Co-financed by the Connecting Europe Facility of the European Union

Legal aspects: an introduction

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DON'T
FORGET!

Introduce yourself

MODULE
Information Ethics and Legal Aspect

- MODULE A – Ethics

- MODULE B – Legal Aspects
  - Amedeo Santosuosso
  - Sara Azzini

ICLT
International Center on Law science and new Technologies
University School for Advanced Studies IUSS Pavia

BIO-MEDICAL INFORMATICS "Mario Stefanelli"

UNIVERSITÀ DI PAVIA
Department of Electrical, Computer and Biomedical Engineering

Laws from international organizations
(UN, Council of Europe)

European Union laws

Italian laws

Translation and legal concept

Where is the law?
In which field of your life?

A short introduction: the law is everywhere

What to do to enter into an agreement?

A short introduction: the law is everywhere

Written agreement

Oral agreement

Agreement through Actions or Facts

«one medium drafted beer, please»
John Searle – Invisible Ontologies

This simple phrase activates an immense invisible ontology: the social exchange between the customer and the waiter, a network of rules, prices, rates, rules, passports and nationalities.

Always consider legal aspects and implications of what you are doing

European Union Types of Legislation

Regulation:
binding legislative act. It must be applied in its entirety across the EU.

Directive:
legislative act that sets out a goal that EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. The Directive must be incorporated by EU countries into their national legislation (ratification), unless the Directive is a «self-executing» directive. Each directive contains a deadline by which EU countries must incorporate its provisions into their national legislation and inform the Commission to that effect.

Decision:
binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable.

Recommendation:
not binding. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinion:
an instrument that allows the institutions to make a statement without imposing any legal obligation on those to whom it is addressed. An opinion is not binding.

What regulation to deal with in the field of AI products

Data Protection Regulation
(GDPR)
Reg. 2016/679/EU

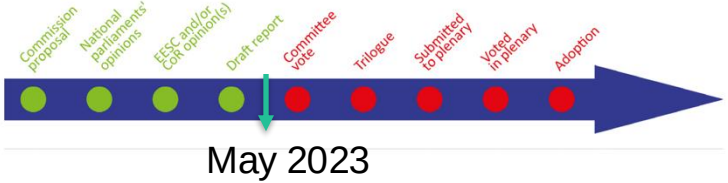
Medical Device Ragulation
(MDR)
Reg. 2017/745/EU

AI Act - Regulation
(proposal April 21, 2021)

Machinery Regulation
Reg. 2023/1230/UE – June 14, 2023
(into force in January 2027)

Directive on liability
for defective product
(proposal)

Directive on Adapting Non
Contractual Civil Liability
Rules to Artificial Intelligence
(proposal, Sept. 28,2022)



2023

Data Protection Regulation
(GDPR)
Reg. 2016/679/EU

Medical Device Ragulation
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2024

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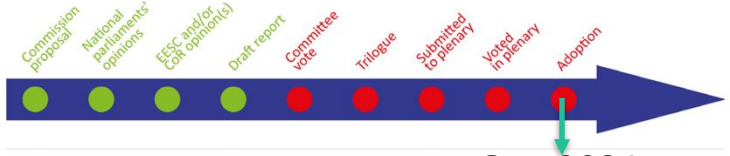

2024

Directive on Adapting Non
Contractual Civil Liability
Rules to Artificial Intelligence
(proposal, Sept. 28,2022)

AI Act - Regulation
(Reg. 2024/1689)

Connection also to other EU legislation:

- Non discrimination
- Gender equality
- Consumer Protection
- Law Enforcement Directive
- Union Competition Law
- E-commerce Directive
- Digital Services Act (proposal)
- Data Governance Act (proposal)
- Open Data Directive

Do you know how to manage overlaps or conflicts among those regulations

Criteria are established in the regulation

E.g.

high-risk AI systems related to products covered by the New Legislative Framework (NLF) legislation (e.g. machinery, medical devices, toys), the requirements for AI systems set out in this proposal will be checked as part of the existing conformity assessment procedures under the relevant NLF legislation.

With regard to the interplay of requirements, *while the safety risks specific to AI systems are meant to be covered by the requirements of this proposal, New Legislative Framework (NLF) legislation aims at ensuring the overall safety of the final product and therefore may contain specific requirements regarding the safe integration of an AI system into the final product.*

Our «stairway to heaven» (cit.)

Our agenda:

Oct., 30, 2024
Nov. 4, 2024
Nov. 12, 2024
Nov, 27, 2024
Dec. 2, 2024
Dec. 3, 2024
Dec. 5, 2023

Medical Device Regulation

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Regulation (EU) 2017/746 (EU IVDR) - ***In vitro* diagnostic medical devices Regulation**

- placing on the European Union market, making available and putting into service in vitro diagnostic (IVD) medical devices for human use and their accessories.
- rules on the conduct of performance studies.
- **stricter procedures for conformity assessment** (to ensure that unsafe or non-compliant devices do not end up on the market)**and post-market surveillance**.

Directive 90/385/EEC
(active implantable medical devices)

Directive 93/42/EEC
(other medical devices)

Regulation (EU) 2017/745 (EU MDR) - **medical devices Regulation**

Regulation:
binding legislative act.
It must be applied in its entirety across the EU.

5.5.2017 EN Official Journal of the E

I

(Legislative a

REGULATIONS

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

of 5 April 2017

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

(Text with EEA relevance)

DeJure
Banche dati editoriali GFL

INTERO PROVVEDIMENTO

Decreto legislativo - 05/08/2022, n.137
Gazzetta Ufficiale: 13/09/2022, n. 214

EPIGRAFE

DECRETO LEGISLATIVO 5 agosto 2022, n. 137 (in Gazz. Uff. 13 settembre 2022, n. 214). – Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio, nonché per l'adeguamento alle disposizioni del regolamento (UE) 2020/561 del Parlamento europeo e del Consiglio, del 23 aprile 2020, che modifica il regolamento (UE) 2017/745 relativo ai dispositivi medici, per quanto riguarda le date di applicazione di alcune delle sue disposizioni ai sensi dell'articolo 15 della legge 22 aprile 2021, n. 53.

IL PRESIDENTE DELLA REPUBBLICA

In Italy:

Reg. 745/2017
+
Decreto Legislativo n. 137/2022
+
Decreti ministeriali (March April 2023)

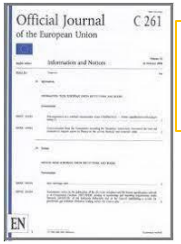
= is a technical term in law which designates the period between the announcement of a legislation and its entering into force.
= is a technical term in civil law which refers to the period between the promulgation of a law and the time the law takes legal effect.

promulgation: the act is publish on the Official Journal of the European Union (or, for Italy, Gazzetta Ufficiale)

MDR Vacatio Legis

the act entries into force
- enforceable
- penalty and fines in case of breach

DISCUSSION | TIME FOR PROVIDERS FOR COMPLYING WITH NEW PROVISIONS


Official Journal of the European Union C 261
Information and Notices
EN

MD Regulation of April 5, 2016
published on May 5, 2016

MD Regulation → May 26, 2021

A. enforcement of all provisions
B. enforcement of some of the provisions of the act

MDR Timeline

MDR Dates of Application

26 May 2021 — All devices, except those covered by the extended transition period, must comply with the MDR (e.g. class I, new devices, devices with a significant change)

26 May 2024 — End of transition period for legacy devices that do not meet the conditions for application of the new transition periods (see conditions in red boxes below)

26 May 2026 — End of derogation for class III custom-made implantable devices

Only devices covered by a notified body certificate or a manufacturer's declaration of conformity issued before 26 May 2021 can potentially benefit from the extended transition period

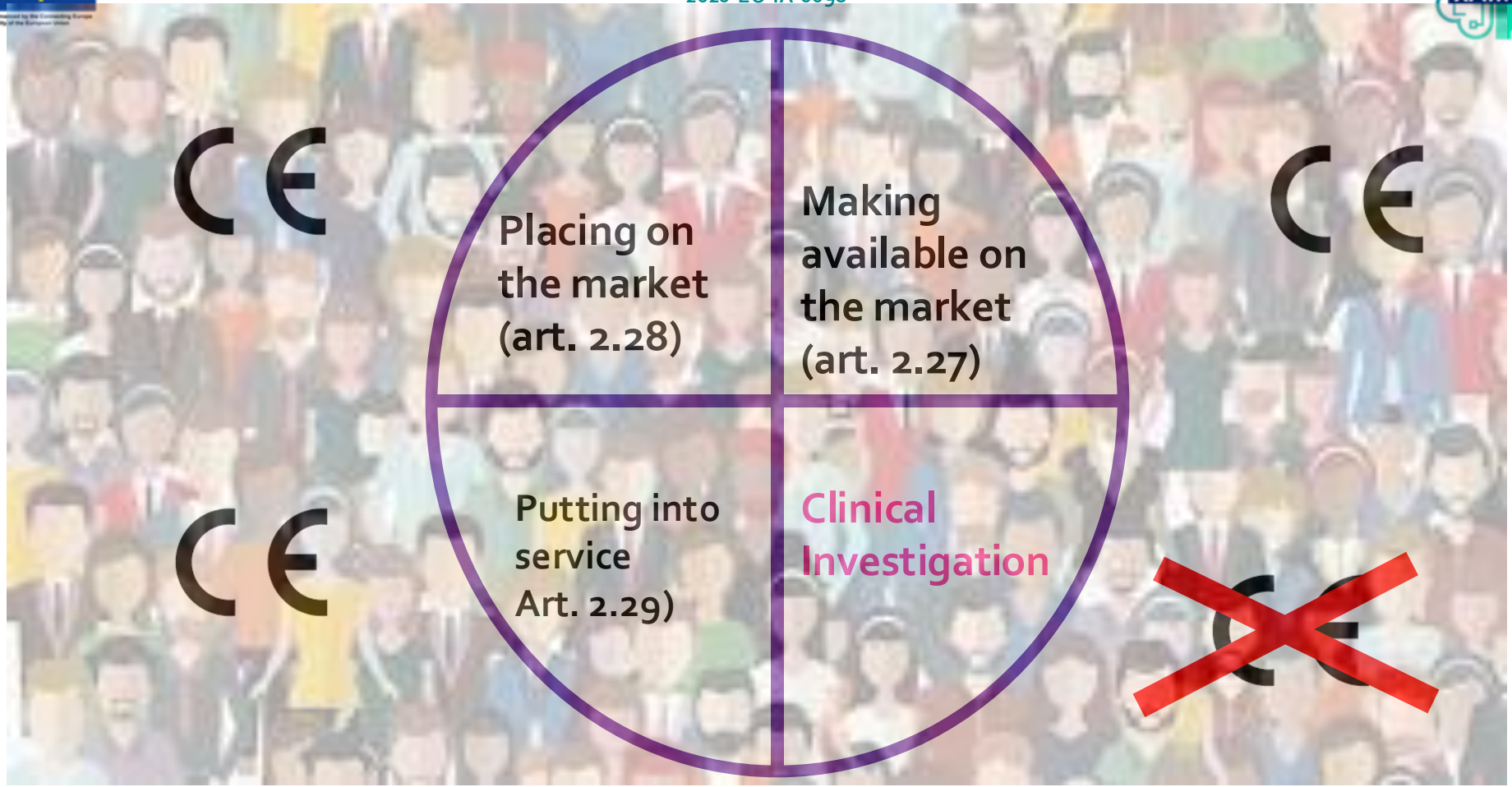
31 Dec 2027 — End of transition period for class III and class IIb implantable devices (if not excepted, e.g. sutures)

31 Dec 2028 — End of transition period for other class IIb, IIa, class I sterile/measuring devices, devices requiring notified body involvement for the first time under MDR

***Conditions to be fulfilled to benefit from extended transition period**

- **26 May 2024**: Deadline to lodge an application for MDR conformity assessment & have an MDR QMS in place
- **26 Sep 2024**: Deadline to sign a written agreement with an NB & transfer appropriate surveillance to an MDR NB (where applicable)
- Devices continue to comply with previously applicable EU legislation (MDD/ AIMDD)
- No significant changes in design or intended purpose
- Devices do not present an unacceptable risk to health or safety

In which situation we need to be compliant with the MDR


CE
Placing on the market (art. 2.28)
Making available on the market (art. 2.27)
CE
CE
Putting into service Art. 2.29)
Clinical Investigation
CE

MDR philosophy - pillars

Protection of health for patients and users

Set high standards for quality and safety

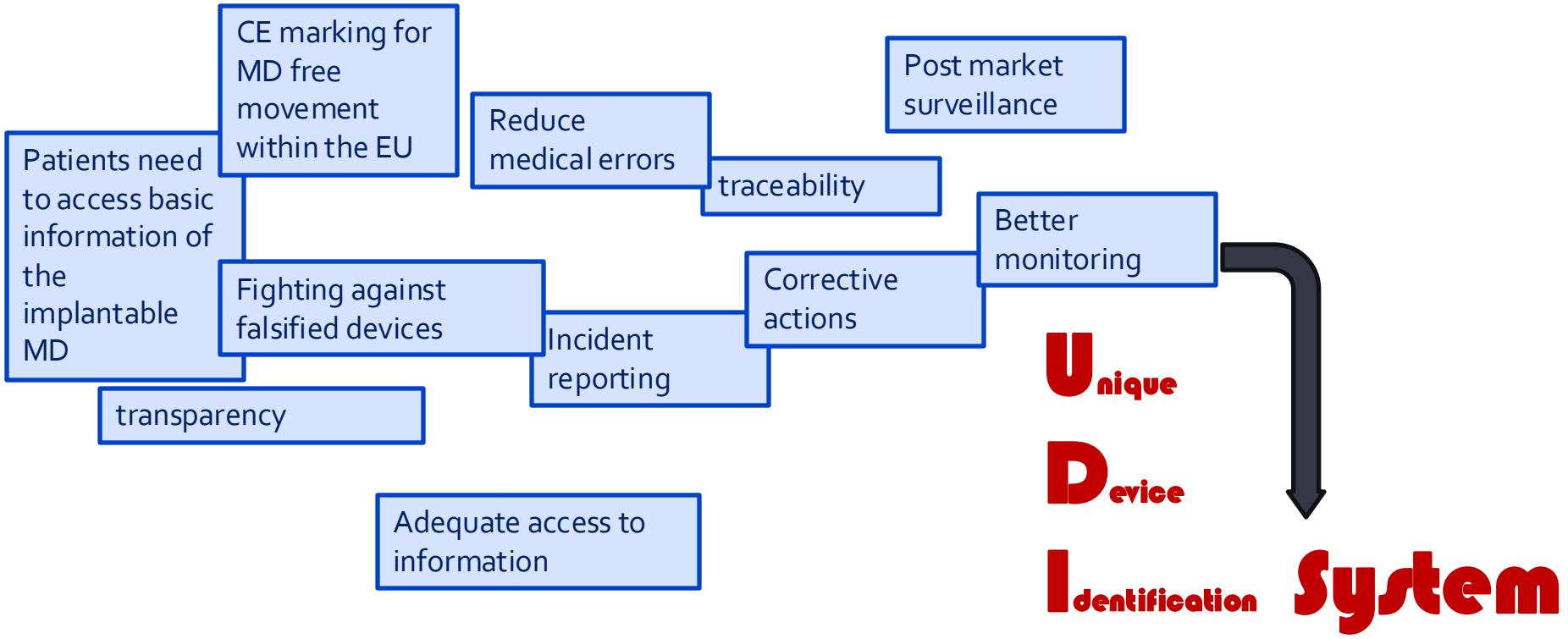
protect the safety of the subjecs participating in clinical trial

Generate reliable and robust data in clinical trial

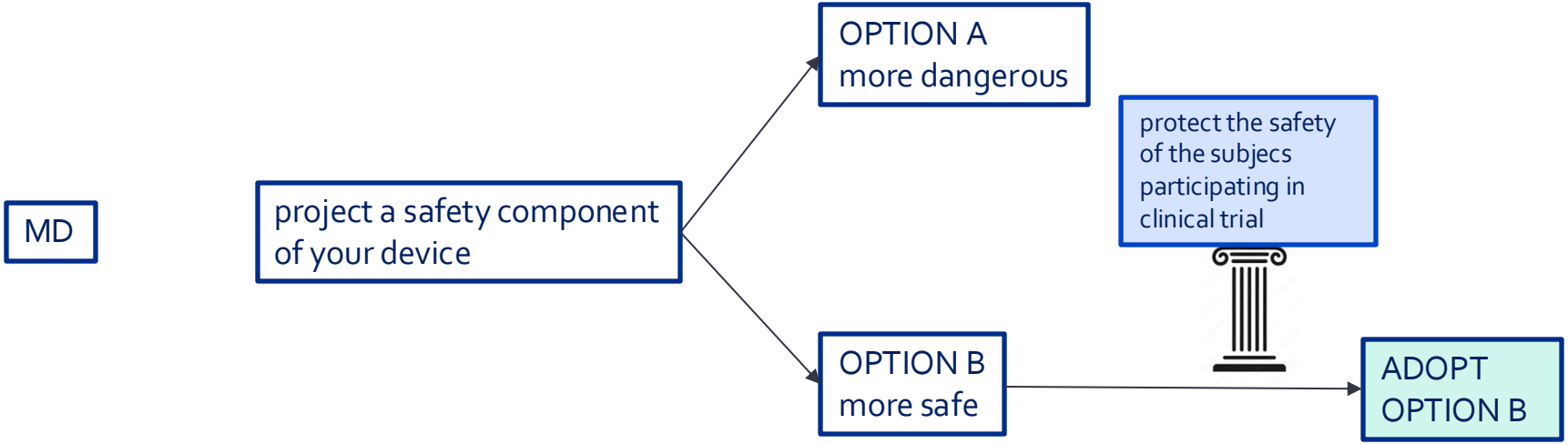
Market

Clinical Investigation

MDR philosophy – basic needs



What do the pillars mean in the everyday decisions on the MD you are implementing


MD
project a safety component of your device
OPTION A more dangerous
OPTION B more safe
protect the safety of the subjecs participating in clinical trial
ADOPT OPTION B

MDR philosophy (UDI & EUDAMED)

creation of a European database on medical devices (**Eudamed**) that should integrate different electronic systems to collate and process some information

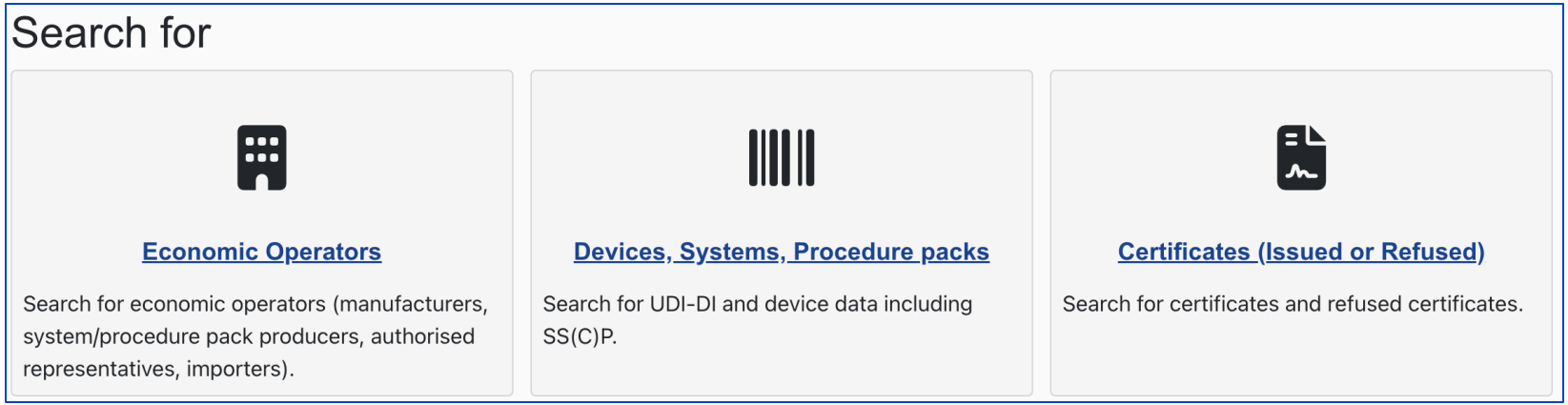
https://ec.europa.eu/tools/eudamed/#/screen/home

EUDAMED modules

EUDAMED will be composed of **six modules**:
- Actor registration;
- Unique device identification (UDI)/ device registration;
- Notified bodies and certificates;
- Clinical investigations and performance studies;
- Vigilance and Post-Market Surveillance,
- Market Surveillance

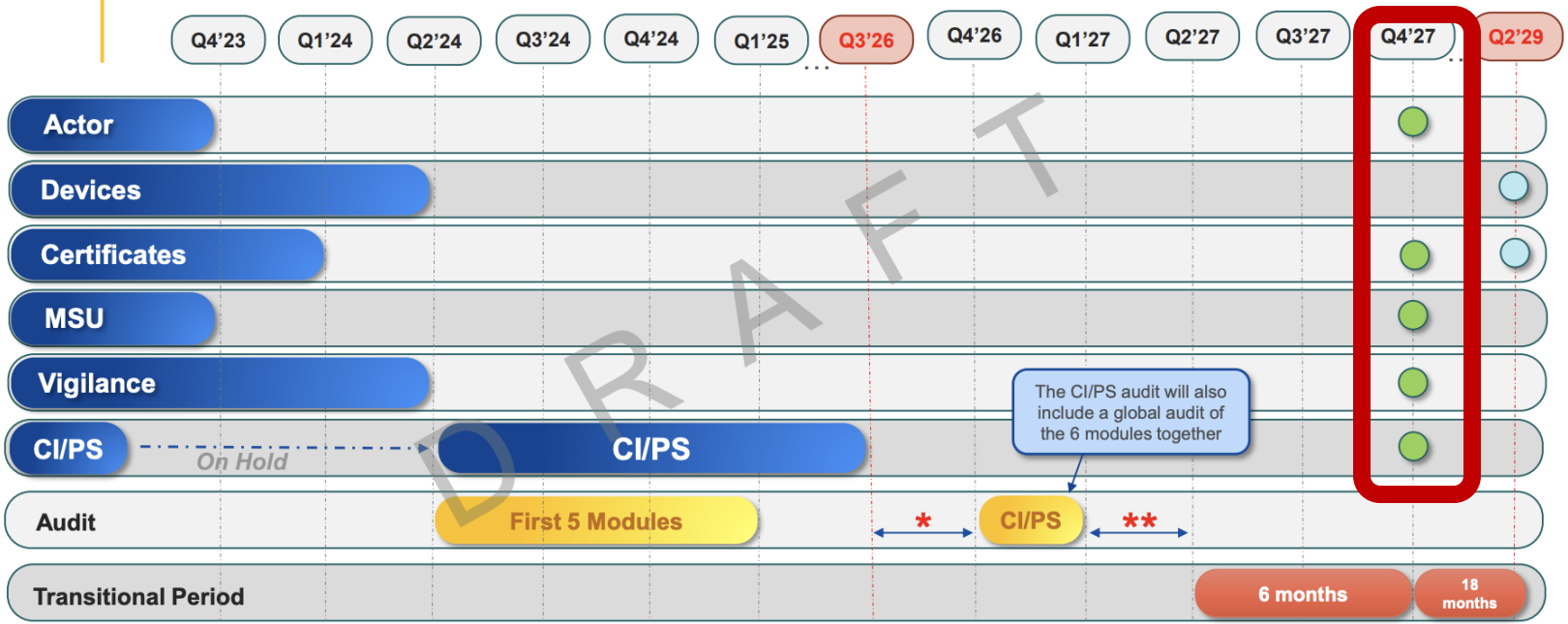
At the moment modules are not fully implemented

Modules available:



EUDAMED Roadmap

Blue colour represents development

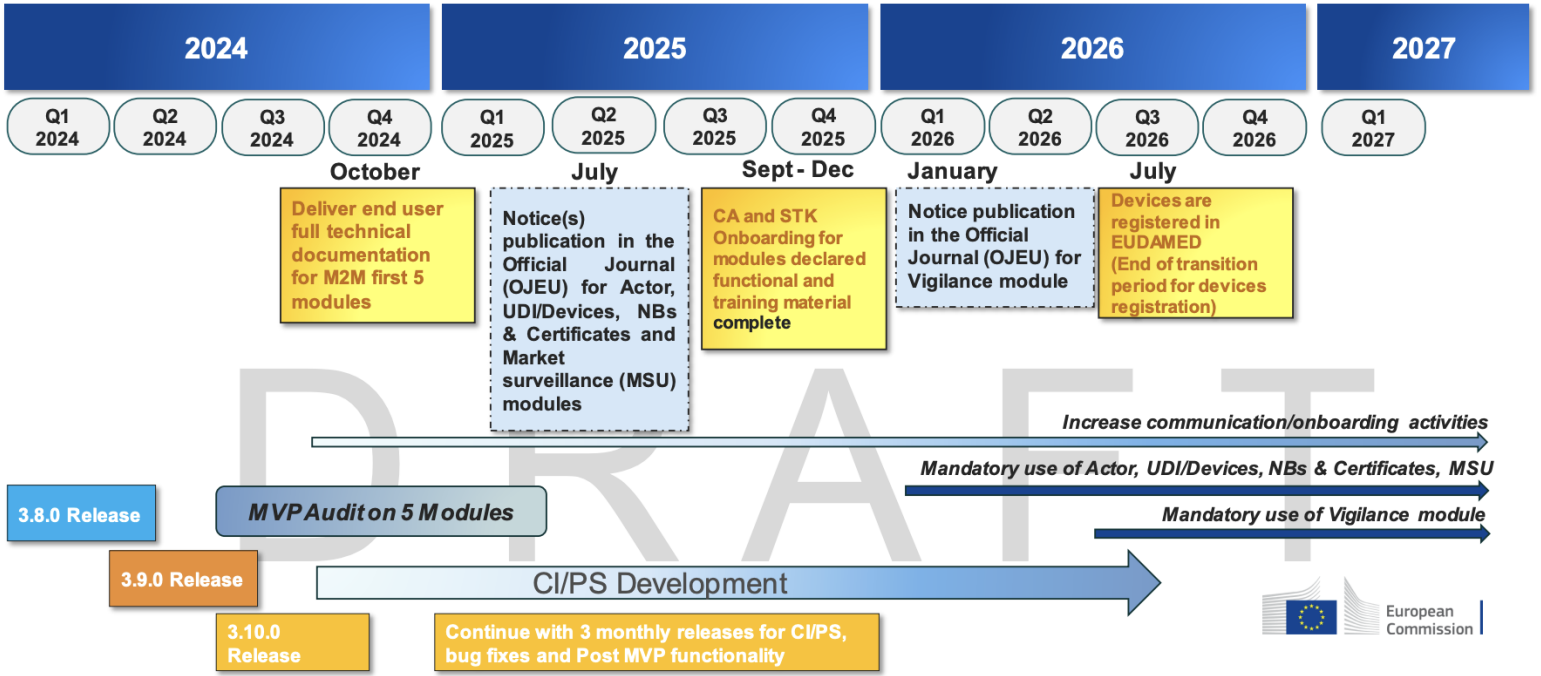


* *Stabilisation of the system for the audit*
** *Publication of the notice of EUDAMED full functionality in the EU OJ*

- *Mandatory use of the module as per Article 123 (3) (d) MDR/113 (3) (f) IVDR*
- *Use of EUDAMED for Devices and Certificates registration becomes mandatory as per Article 123 (3) (e) MDR/113 (3) (a) IVDR*

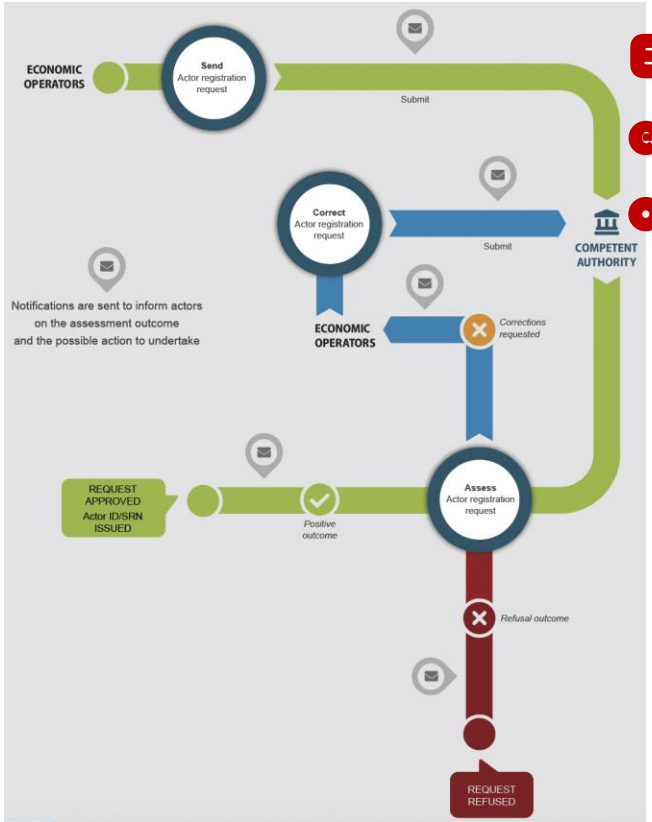
European Commission

Current planning for gradual roll out and modules' functionality view



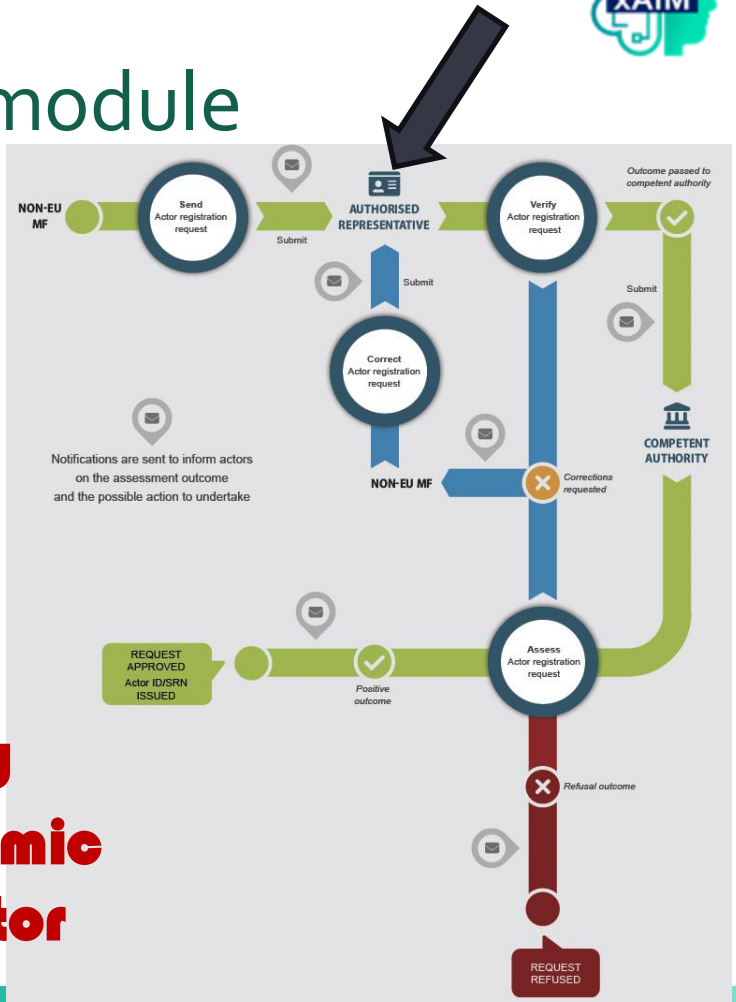
https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf

Actors' registration module

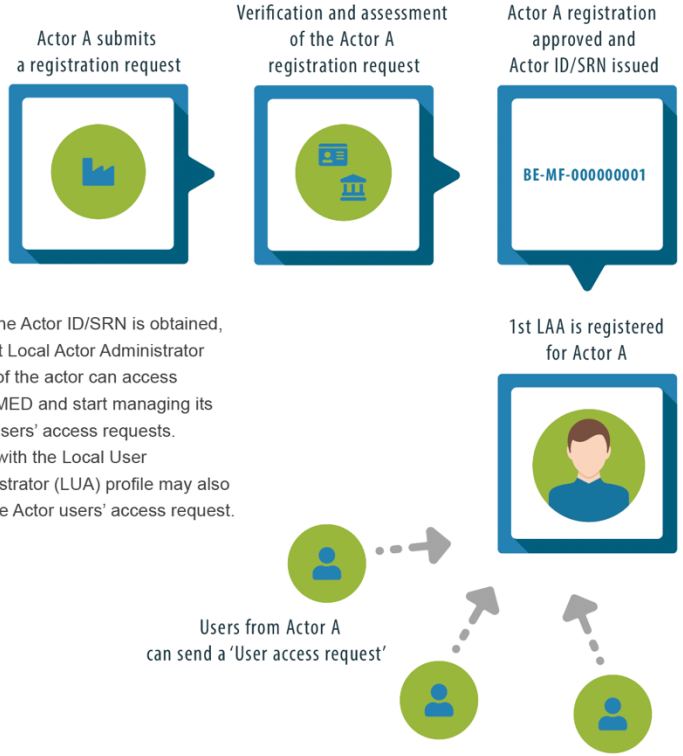


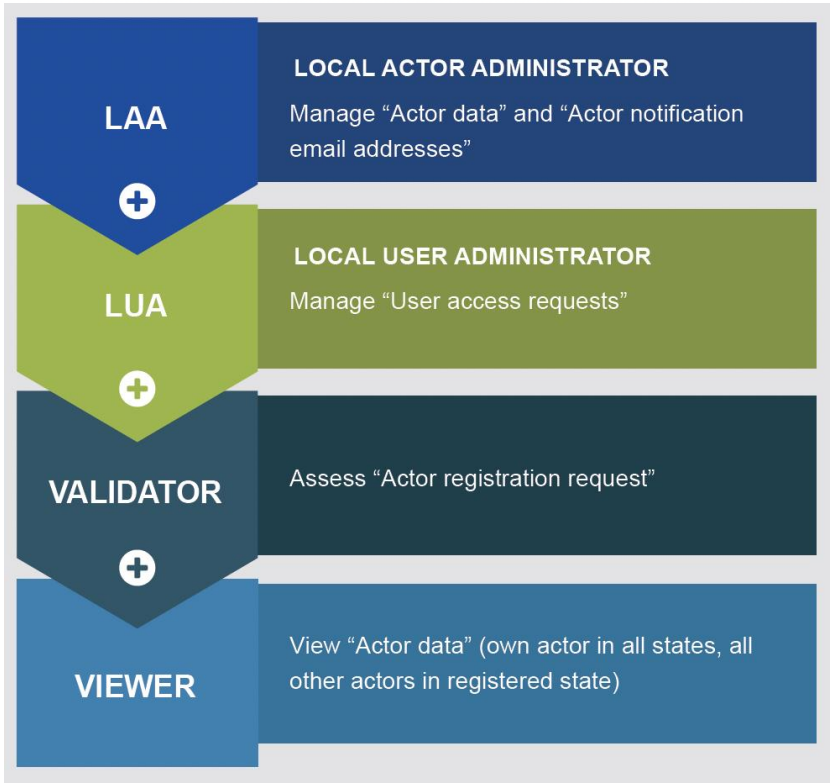
EU economic operator

Non-EU economic operator



Once an actor is registered in EUDAMED with its first Local Actor Administrator (LAA) and has obtained an Actor ID/SRN, more **users** of this actor can **request access** to EUDAMED.





Who is entitled to decide wheter or not a product is a Medical Device

Article 2

Definitions

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

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

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

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

in the MDR

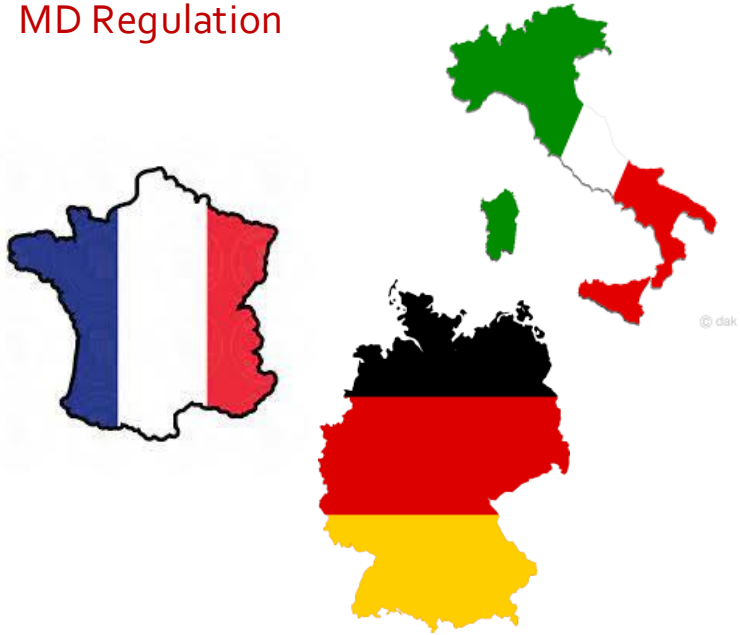
Recital

L 117/4 EN Official Journal of the European Union 5.5.2017

(19) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

For borderline cases

Each **Member State decides** (case-by-case) whether or not a product falls within the scope of MD Regulation



European Commission

Consultation on its own request

Request of evaluation of a case

Medical Device Coordination Group

What is a Medical Device

Definition: MD

instrument, apparatus, appliance, software, implant, reagent, material or other article **intended by the manufacturer to be used**, alone or in combination, for human beings **for** one or more of the following specific **medical purposes**:

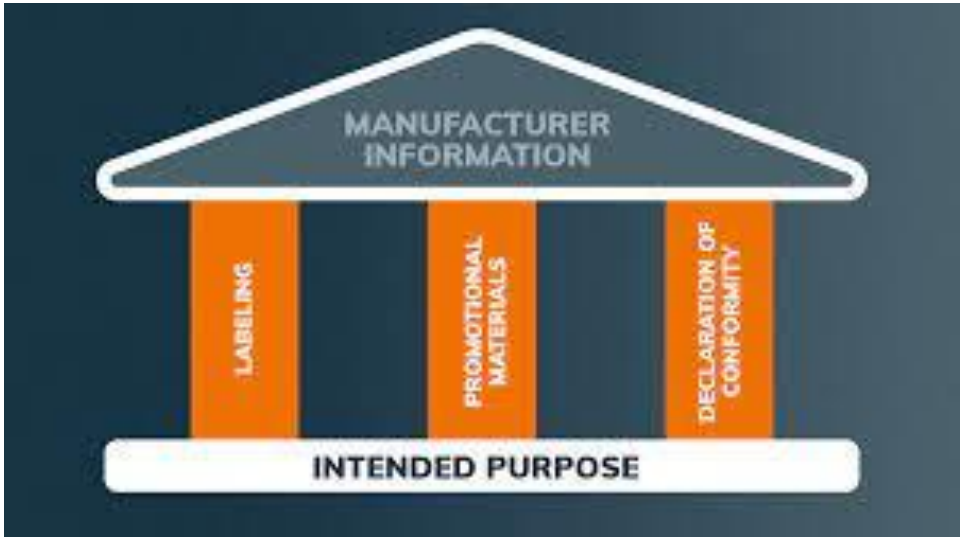
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of *disease*,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an *injury or disability*,
— investigation, replacement or modification of the *anatomy* or of a physiological or pathological *process* or *state*,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

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

The following products shall **also be deemed to be medical devices**: #3
— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Definition: intended purpose

'intended purpose'
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 or statements and as specified by the manufacturer in the **clinical evaluation**



In your opinion, is a smartwatch a MD

A smartwatch is not a MD as its intended use declared by the manufacturer is not a medical purpose

In your opinion, is a software a MD

MD Software

(Recital 19) It is necessary to clarify that **software** in its own right, *when specifically intended by the manufacturer to be used for one or more of the medical purposes* set out in the definition of a medical device, **qualifies as a medical device**, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

Medical purpose intended by the manufacturer

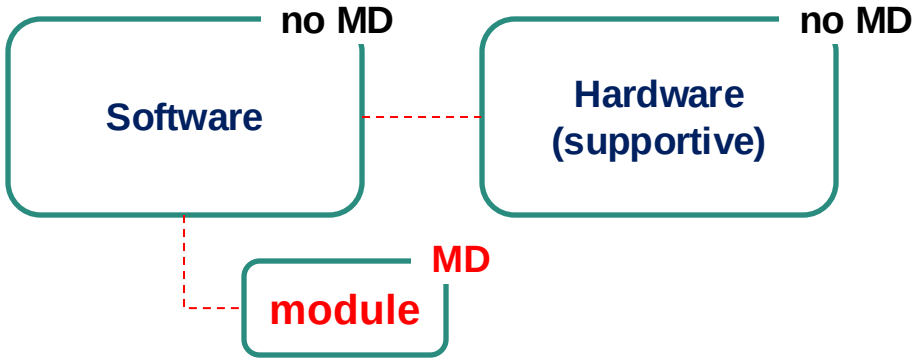
In	Out
Medical p.	Life-style p.
	Well-being p.

MD Software - examples

example = stand-alone sw

Rugulatory requirements:

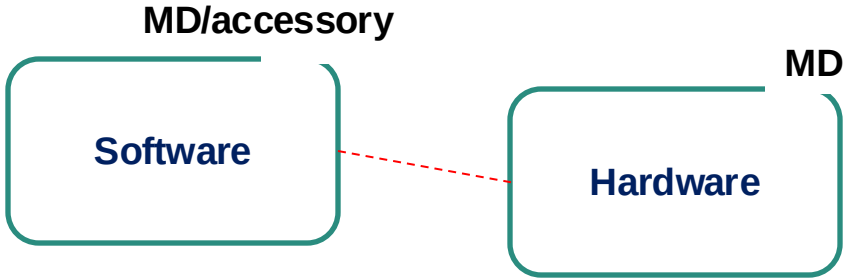
1. Manufacturer shall achieve the MD **conformity to General Safety and Perfomance Standards** (Annex I).
2. Manufacturer shall established and document the **hardware minimum requirements**.
   - ✓ HW shall conform to other technical rules (product, radio appliances…).



example= teleconsultation sw with a module for prescription

Regulatory requirements:
Manufacturer is responsible for **defining module interfaces** as well as for **module medical compliances to the MDR**.

MD Software - examples



example: sw for analyzing data deriving from an exoskeleton in order to control exercises executed by the patient through the exoskeleton.

Regulatory Requirements:

1. The MD Hardware shall be CE marked and used in conformity to its intended use. Otherwise it is itself a MD whose conformity needs to be investigated.
2. The MD software shall comply with General Safety and Performance Requirements (Annex I). Compatibility and Interoperability between HW and SW shall be investigated.
3. Risk analysis shall include risks deriving from the interaction between the two components.

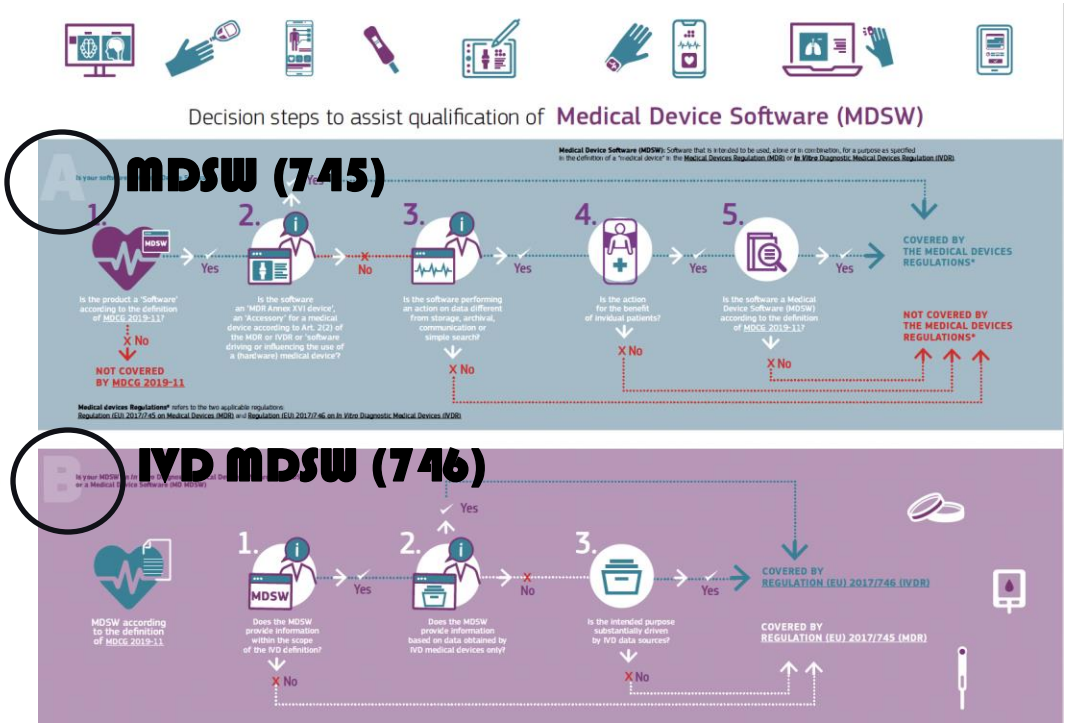
MD Software

Medical Device
Medical Device Coordination Group Document MDCG 2019-11

MDCG 2019-11
Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

October 2019

Available at: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf

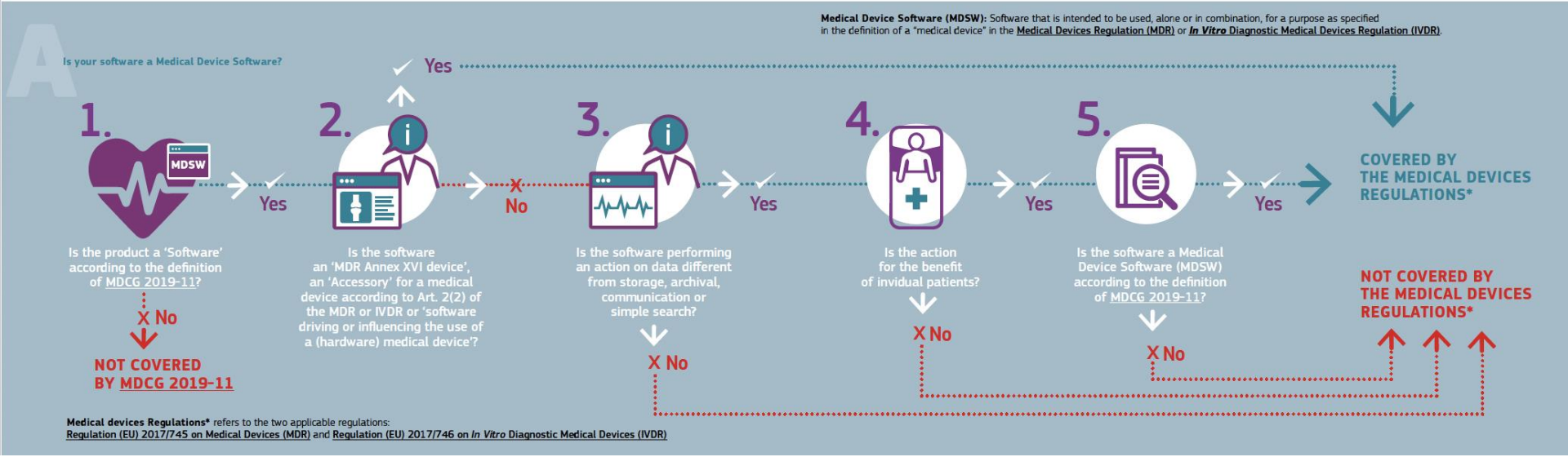


Available at: https://health.ec.europa.eu/system/files/2021-03/md_mdcg_2021_mdsw_en_0.pdf

MD Software

(more in detail)

Decision steps to assist qualification of **Medical Device Software (MDSW)**



MD accessories

'accessory for a medical device'

article which, whilst **not being itself a medical device,** is **intended by its manufacturer to be used together with one or several particular medical device(s)** to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)

IT MEANS THAT WE NEED TO CERTIFY ALSO THE ACCESSORIES UNDER THE MDR:

A) If they are already on the market with a intended use different form a medical one
B) If they entered the market for the first time

ASSESSMENT FOR THE MD ACCESSORIES TOO

Co-financed by the Connecting Europe Facility of the European Union

See you soon

Nov. 4, 2024
Nov. 12, 2024
Nov, 27, 2024
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Dec. 3, 2024
Dec. 5, 2023