GLOBAL CLINICAL ENGINEERING ALLIANCE™

FEBRUARY 9
7PM LONDON TIME (UTC)

WEBINAR

Global Regulations and Standards During the COVID-19 Era

SITTA AGNES KIJO
Technical Officer at
WHO Headquarters

STEFANO BERGAMASCO
Director at MedTech Projects Srl & GCEA
Founders Council Member

ALMIR BADNJEVIC
IFMBE Clinical Engineering Division
Board Member & Director of Verlab Doo

MLADEN POLUTA
Moderator
Health Technology Deputy Director at the Western Cape Department
of Health & GCEA Founders Council Member

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Global overview of medical devices regulation

Agnes Sitta Kijo

Technical Officer, WHO-HQ

Kijoa@who.int

Global commitment to securing access to health technologies and systems strengthening

WHA Resolutions 60.29

In 2007, the first resolution which set the framework for an unprecedented focus on health technologies, but more specifically on medical devices.

WHA Resolution 67.20

In 2014, Call regarding regulatory system strengthening for medical products including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf

The Spirit of Regulation

Public Safety **Innovation**

- ✓ Protect public health and safety.
- ✓ Ensure that useful/valuable new technologies are made available while preventing unsafe and ineffective devices from reaching the market.
- ✓ Regulations clearly articulated to stakeholders.
- ✓ Adequate post-market and pre-market controls.
- ✓ Being cognizant of ongoing international convergence efforts to avoid regulatory controls that conflict with the goal and spirit of international convergence.
- ✓ Regulatory decision (s) must be based on transparent processes and strong scientific evidence that facilitates ACCESS.

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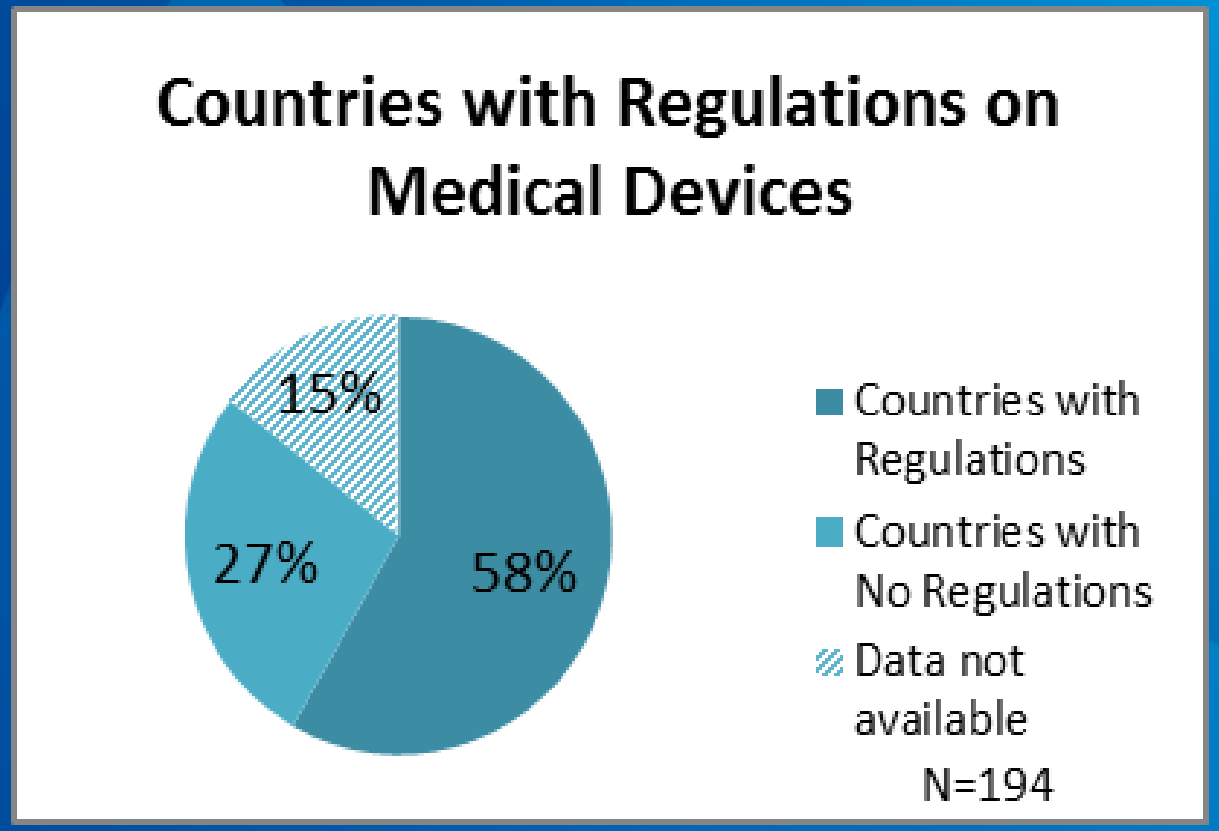
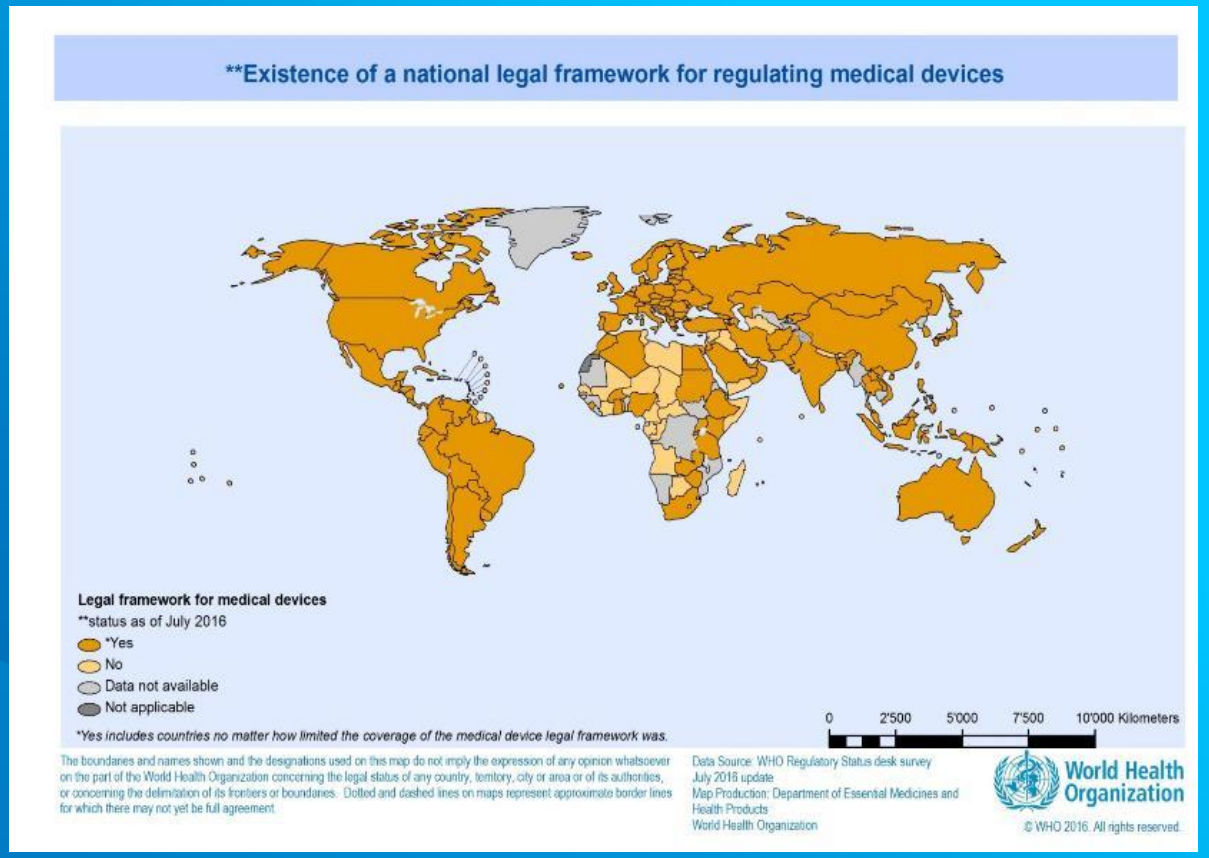
Regulation of medical devices……





Regulatory barriers

REGULATORY BARRIERS

- Processes are often lengthy, not predictable and transparent.
- Uncoordinated activities among stakeholders and overlapping of activities
- Unclear regulations and requirements
- Lack of harmonization. Regulatory landscape for IVDs highly variable
- Inadequate market surveillance
- Inadequate capacity for implementation (human and financial
- Duplicate evidence (evidence to support product registration is not properly leveraged)
- Lack of policy, legal framework and lack of regulatory control.

Addressing the existing regulatory barriers

Existence of Policy, Law/legislation Regulation,

-Guidelines

-Mandate

-Definition, classification

- Existence of NRA

Transparent and predictable timelines

Harmonization /Collaboration (regional/ international)

-AMDF

-- Joint activities

Reliance

-CRP

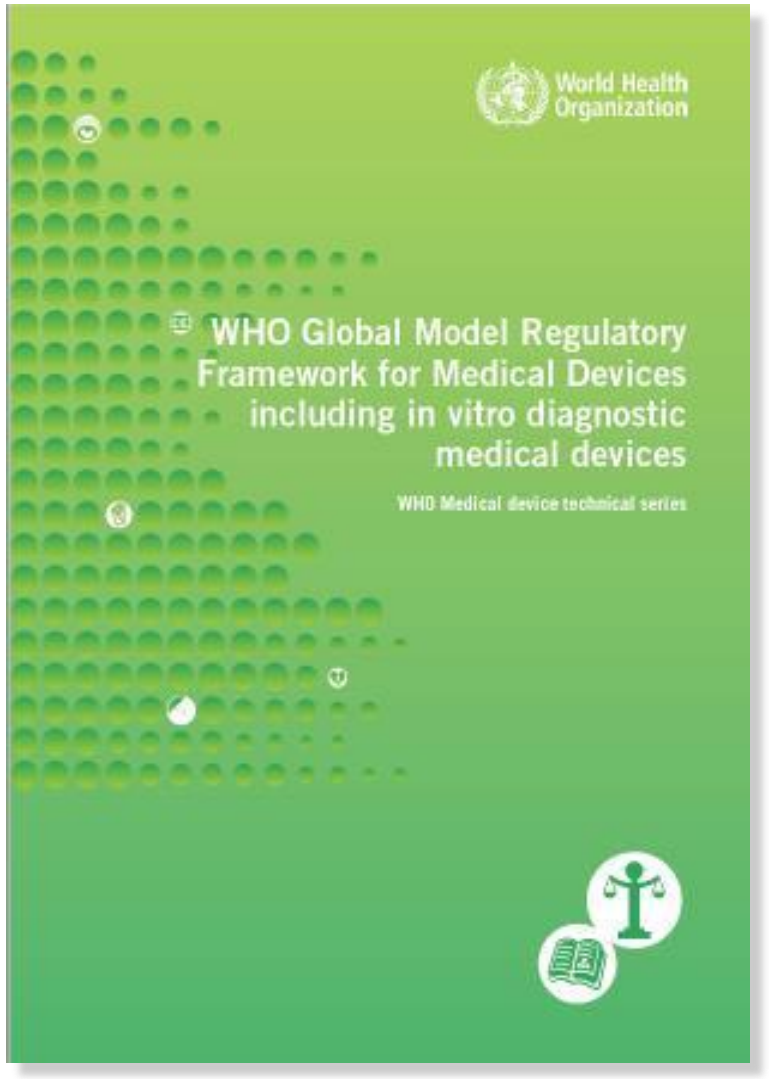
-SRA

Clarity in roles and responsibilities between key stakeholders within the Government

Resource pooling networking and information sharing.

Platforms AMDF

Regulation of medical devices including in vitro diagnostic medical devices

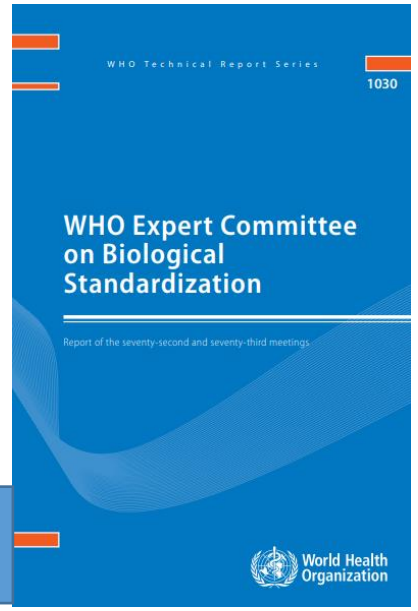


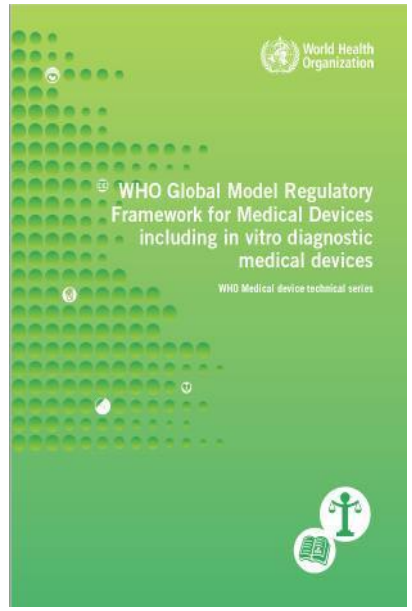
GMRF for MD including IVDs is currently under revision

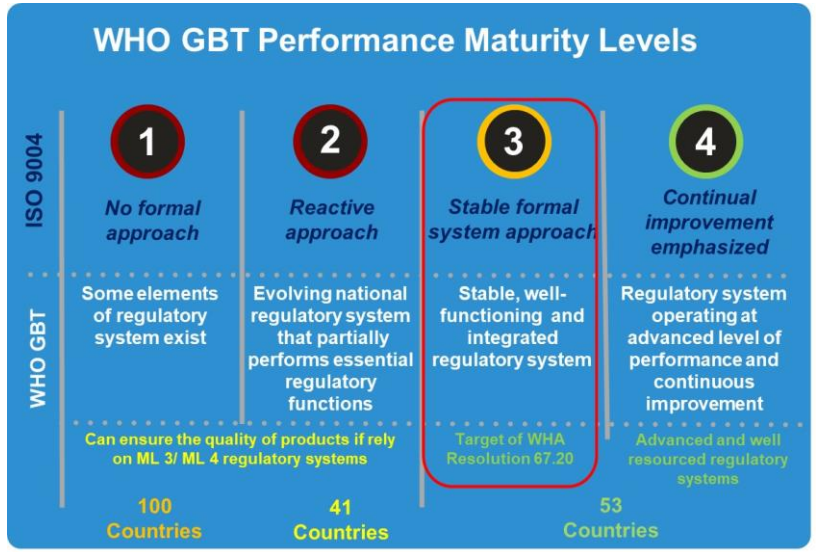
https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/

Tools

Annex 4
Annex 10
Annex 11







https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

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apps.who.int/iris/handle/10665/341239

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/eul-facilitated-procedure

https://apps.who.int/iris/handle/10665/255177

COVID-19 pandemic …….

Unprecedented times when:

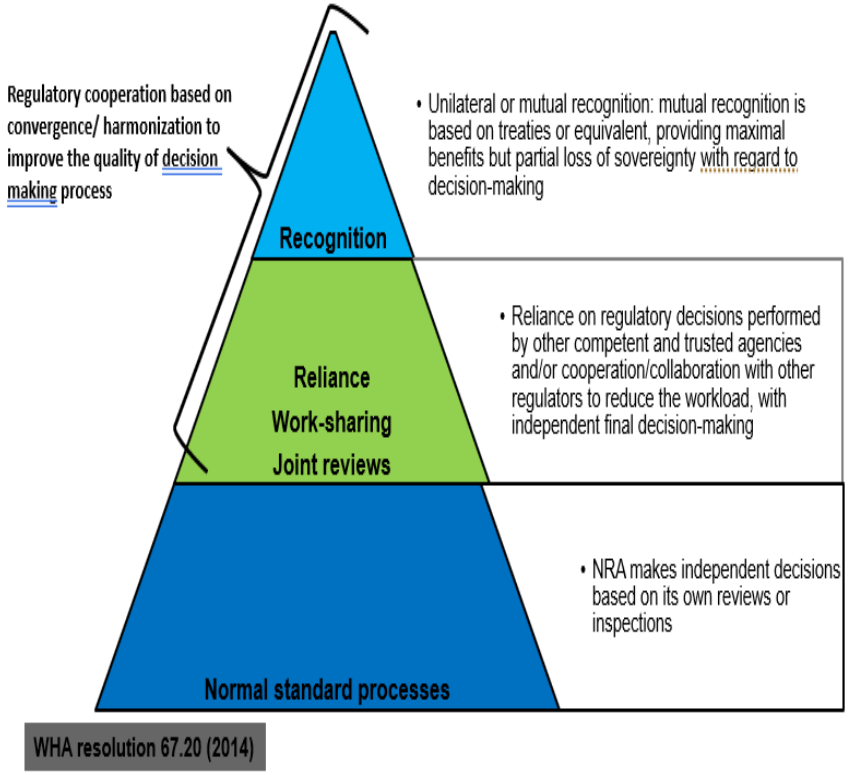
- ✓ Very few available diagnostics with limited performance data and yet there is an urgent demand for IVDs;
- ✓ There are no readily available regulatory-approved, mass-produced in vitro diagnostics (IVDs).
- ✓ There is a need for fast, efficient regulatory procedures to bring new diagnostics to the affected communities

- **NRAs:**
  - ✓ *Lack of regulations for exceptional market situations including public health emergencies,*
  - ✓ *lack of capacity (human resources and expertise) to evaluate the products, multiple institutions,*
  - ✓ *No clear pathway,*
  - ✓ *Divergent requirements among NRAs and inadequate preparedness and response plans.*

- **Manufacturers:**
  - ✓ *Pressure to **develop assays in a very short period (years to months)***
  - ✓ *Lack of clarity in regulation**, divergent emergency regulatory mechanisms** around the world*
  - ✓ *Requirements to conduct **clinical studies** as part of premarket requirements*

Approaches during emergencies

- ✓ Reliance/recognition - WHO EUL (Survey in February 2021: 80% of NRAS rely on listing/authorization by trusted institutions such as WHO and mature NRA for COVID 19 assays; 94% of countries aware of the WHO EUL and its utilization (68%) to facilitate in country authorization.
- ✓ Regulatory flexibilities (import control, market authorization, conditional approvals etc). Marketing Approval – registration (12 - 24 months) to listing/authorization through expedited review (up to 3 months).
- ✓ Collaboration through establishment of task force/special team with key stakeholders such as NRA, NRL, research institutes, academia to identify, review and authorize assays for use in the country.
- ✓ Sharing of information among regulators through the Regional Harmonization Initiatives and on NRAs websites.
- ✓ Development of guidelines, standards and other documents within a very short time to guide NRAs.



Key messages

- Appropriate legislative and regulatory requirements:
  - ✓ Legal framework to define the basis and conditions for collaboration and work sharing/acceptance of information and decisions;
  - ✓ Technical framework: applicable guidelines.

- Application of practical arrangements: operational procedures for implementation. Harmonization means nothing if the established common guidelines are not implemented;

- Appropriate interpretation of the requirements: competence of the personnel; capacity development, training and stakeholders' engagement

- Regulatory capacity building, promotion of collaboration, convergence and harmonization will continue to be one of the WHO priorities;

- There is no Good Regulatory Practice without Good Governance (accountability, transparency, fairness and equal treatment of all regulated parties etc.)

- Not using the outputs and outcomes from other trusted regulatory authorities = lost opportunity, duplication of efforts, increased regulatory burden and waste of scarce resources

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Thank You!

Agnes Sitta Kijo

Technical Officer, Regulation and Safety Unit, Facilitated Products Introduction Team, WHO-HQ

kijoa@who.int

The European Medical Devices Regulations

Stefano Bergamasco

Director at MedTech Projects Srl and GCEA Founders Council member

stefano.bergamasco@medtechprojects.com

EU context

Established 1957 (EEC Rome treaty)
1992 (EU Maastricht treaty)

27 member states (450M people)
5 candidate member states

Main legislative bodies:
- **European Council** (heads of states)
- **European Commission** (executive power)
- **European Parliament** (legislative power)

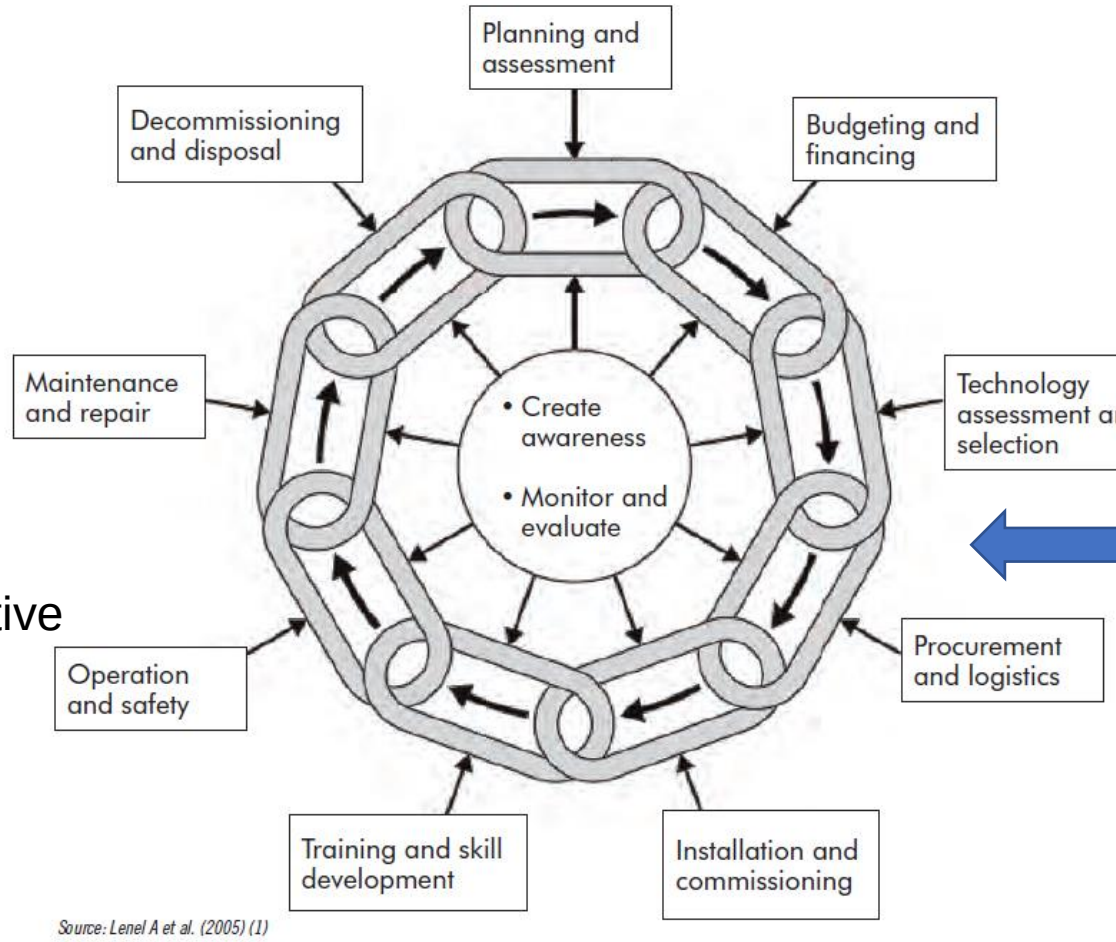
Main legislative acts:
- **EU Directives** (must be adopted by member states to become effective as national laws)
- **EU Regulations** (apply directly to all member states, no need of national transposition)

HT regulations and the lifecycle of health technology

World Health Organization

Introduction to medical equipment inventory management

WHO Medical device technical series



Source: Lenel A et al. (2005) (1)

Post-market Surveillance
Post-market Clinical Follow-Up
Vigilance: Reporting of serious incidents and field safety corrective actions

Medical Device Directives and the new Medical Device Regulation harmonise the rules for the **placing on the market** and **putting into service** of medical devices and their accessories

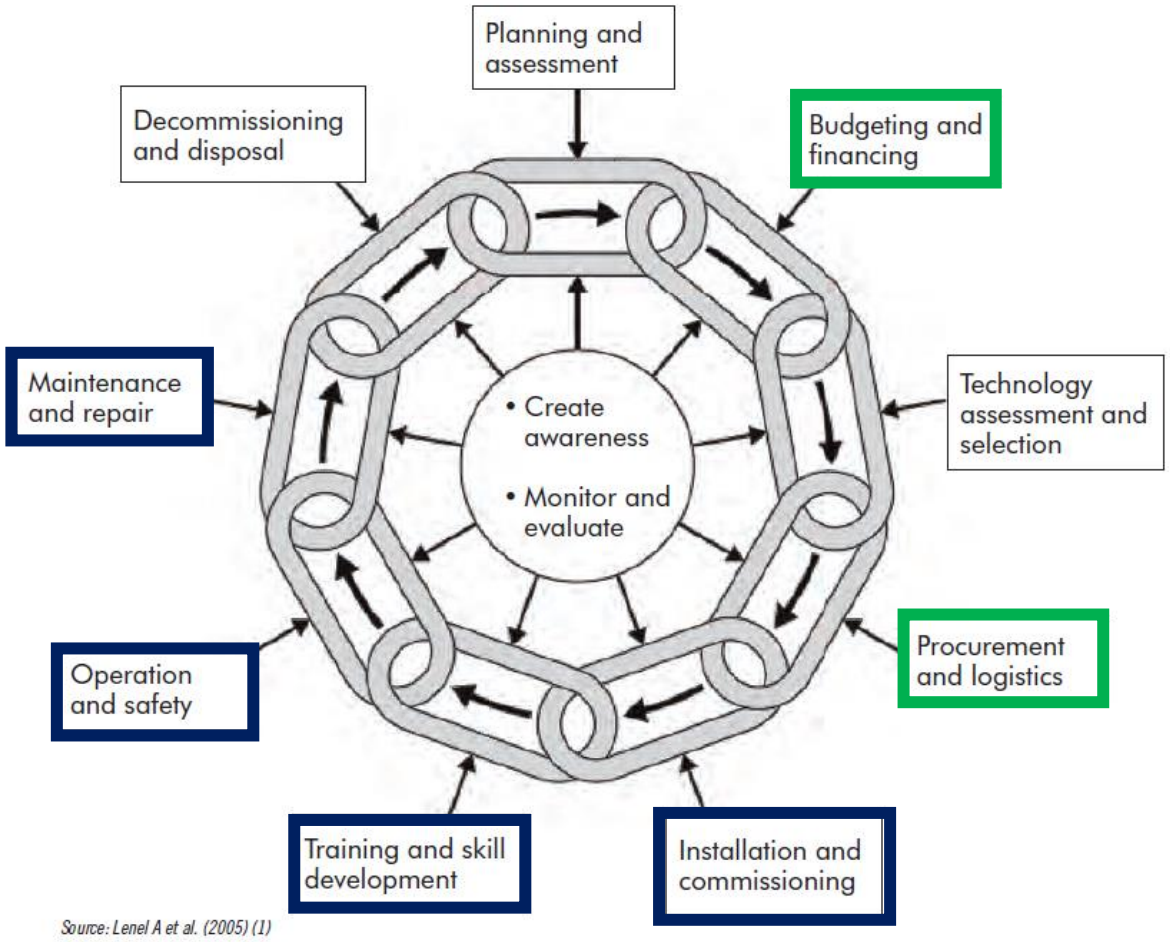
CE

HT regulations and the lifecycle of health technology

World Health Organization

Introduction to medical equipment inventory management

WHO Medical device technical series



Source: Lenel A et al. (2005) (1)

EU Directives on public procurement and accounting

EU Directives on Occupational Health and Safety have rules for the safety of **working tools** (medical equipment are working tools!)

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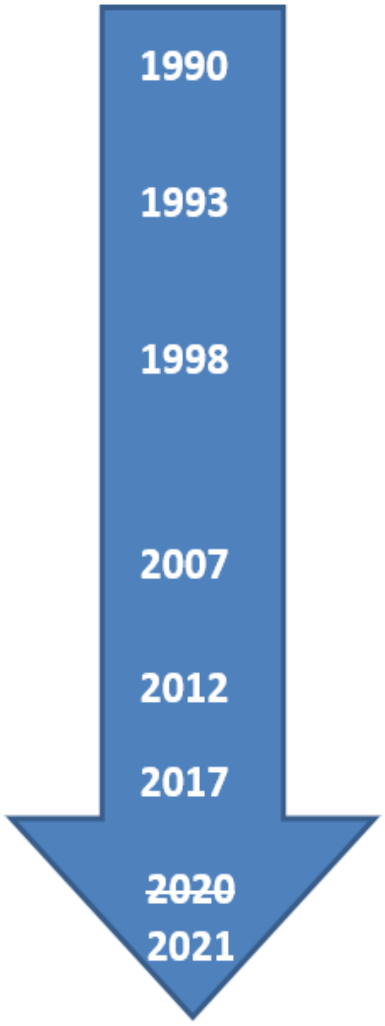
EU medical device legislation



Directive 90/385 (Active Implantable Medical Devices)

Directive 93/42 (Medical Devices)

Directive 98/79 (In Vitro Diagnostic Medical Devices)

Directive 2007/47 (modifications to previous Directives on Medical Devices)

Proposal of draft Regulations from the EU Commission to the EU Parliament

Adoption of the new Regulations 2017/745 (MD) and 2017/746 (IVD)

Full implementation of the new Regulation 2017/745 (MD)

The new european Medical Devices Regulation

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

The new european In Vitro Medical Devices Regulation

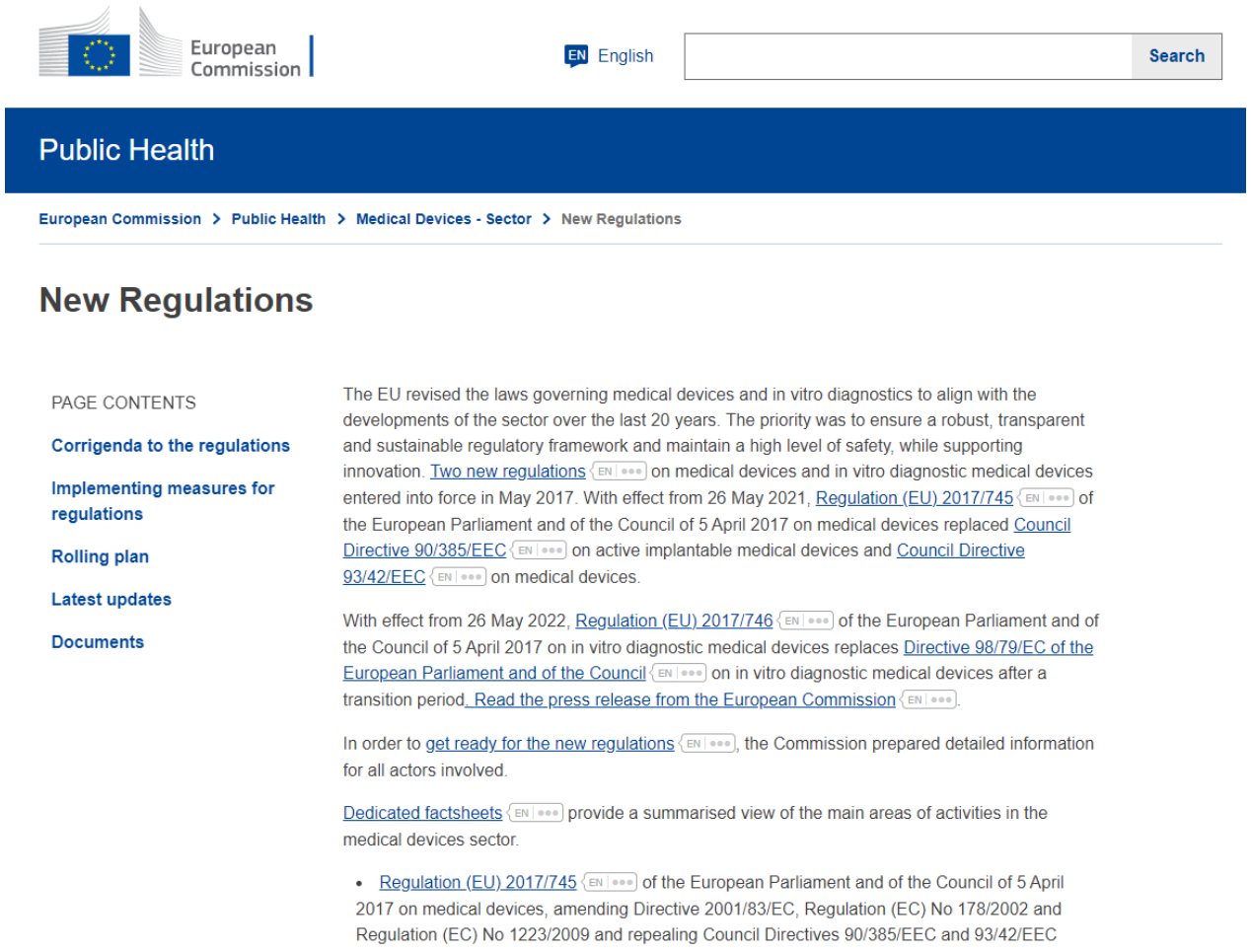
L 117/176 EN Official Journal of the European Union 5.5.2017

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

EU Commission webpage



https://ec.europa.eu/health/md_sector/new_regulations_en

MDR and IVDR new elements

The new regulations contain a series of extremely important improvements to modernise the current system. Among them are

- **stricter previous control for high-risk devices** via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- **reinforcement of the criteria for designation and processes for oversight of notified bodies**
- **inclusion of certain aesthetic devices** that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations
- **anew risk classification system for in vitro diagnostic medical devices** in line with international guidance

MDR and IVDR new elements

- improved transparency through a comprehensive **EU database on medical devices** and a device traceability system based on a **unique device identification**
- introduction of an **‘implant card’** for patients containing information about implanted medical devices
- **reinforcement of the rules on clinical evidence**, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations
- **strengthening of post-market surveillance** requirements for manufacturers
- **improved coordination mechanisms between EU countries** in the fields of vigilance and market surveillance

Key points for stakeholders

European Commission

Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

SOME THINGS TO KEEP IN MIND…

Manufacturers
The new Regulations better reflect recent scientific and technological advancements and will strengthen the image and value of CE marked devices

Procurement ecosystem
The procurement of Directive-compliant devices can continue until the transition ends (2025)

Authorities in non-EU/EEA states
All actors impacted by the Regulations must be informed of the changes and timelines in order to avoid any disruption on the market

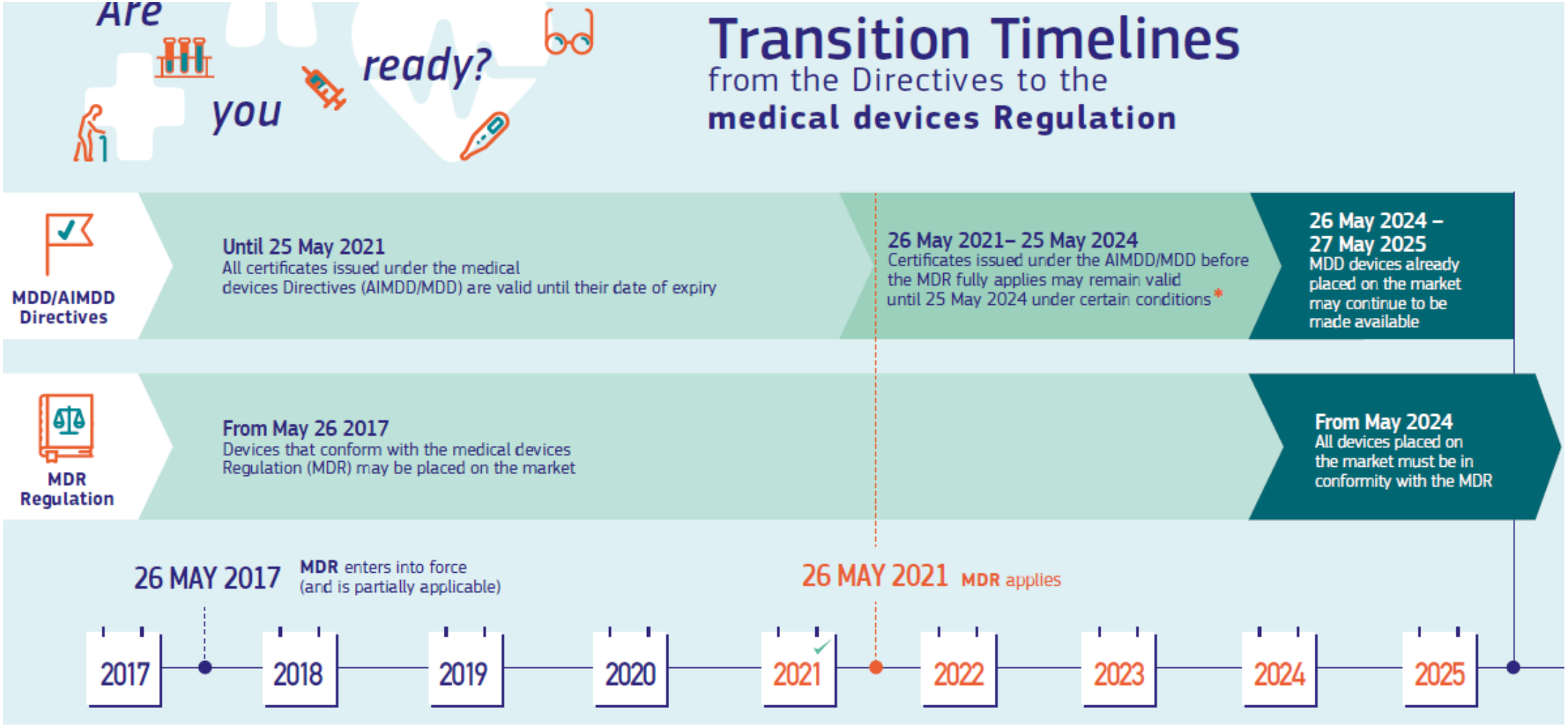
Authorised representatives, importers, distributors
The roles and responsibilities have been clarified and reinforced to ensure the legal compliance of devices on the market

Reprocessing of single-use devices
Strict conditions have been introduced in the case of reprocessing single-use medical devices

Healthcare professionals and health institutions
Healthcare professionals and health institutions will benefit from improved transparency on clinical and vigilance data through EUDAMED

Patients
Patients will benefit from the increased safety and performance of devices, and from more information surveillance and transparency on devices on the EU market

MDR timeline



MDR and harmonized technical standards

Article 8

Use of harmonised standards

1. 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.

The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').

References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*.

2. References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided that references to those monographs have been published in the *Official Journal of the European Union*.

MDR and harmonized technical standards

Medical Devices

Medical Device Coordination Group Document MDCG 2021-5

MDCG 2021-5

Guidance on standardisation for medical devices

April 2021

MDR and harmonized technical standards

… In this kind of legislation, **the role of the harmonised European standards is key**: actually, for product characteristics, **the content of legislation is limited to establishing essential requirements** that products intended to be placed on the EU market must meet. **The technical details and solutions supporting those essential requirements are laid down in harmonised European standards** specifically developed by designated European standardisation organisations on the basis of specific standardisation requests (formerly known as “mandates”) issued by the Commission.

MDR and harmonized technical standards

Products designed and manufactured according to applicable harmonised European standards the references to which are published in the Official Journal of the European Union (OJEU) benefit from a **presumption of conformity with the relevant legal requirements**. This particular legal status of hENs cited in the OJEU generally allows manufacturers and the other sectorial actors (including notified bodies and national competent authorities) to make **easier, quicker and less burdensome the processes related to conformity assessment procedures, affixing of the CE marking and placing on the market, market surveillance, etc**. However, in general **the use of harmonized standards is voluntary**.

Final takeaway messages

EU legislation on medical devices favors free trade across all European countries and sets a common framework for patient safety

Two new EU Regulations are entering into application that replace the previous legislative framework from the ’90s

Many new elements (clinical evidence, post-market surveillance, traceability systems, new conformity assessment requirments, …) will have a huge impact on all stakeholders (manufacturers, distributors, hospitals, …)

A transition period has been defined until 2024/2025

The key role of technical standards have been included in the new Regulations

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Thank You!

Stefano Bergamasco

Director at MedTech Projects Srl and GCEA Founders Council member

stefano.bergamasco@medtechprojects.com

Standards for Conformity Assessment Testing of Medical Devices

for Legal Metrology Purposes

Prof.dr. Almir Badnjević

Director of Verlab Ltd Sarajevo and University of Sarajevo, Bosnia and Herzegovina

IFMBE Clinical Engineering Division Board Member

almir@verlab.ba

PART 1

CURRENT STATE & MOTIVATION

FACTS

- Patient goes under a series of tests;
- Results of the tests are **measurements - the numbers, graphs or images gathered using all sorts of medical devices** used in making a diagnosis and delivering treatments.
- No standardized measurement and/or data.

The doctor, the patient, family members and other medical staff rely on test results!

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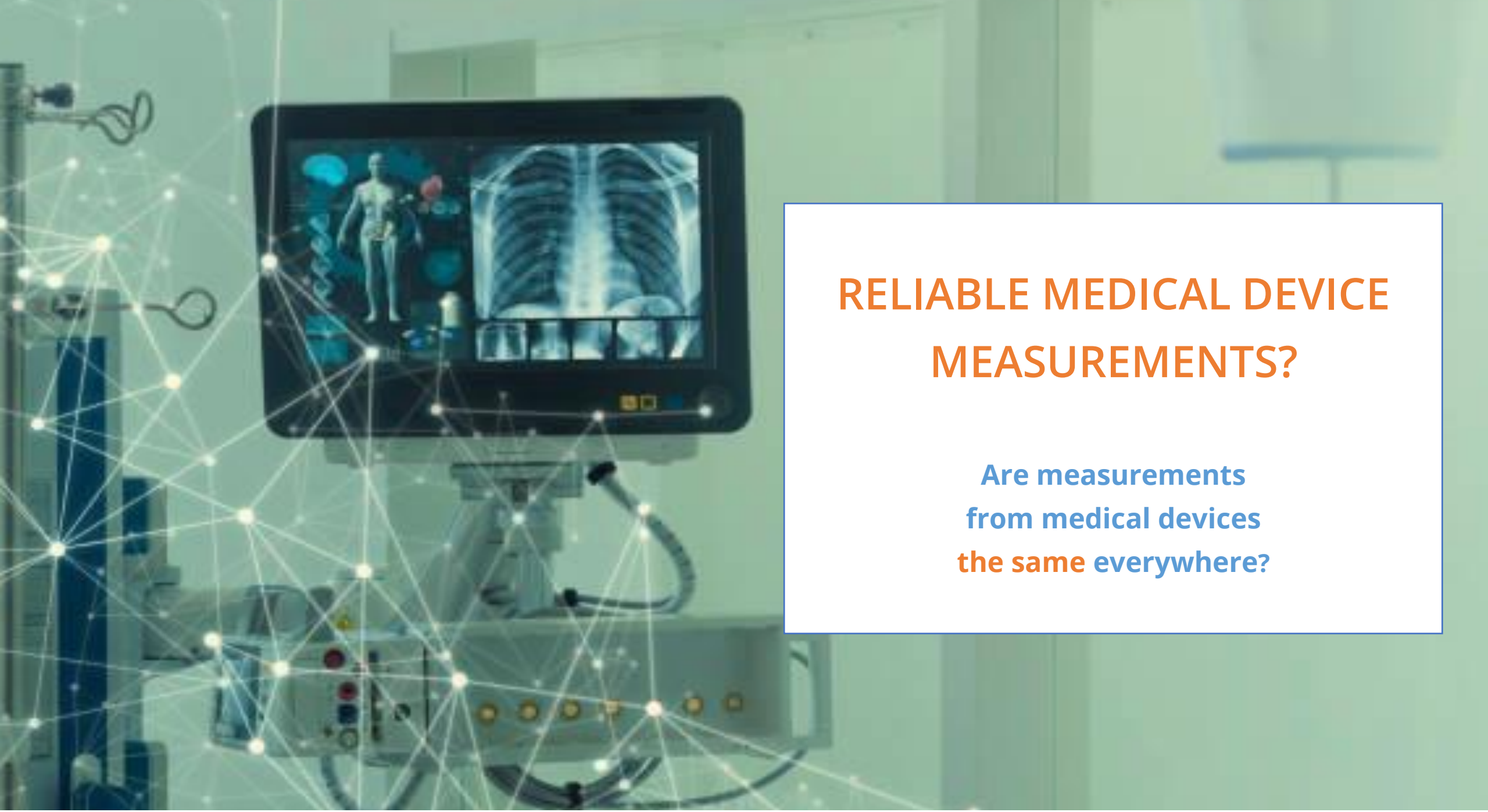


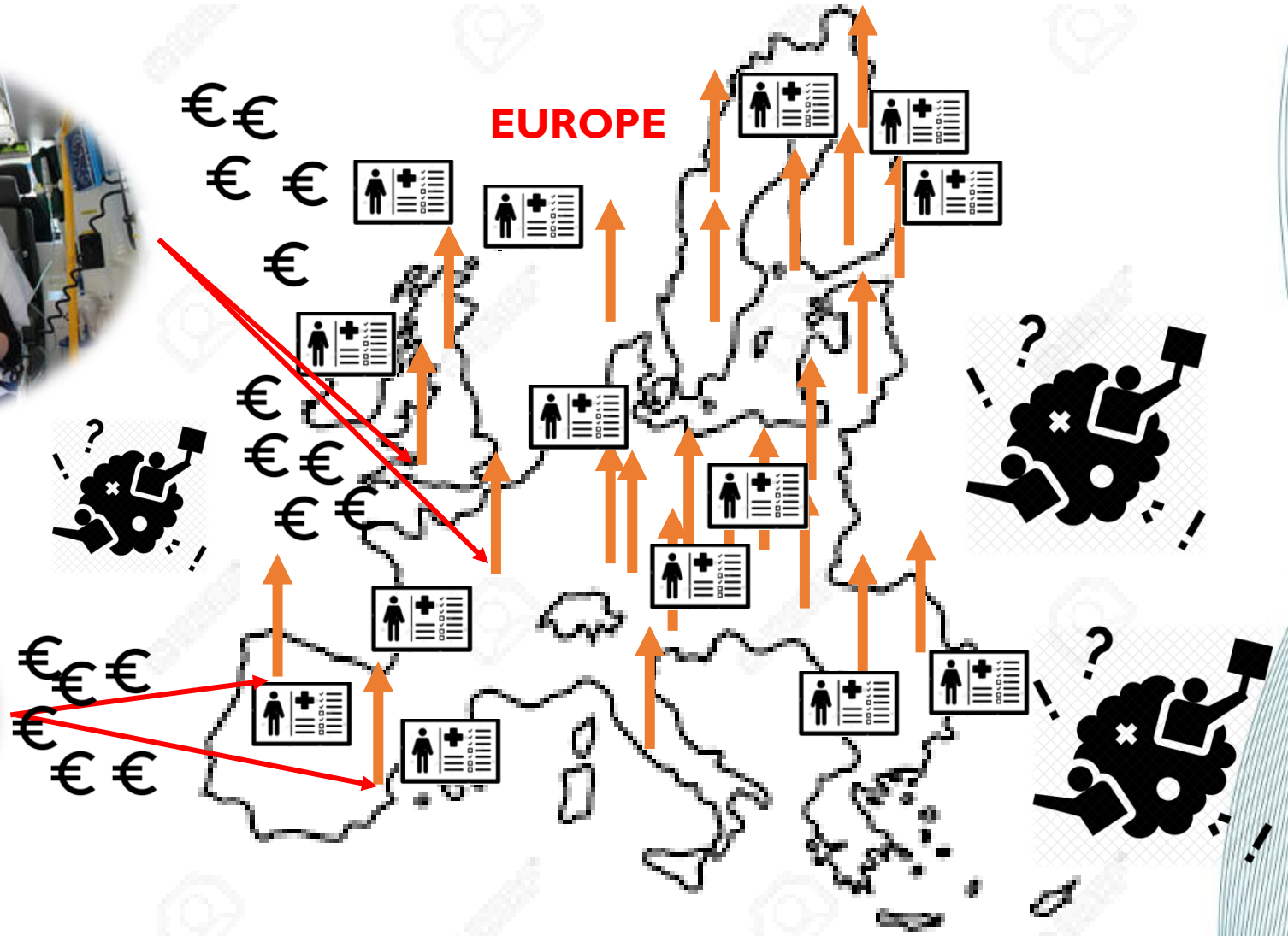
RELIABLE MEDICAL DEVICE MEASUREMENTS?

Are measurements from medical devices the same everywhere?

Reference: Badnjevic A, Gurbeta L, Boskovic D, Dzemic Z. „Measurement in medicine – Past, present, future“, Folia Medica Facultatis Medicinae Universitatis Saraeviensis Journal (2015) 50(1): 43-46

RELIABILITY OF MEDICAL DEVICE MEASSURING

MEDICAL DEVICE MEASUREMENTS - The device must perform a measuring function that provides an absolute quantitative measurement (legal units or reference to a fixed reference) of a physiological/anatomical parameter (or energy/substance delivered/removed from the body) in which the accuracy is critical for the intended purpose of the device.



IMPORTANCE OF MEASUREMENT

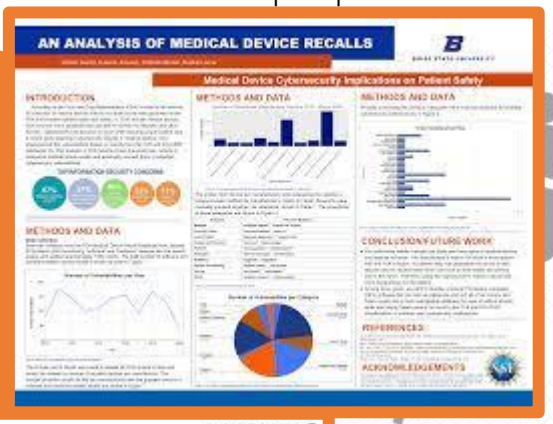
DOES IT MATTER HOW IT IS MEASURED?

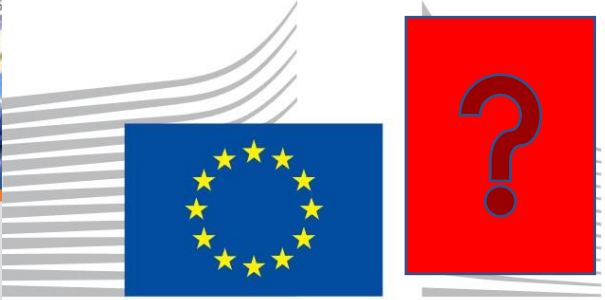
IN GOD WE TRUST

ALL OTHERS MUST BRING DATA

RELIABILITY OF MEDICAL DEVICE MEASSURING

MEDICAL DEVICE MEASUREMENTS - The device must perform a measuring function that provides an absolute quantitative measurement (legal units or reference to a fixed reference) of a physiological/anatomical parameter (or energy/substance delivered/removed from the body) in which the accuracy is critical for the intended purpose of the





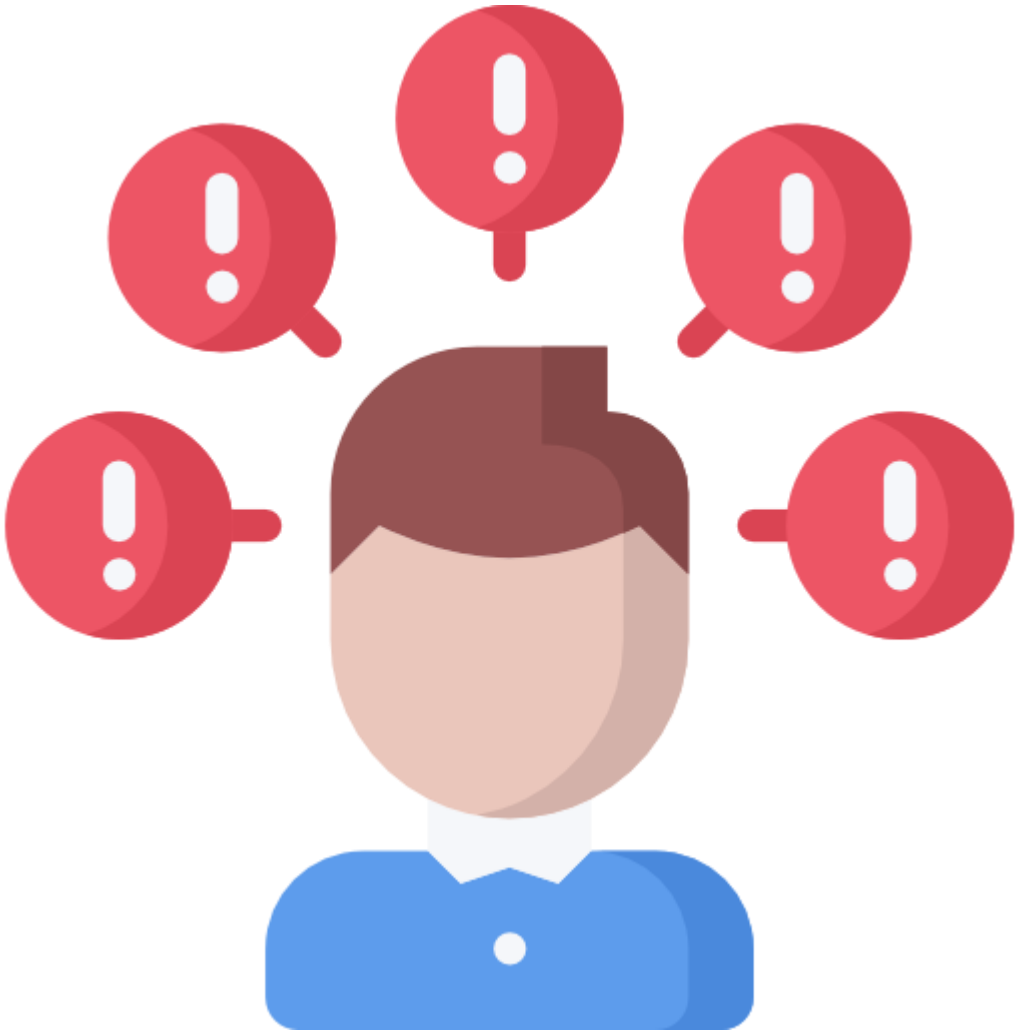
EUDAMED

European Database on Medical Devices

CURRENT STATE

- **PROBLEM**

~ Statistics show that millions of injuries and thousands of deaths have been linked to faulty medical devices in the past decades.



The world has changes, so principles of ensuring safety and performance of medical devices needs to be adapted as well!

MOTIVATION

- **Goal 3: Ensure healthy lives and promote well-being for all at all ages**
  - The lives of billions of people around the globe depend on use of accurate and reliable medical devices.
- Health emergencies such as COVID-19 pose a global risk and have shown the critical need for preparedness.
  - **It is recognized that now more than ever, raising global awareness and knowledge about the importance of respecting the essential requirements is needed in order to guarantee the appropriate quality, performance and safety of medical products, especially during outbreak situation, such as the COVID – 19 pandemics.**

https://www.un.org/sustainabledevelopment/health/

- **SCOPE** Post-market surveillance of diagnostic and therapeutic Medical Devices.

STEP BY STEP SOLUTION

- **GOAL** To implement accredited laboratory (Notified Body) for inspection of medical devices and to establish medical measurement traceability chain for accurate and reliable diagnosis and treatments.
- **BENEFITS** Protected patients. Accurate and reliable diagnosis and tretments. Post market control of Medical Devices. Decrease of maintenance costs in Heathcare institutions.
- **NEEDS** Adjustment with new Medical Device Regulation and World Health Organisation (WHO) Guidelines.
- **DURATION** Approximate 6 months for implementation and training + Accreditation

Specific goal: Reduce the global mortality and injury ration caused by inaccurate medical devices;

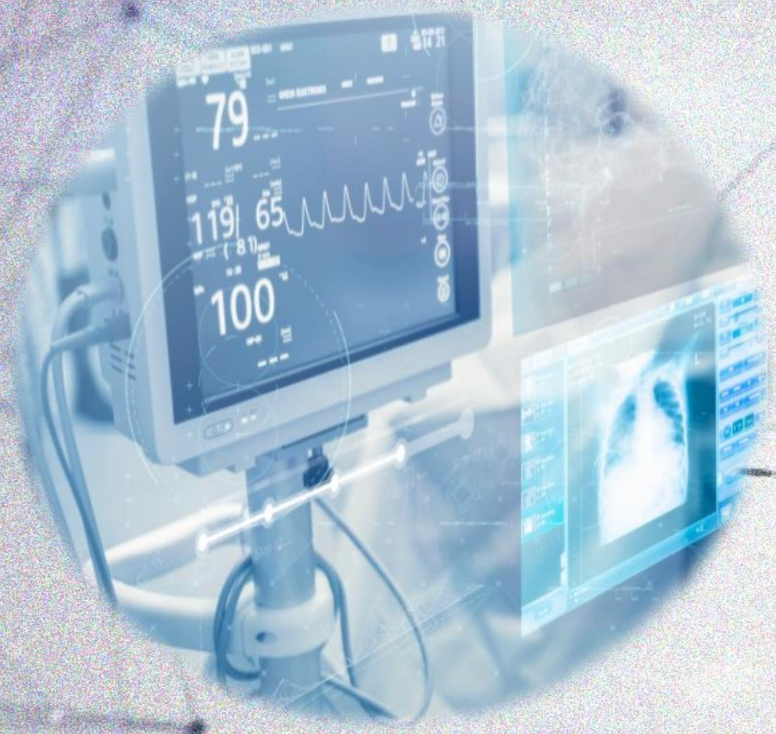
Connection to SDG3: 3.8 Achieve universal health coverage, including financial risk protection, **access to quality essential health-care services** and access to safe, effective, quality and affordable essential medicines and vaccines for all.

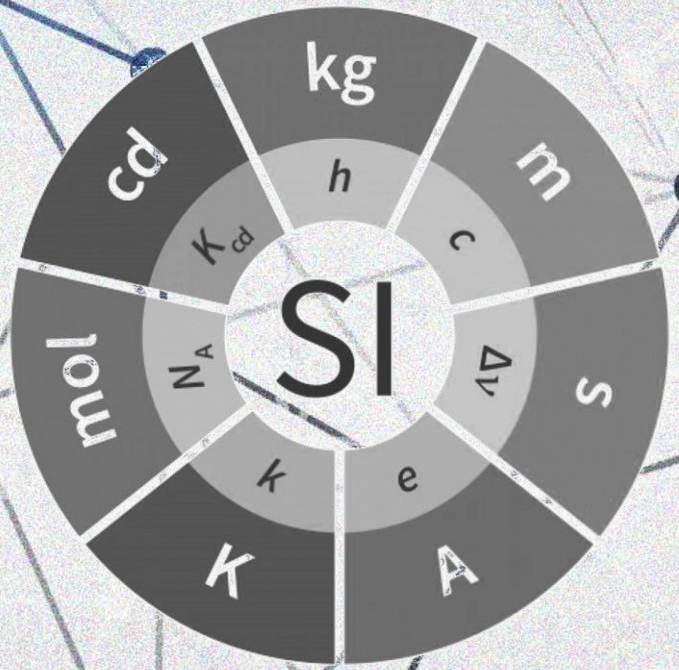
https://www.un.org/sustainabledevelopment/health/

PART 2

INSPECTION OF MEDICAL DEVICES FRAMEWORK

DEVELOPMENT





MEDICAL DEVICES

METROLOGY

STANDARDIZATION

Badnjevic A, Gurbeta L, Boskovic D, Dzemic Z. „Measurement in medicine – Past, present, future“, Folia Medica Facultatis Medicinae Universitatis Saraeviensis Journal (2015) 50(1): 43-46

IEEE Standards for Medical devices with measuring function

https://sagroups.ieee.org/2727/

IEEE P2727 MEDICAL DEVICES WITH MEASURING FUNCTIONS WORKING GROUP

Sponsor: EMB Standards Committee, Engineering in Medicine and Biology Society
Sponsor Chair: Carole C. Carey c.carey@ieee.org

Title: Standard for General Vocabulary for Conformity Assessment of Medical Devices with Measuring Function

Scope: The standard defines commonly-used terms used in the conformity assessment of medical devices with measuring function for legal metrology purposes.

If you wish to participate in the IEEE P2727™ Working Group

Please subscribe to Listserv by sending an email to ListServ@ieee.org. Please include the following text in your email:

Subject: stds-27271-wg

Body: subscribe stds-2727-wg YourFirstName YourLastName

Link to EMBS Standards Page

https://standards.ieee.org/project/2727_1.html

P2727.1 - Standard for Conformity Assessment Testing of Cardiac Defibrillators for Legal Metrology Purposes

Explore This Project

- Project Details
- Working Group

Project Details

The standard develops protocols and procedures for conformity assessment testing of external cardiac defibrillators for legal metrology purposes.

Sponsor Committee	EMB/Stds Com - Standards Committee
Par Approval	2018-03-08
Pars	Approved PAR

PART 3

INSPECTION OF MEDICAL DEVICES FRAMEWORK

SOLUTION

SOLUTION

MEDICAL DEVICES

METROLOGY

STANDARDIZATION

INSPECTION OF MEDICAL DEVICES - FRAMEWORK

- ✓ Safety
- ✓ Performance
- ✓ Accuracy
- ✓ Reliability

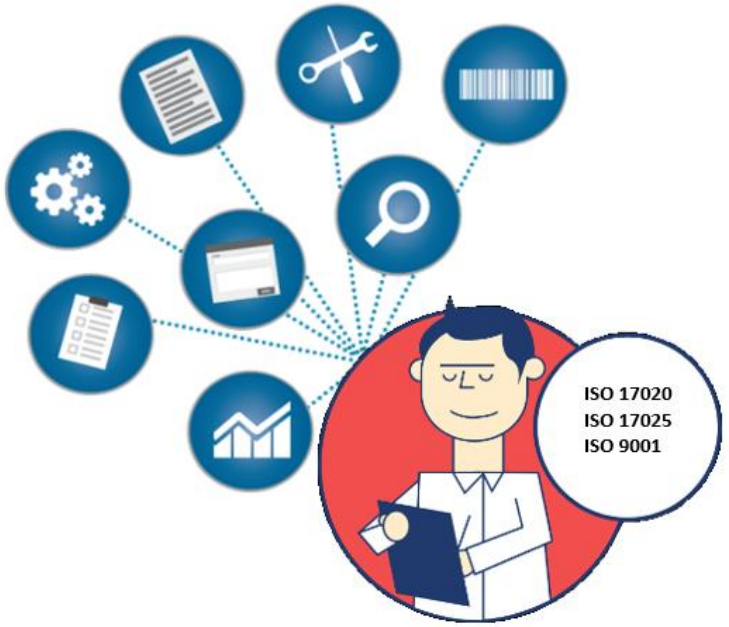
- ✓ Inspection
- ✓ Etalon
- ✓ Calibration
- ✓ Traceability
- ✓ National Body

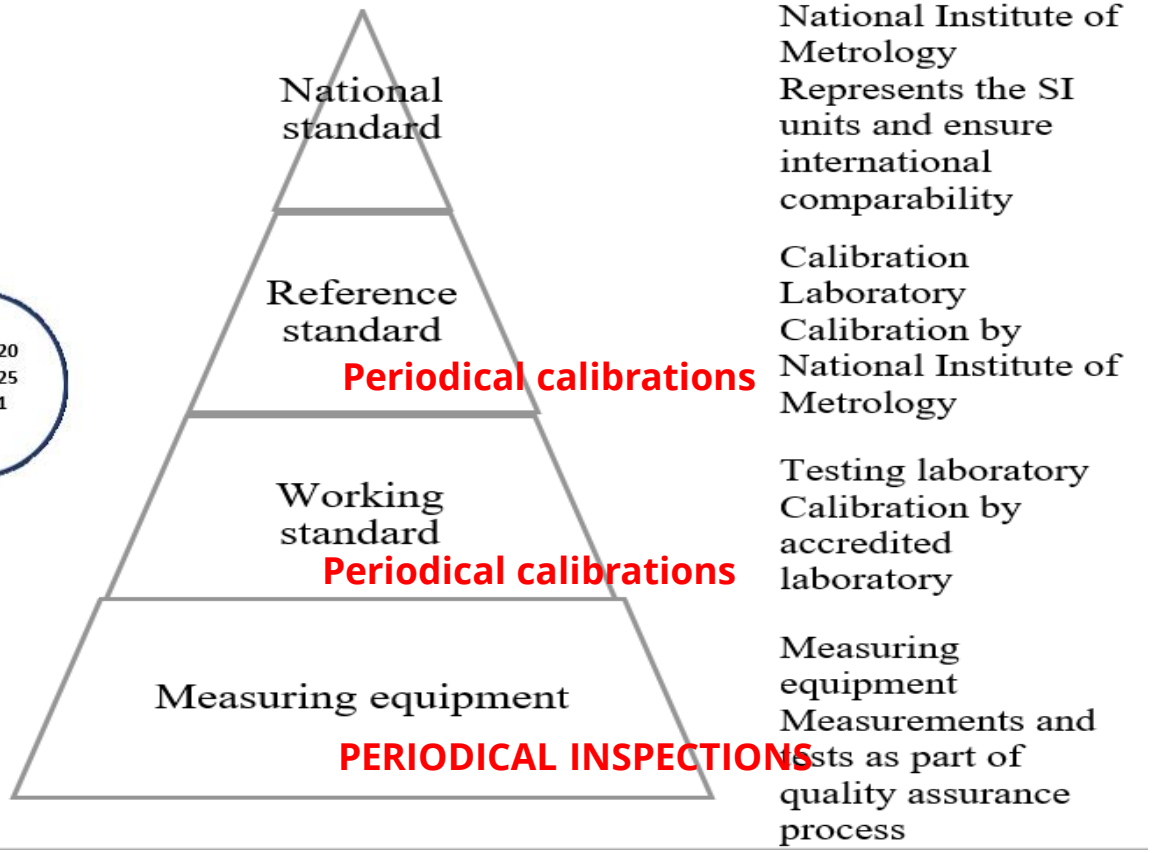
- ✓ ISO 9001
- ✓ ISO 17020
- ✓ ISO 17025
- ✓ IEC 60601

Badnjević A., Cifrek M., Magjarević R., Džemić Z. (eds) Inspection of Medical Devices – for regulatory purposes. Series in Biomedical Engineering. Springer, Singapore

SOLUTION

MEDICAL MEASUREMENT RELIABILITY IS ENSURED BY TRACEABILITY CHAIN





REPRESENTATION OF SI UNIT

REFERENCE ETALON

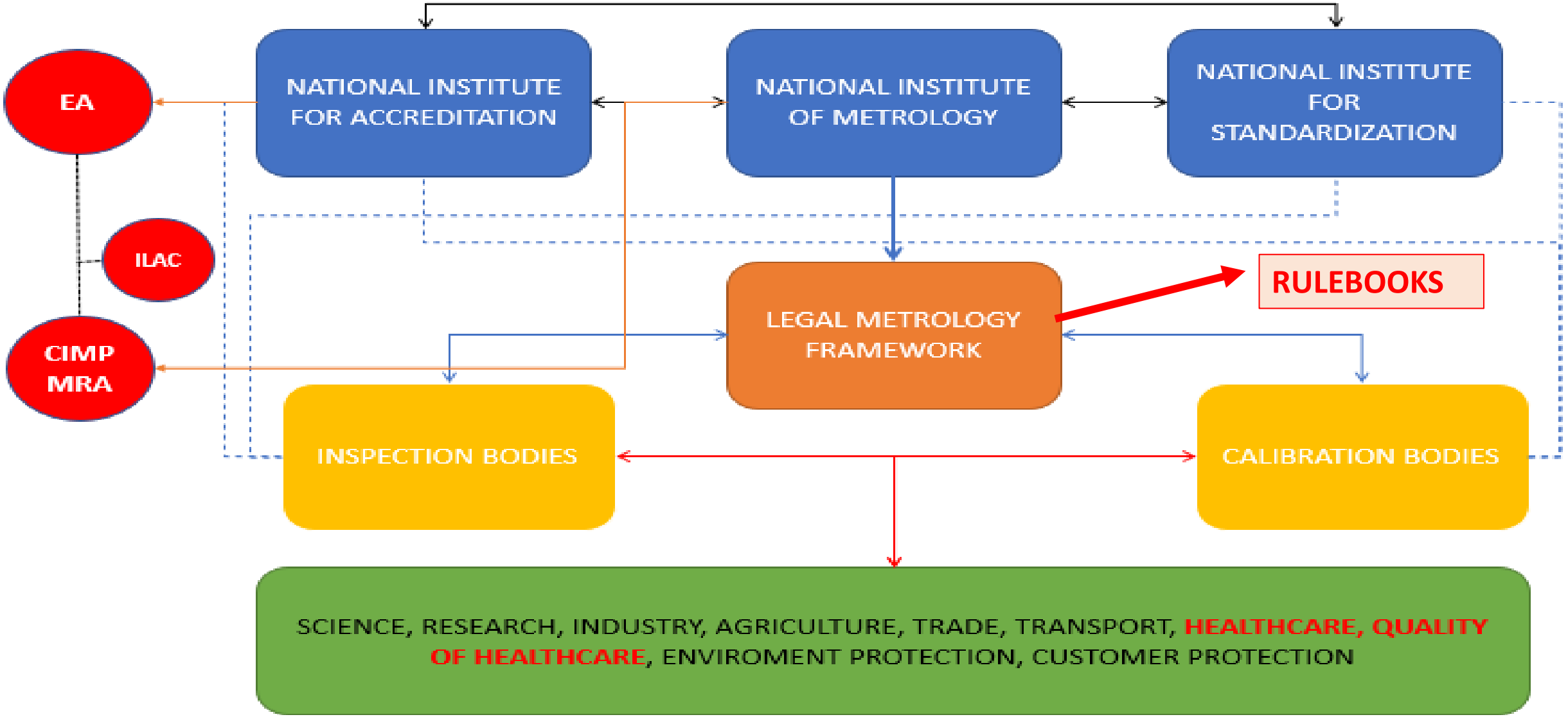
WORKING ETALON

MEDICAL DEVICE

DOCUMENTATION

GLOBAL CLINICAL ENGINEERING ALLIANCE

MEDICAL DEVICES INSPECTION FRAMEWORK



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Thank You!

Prof.dr. Almir Badnjević
Director of Verlab Ltd Sarajevo and University of Sarajevo, Bosnia and Herzegovina
IFMBE Clinical Engineering Division Board Member
almir@verlab.ba


Q&A

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A list of additional topics and dates for next webinars will be soon published on our website www.GlobalCEA.org

THANK YOU
for your participation