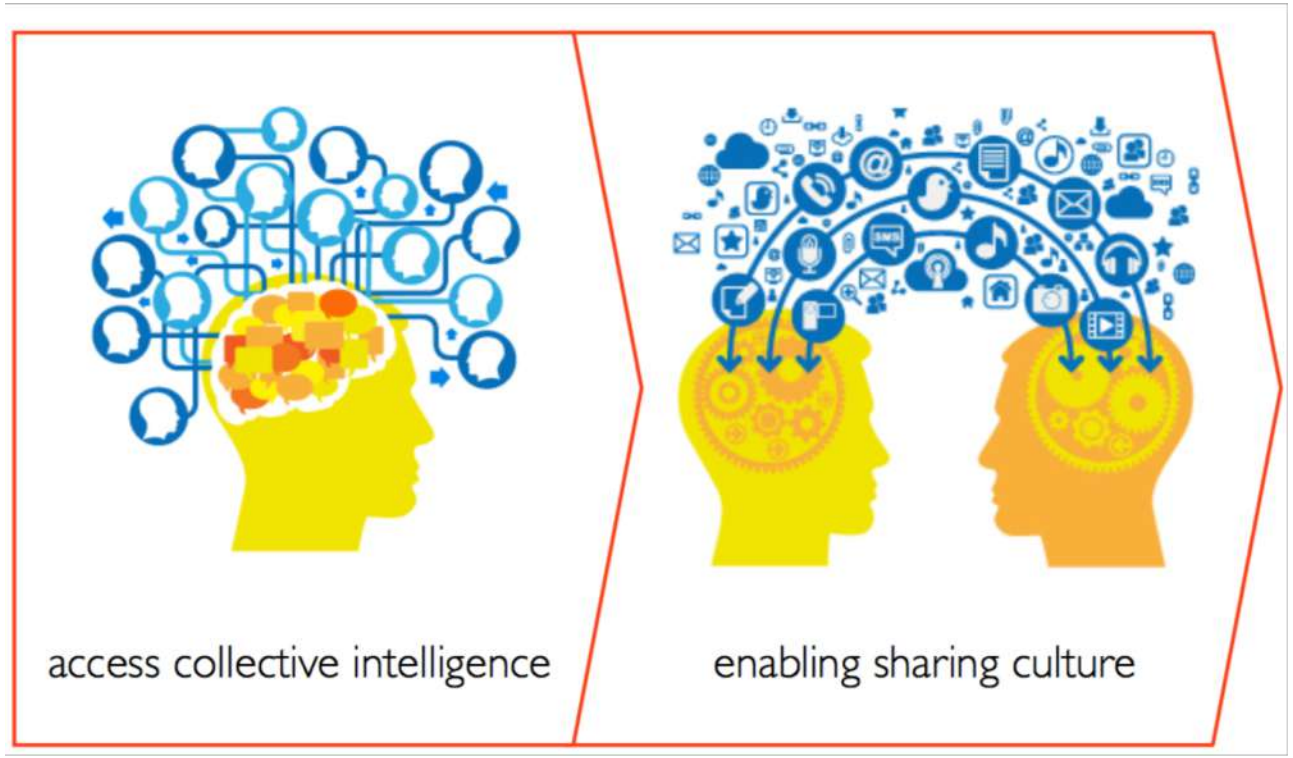
UBORA: 'EXCELLENCE' IN SWAHILI

e-Infrastructure for collaborative design open source medical devices to address current and future global healthcare challenges

WHAT IS "OPEN SOURCE":

- Sharing of "blueprints" so anyone with the appropriate knowledge can reproduce the device
- Sharing of open data on device statistics (performance, field tests, quality control)
- Sharing of design errors or dead ends
- Needs based design on the highest priority medical devices backed with research on current disease burdens

SAFETY AND INNOVATION BY OPEN AND COLLABORATIVE DESIGN



The open source approach results into:

- accessibility,
- sustainability,
- improved performance,
- reliability
- and safety

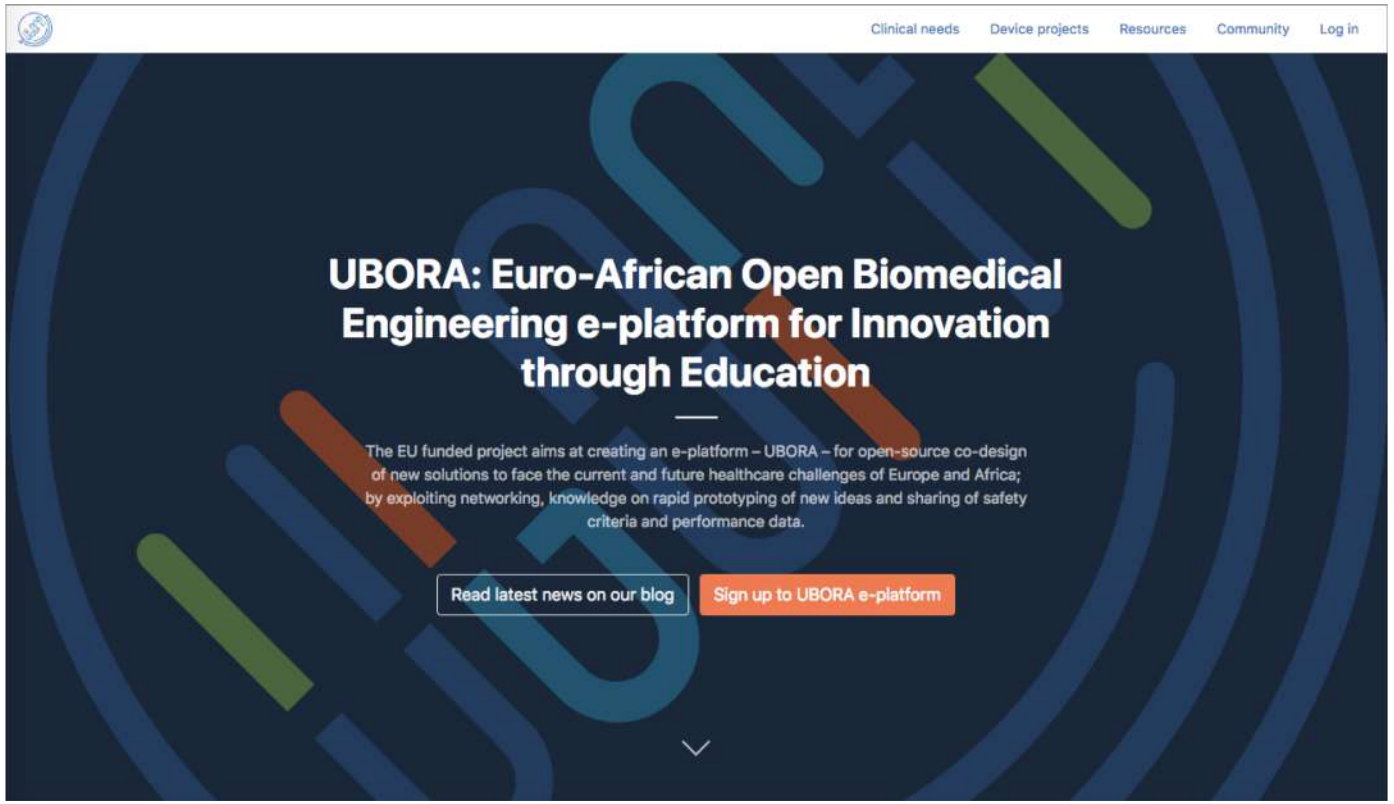
because everyone can review the design dossier

THE UBORA APPROACH

Empowering open source approach

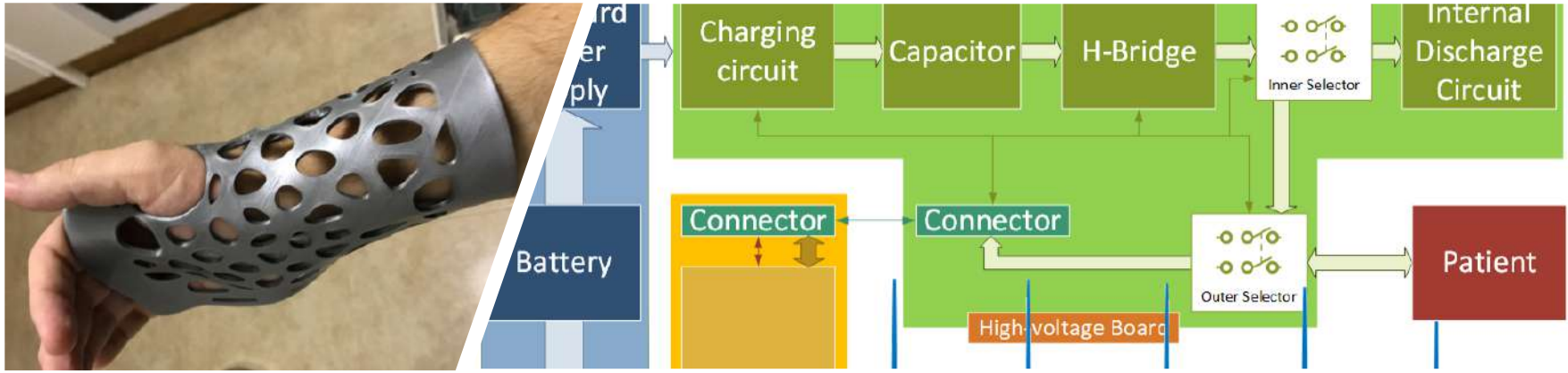
- Quality and safety guidelines for biomedical devices, under the guidance of international standards and European MDR are the foundations
- Expert mentoring will ensure that the designs comply to highest technical standards at all steps
  - Mentors from Academia and Industry

UBORA e-Infrastructure



HTTPS://PLATFORM.UBORA-BIOMEDICAL.ORG

- Open source automatic external defibrillator
- Solar powered autoclave
- 4D printed articular splint
- 3D printed cast for Ponseti method
- Breast Pump with Cooling and Preservation System of the Breastmilk
- Infant warmer
- …



EU Medical Device Regulation 2017/745

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WHAT THEY HAVE IN COMMON?

European Medical Device Legislation

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

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?

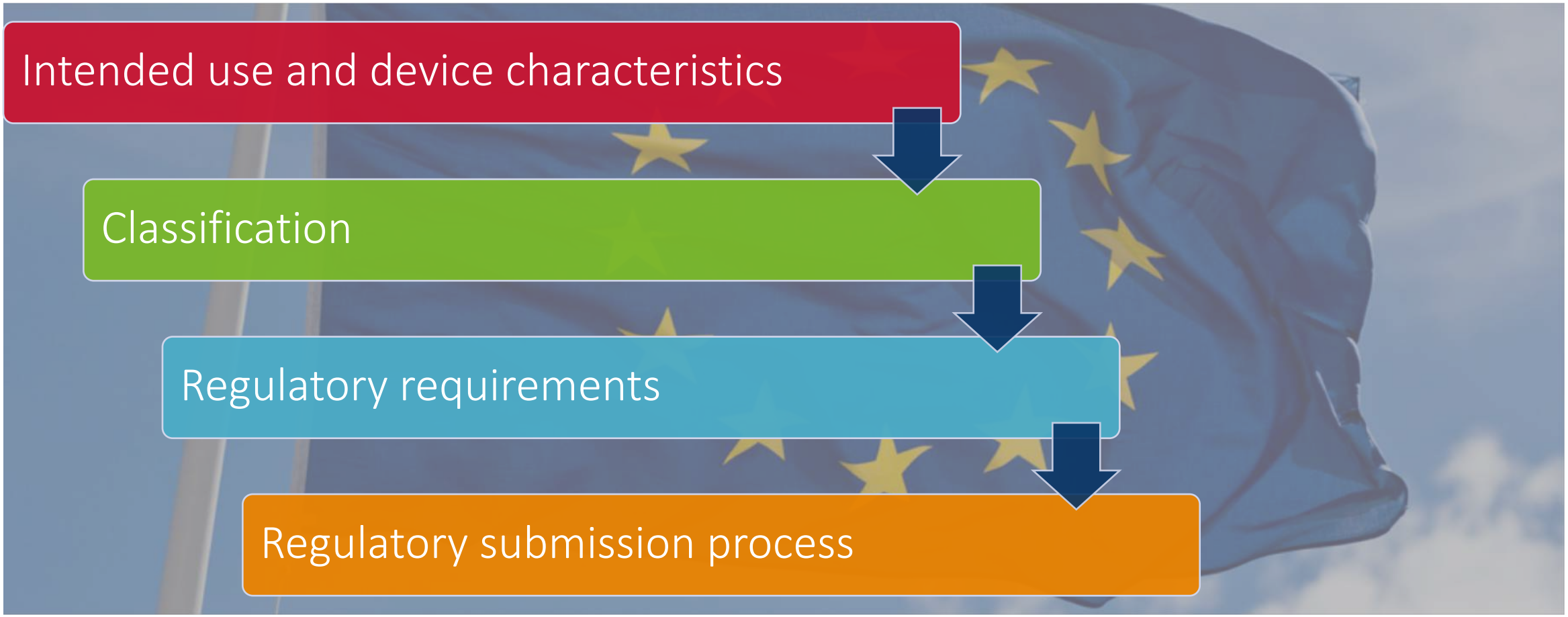
MDR 2017/745 – Article 2 (1)

"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,

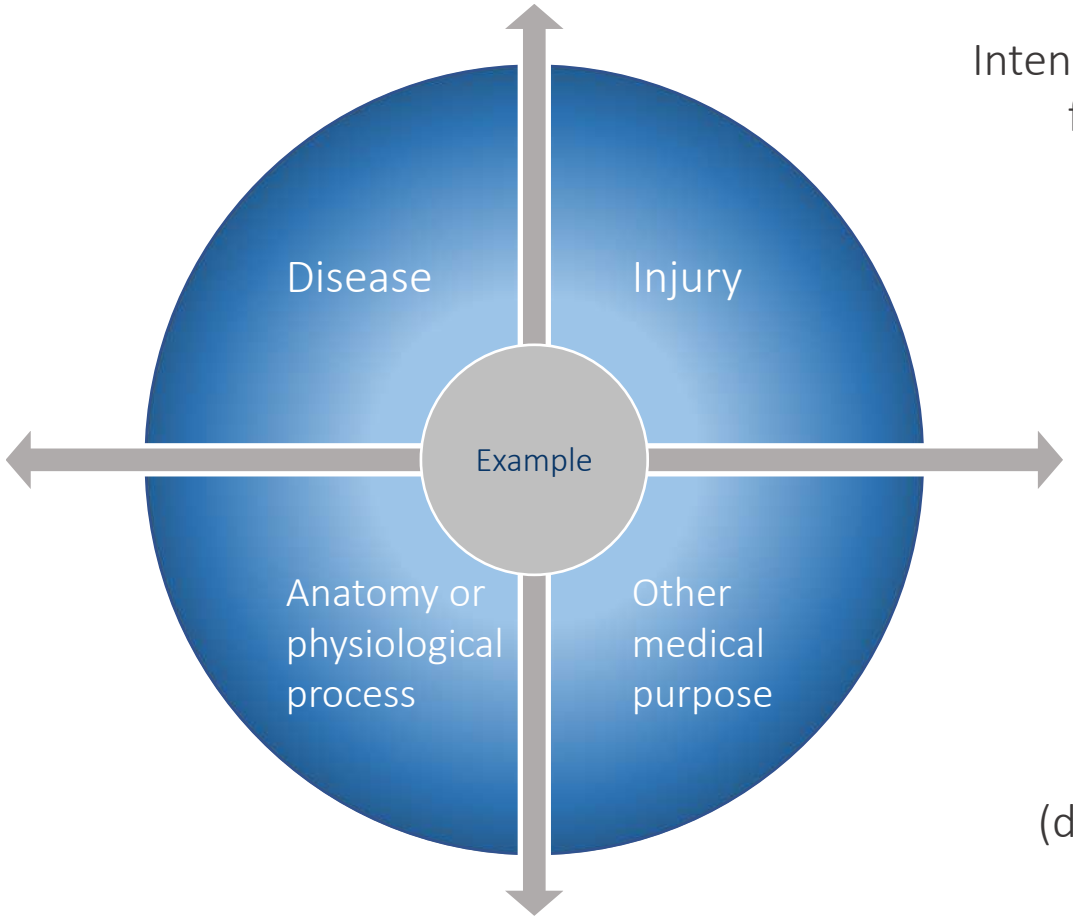
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Overview of Regulatory Framework

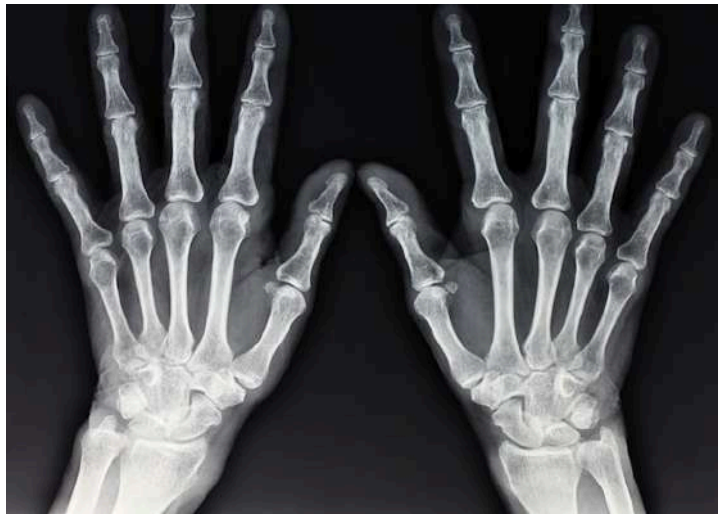


STEP 1
INTENDED USE

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: This picture was generate by a medical device (diagnostic x-ray system) whose purpose is the examination of various internal anatomical regions

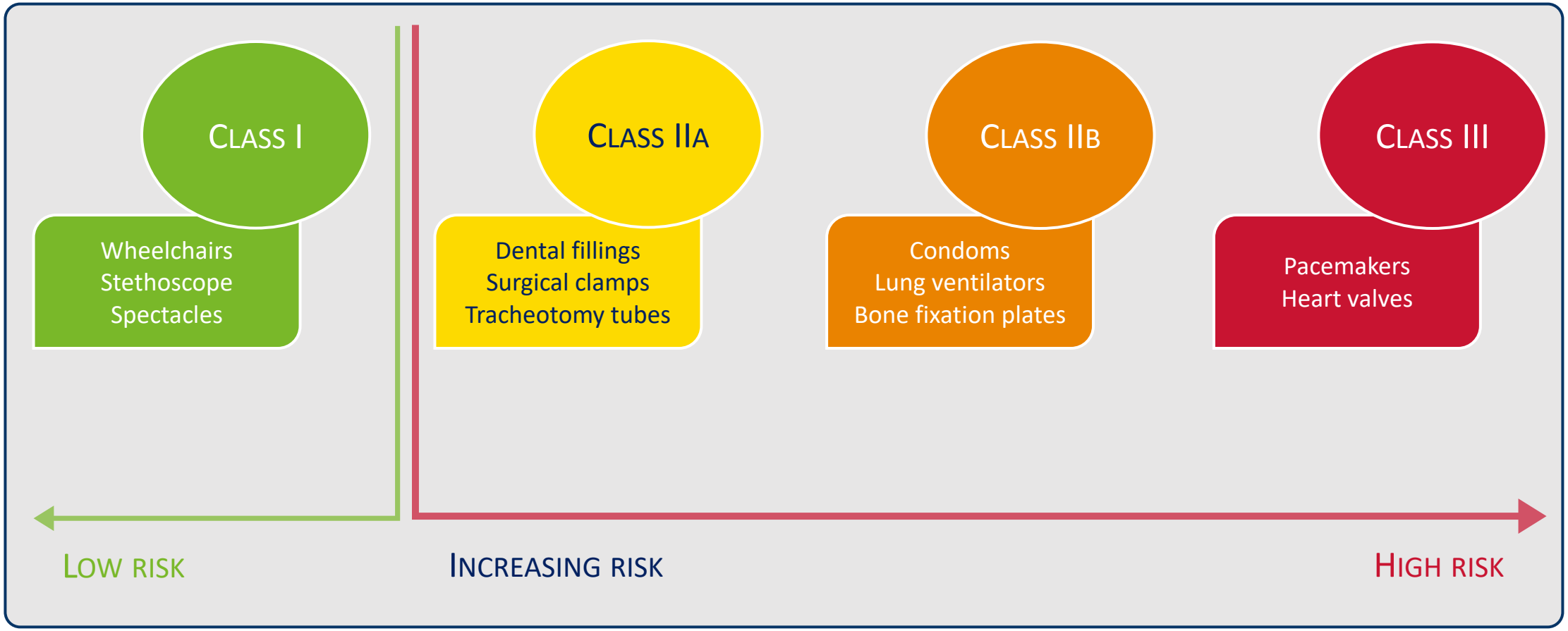
STEP 2
MDR 2017/745 CLASSIFICATION

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



STEP 3
REGULATORY REQUIREMENTS

ON THE BASIS OF THE CLASSIFICATION, WE CAN DETERMINE THE APPROPRIATE CONFORMITY ASSESSMENT PROCEDURE…

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

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

ISO International Organization for Standardization

European Standards Organization

CEN CENELEC

Official Journal of the European Union

L 117

English edition

Legislation

Volume 60

5 May 2017

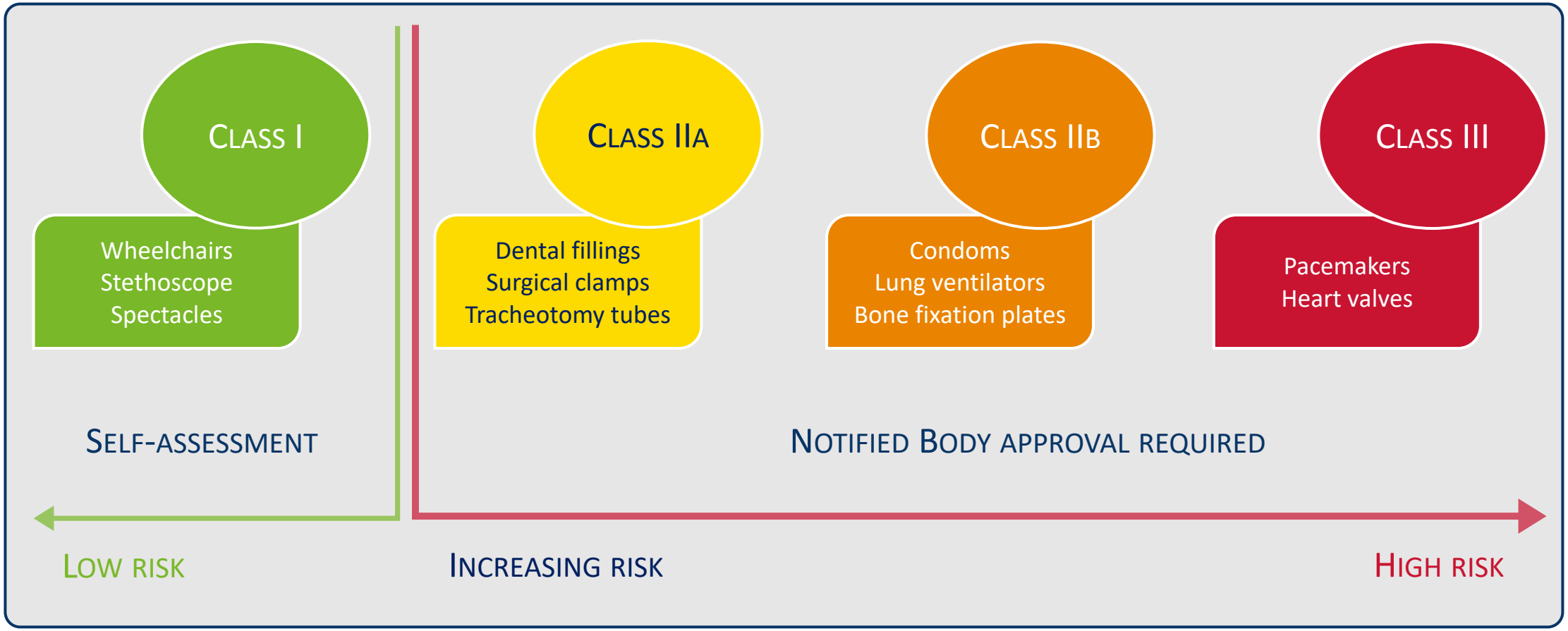
Contents

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
- 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 (*) 176

MDR 2017/745 – Class Risk

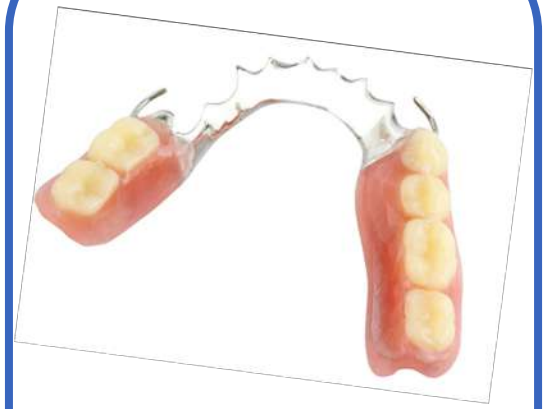


MDR 2017/745 – CUSTOM-MADE MD

"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

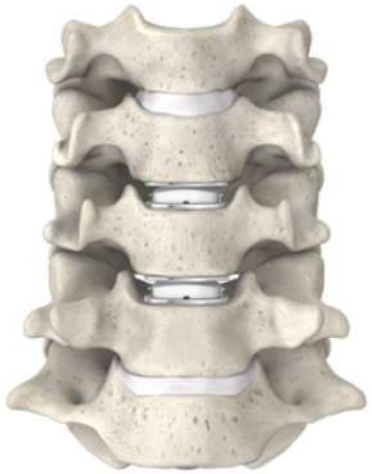
CUSTOM INSOLE

"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)

CUSTOM-MADE MD NOT INCLUDE…

KNEE REPLACEMENT



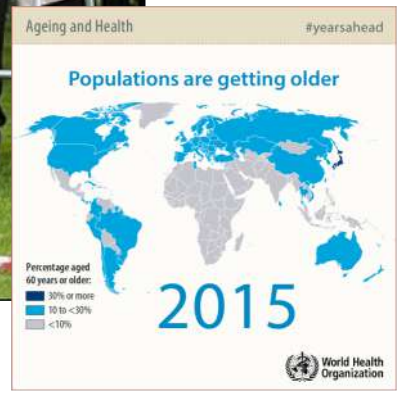
LUMBAR INTERBODY CAGES

PROSTHETIC LEGS

CASE STUDY 1

WALKING FRAME FOR OLDER PEOPLE
CLASS I MEDICAL DEVICE

WALKING FRAME FOR OLDER PEOPLE



Class 1 Medical Device

Standard	Description
ISO 24415:2009	Tips for assistive products for walking -- Requirements and test methods -- Part 1: Friction of tips
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 11199:2005	Walking aids manipulated by both arms -- Requirements and test methods -- Part 2: Rollators

CASE STUDY 2

AUTOMATED EXTERNAL DEFIBRILLATOR (AED)

CLASS III MEDICAL DEVICE

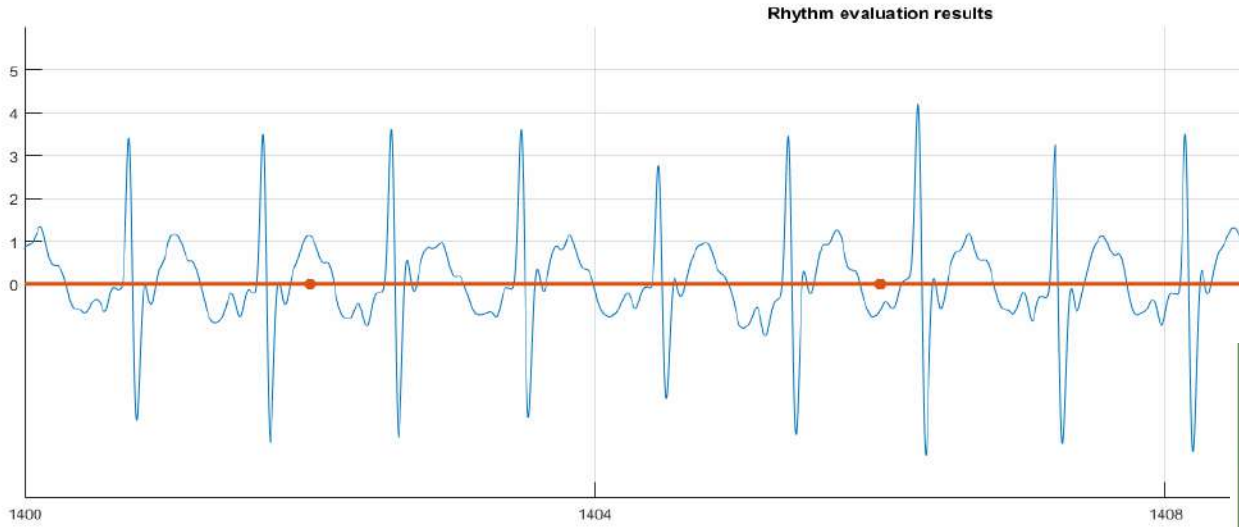
AUTOMATED EXTERNAL DEFIBRILLATOR (AED)

MDR 2017/745, Annex VIII, Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or **automated external defibrillators**, are classified as **CLASS III**.

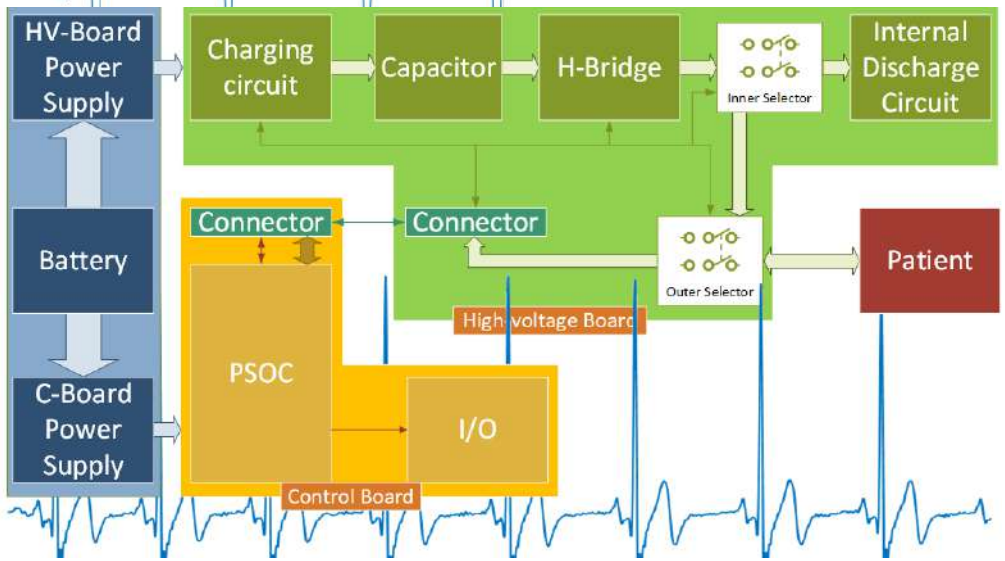
Standard	Description
IEC 60601-1	Requirements for electromedical devices
EN ISO 62304:2006	Design and code software for medical devices and requirements for SW change control
ISO 10993-1	Biocompatibility requirements
EN ISO 13485:2016	Life cycle
EN ISO 14971:2012	Risk management requirements
IEC 62366-1	Usability requirements
EN ISO 15223	Symbols for labels of medical device

O-SCA Recognition Algorithm



The AED will check the heart rhythm and will tell if the shock is advised. If the AED says " SHOCK ADVISED" the shock will be delivered.

Recognised the SDA condition is fundamental

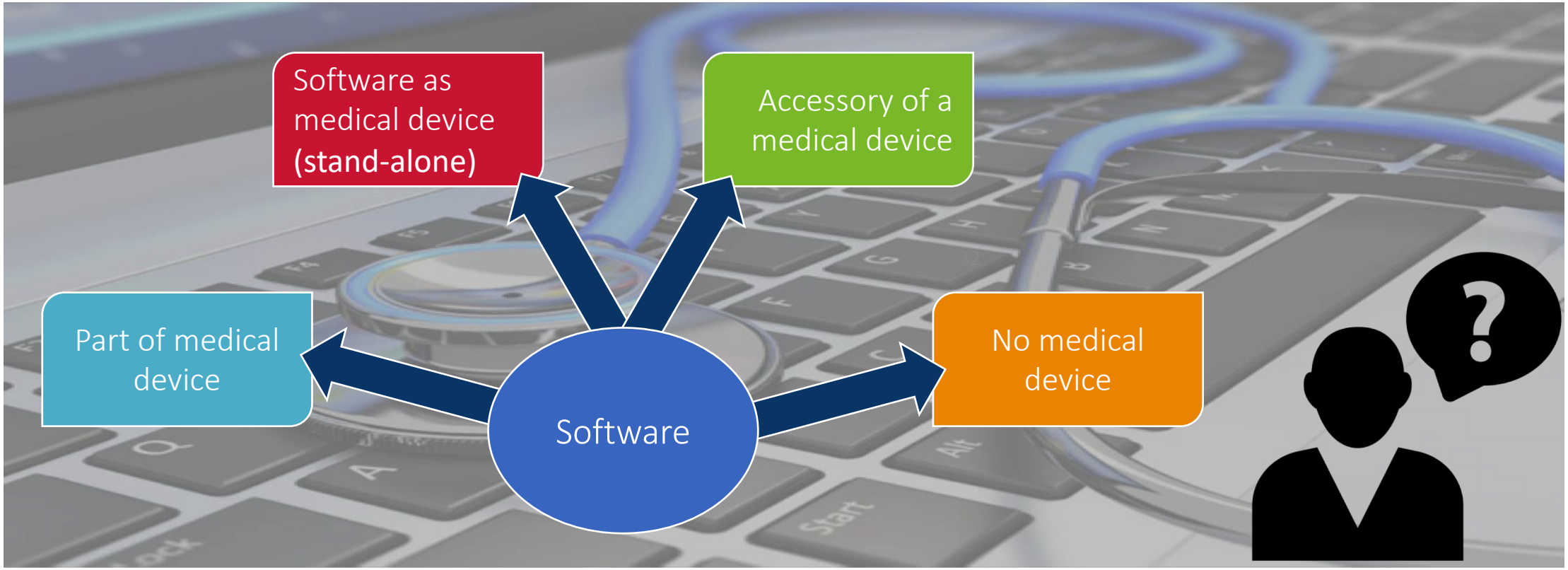


CASE STUDY 3

MEDICAL SOFTWARE

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 device

MDR 2017/745 (19)

BLOOD GLUCOSE METERS

RADIOTHERAPY TREATMENT

ECG INTERPRETATION

STAND-ALONE SOFTWARE – CLASSIFICATION

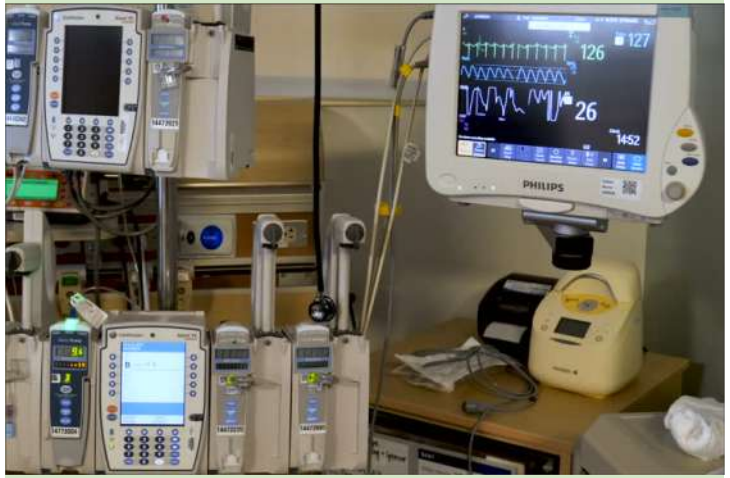
Stand shall also be deemed to be an ACTIVE device.

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

ORTHOPAEDIC PLANNING SOFTWARE

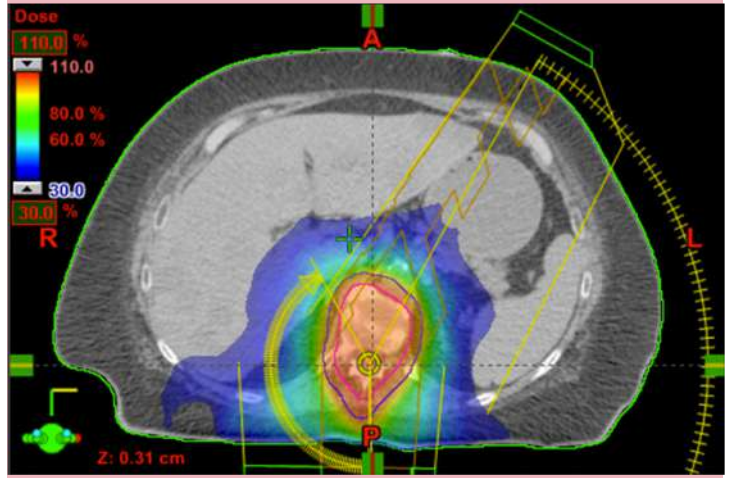
CLASS I

SOFTWARE FOR INTENSIVE CARE MONITORING



CLASS IIB

RADIOTHERAPY PLANNING SYSTEM



CLASS III

IEC 62304 – Medical device software – Software life cycle processes

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

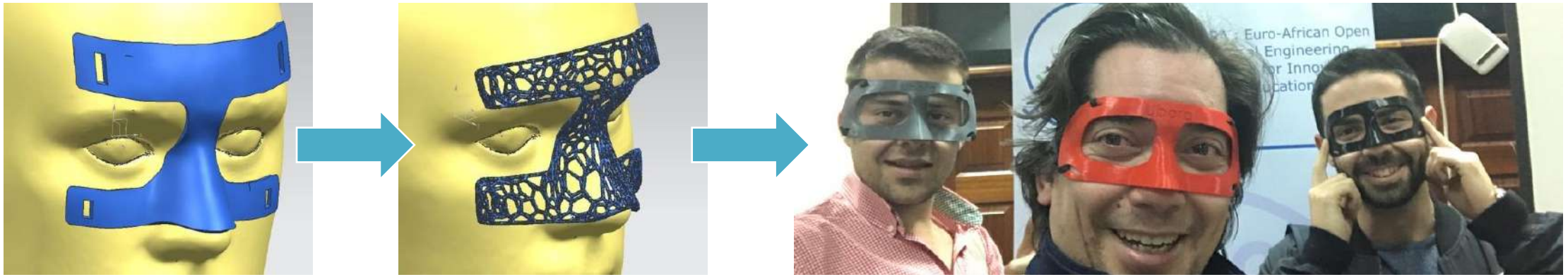
CASE STUDY 4

SPLINT FOR FACE PROTECTION
CUSTOM-MADE MEDICAL DEVICE

Face protection for Broken nose

Class I – Custom-Made Medical Device

Standard	Description
EN ISO 10993-1	Biocompatibility requirements
EN ISO 13485:2016	Life cycle
EN ISO 14971:2012	Risk management requirements
IEC 62366-1	Usability requirements
EN ISO 15223	Symbols for labels of medical device



THANK YOU!

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