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Ibrugtagning af AI-løsninger – Gældende og kommende regler for udstyr og forskning

Temadag om klinisk anvendelse af kunstig intelligens på kræftområdet, 3 Oktober 2024
Rolf Oberlin Hansen, Specialkonsulent, Medicinsk udstyr

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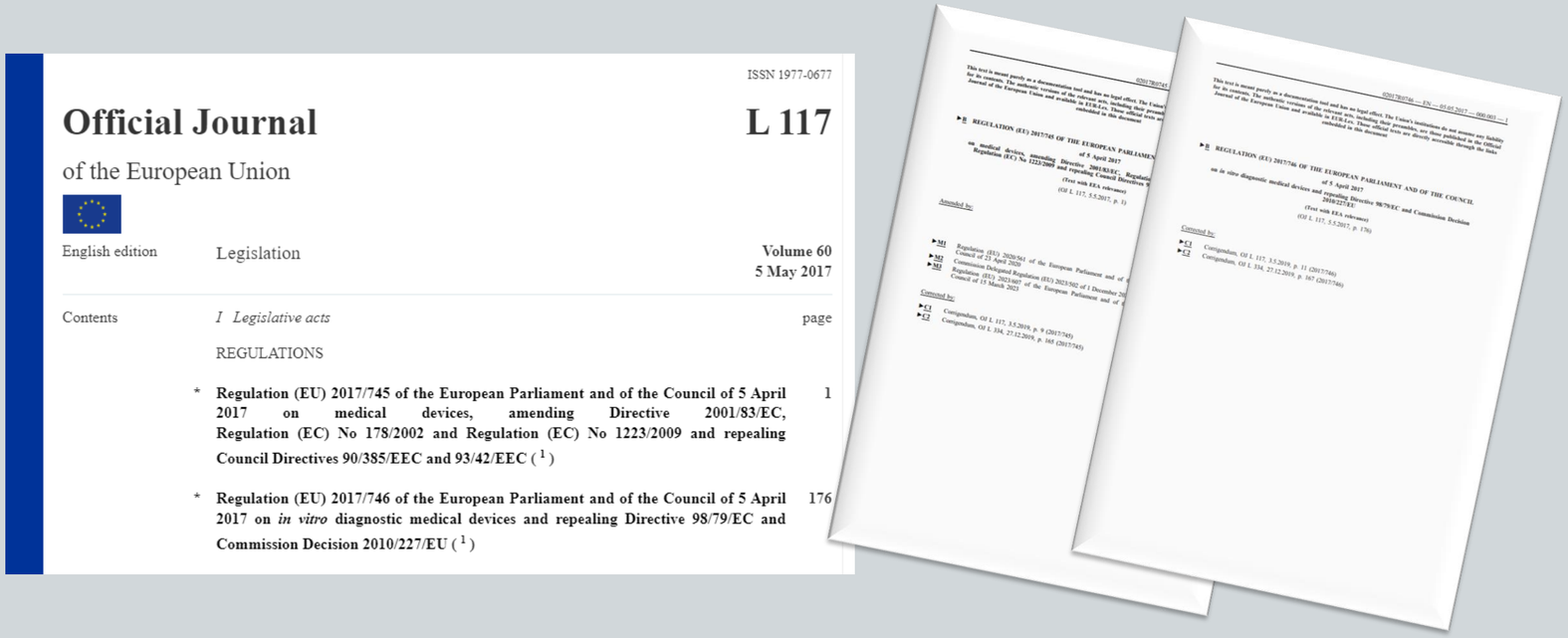
Regulatory Framework

Regulation (EU) 2017/745 on medical devices (MDR)

- applicable since 26 May 2021, plus extra transitional period for ‚legacy devices‘

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

- applicable since 26 May 2022, plus extra transitional period for ‚legacy devices‘



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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

Definitions of a medical device & IVD

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.*

MDR Article 2 (1)

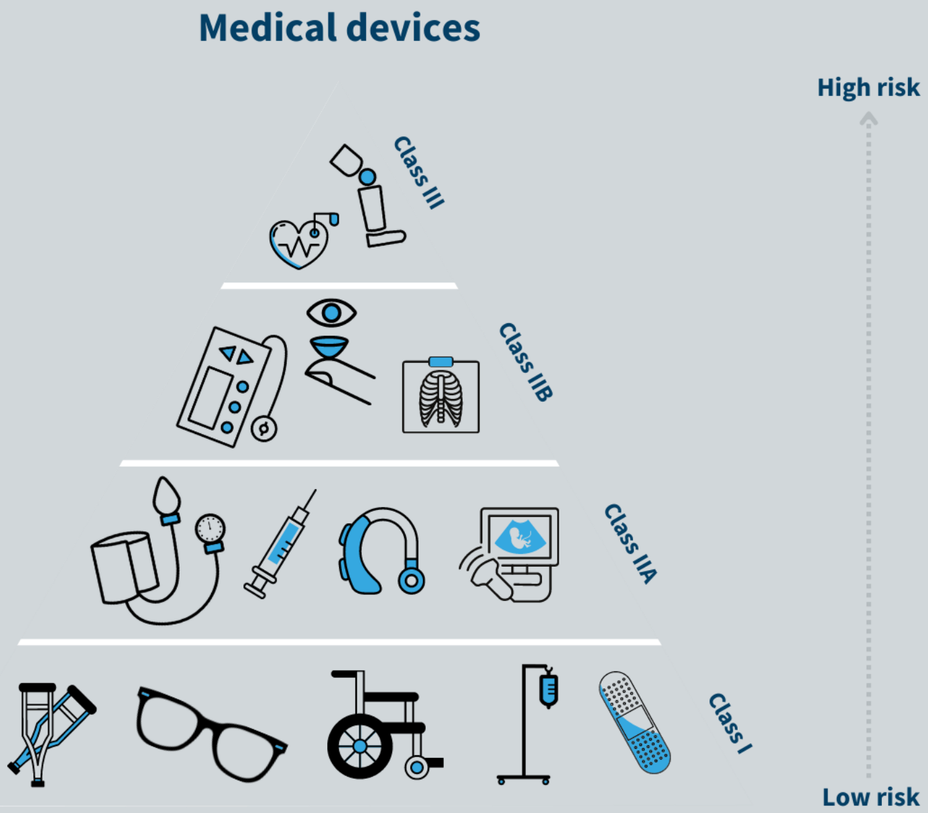
any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue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

- *concerning a physiological or pathological process or state;*
- *concerning congenital physical or mental impairments;*
- *concerning the predisposition to a medical condition or a disease;*
- *to determine the safety and compatibility with potential recipients;*
- *to predict treatment response or reactions;*
- *to define or monitoring therapeutic measures.*

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

IVDR Article 2 (2)

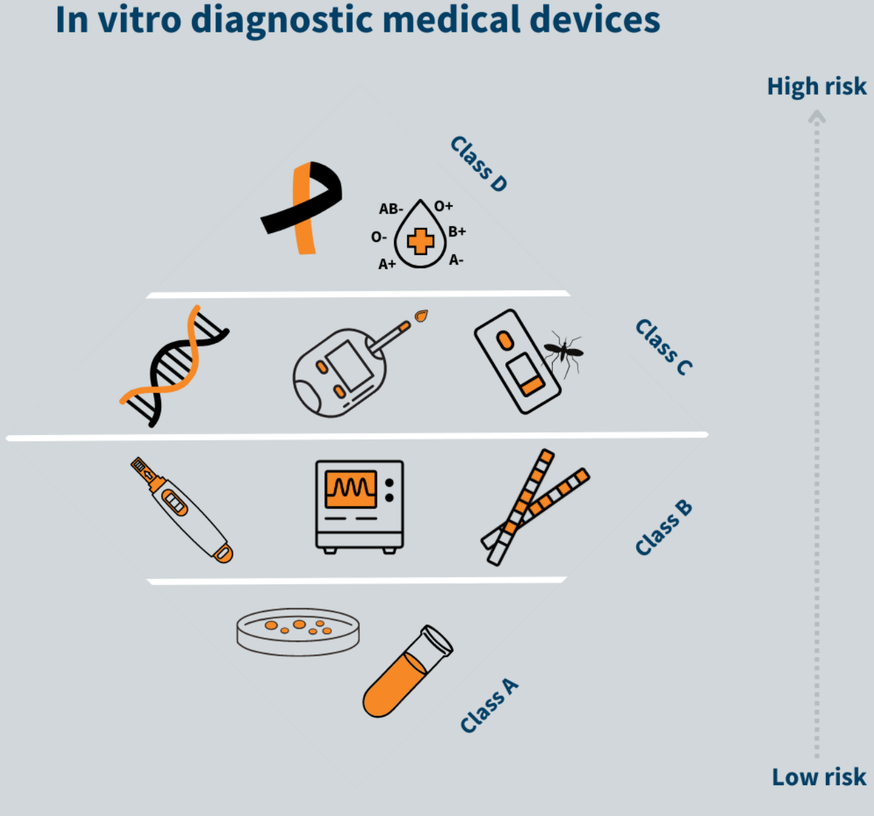
Classification of products



The classification reflects the risk associated with:

- using the product,
- the vulnerability of the body parts on which the device is used,
- and for how long the device is to be used.

The manufacturer is responsible for the classification of devices in accordance with the applicable legislation.
For products classified higher than class I/class A, the classification of products is carried out in collaboration with a notified body.



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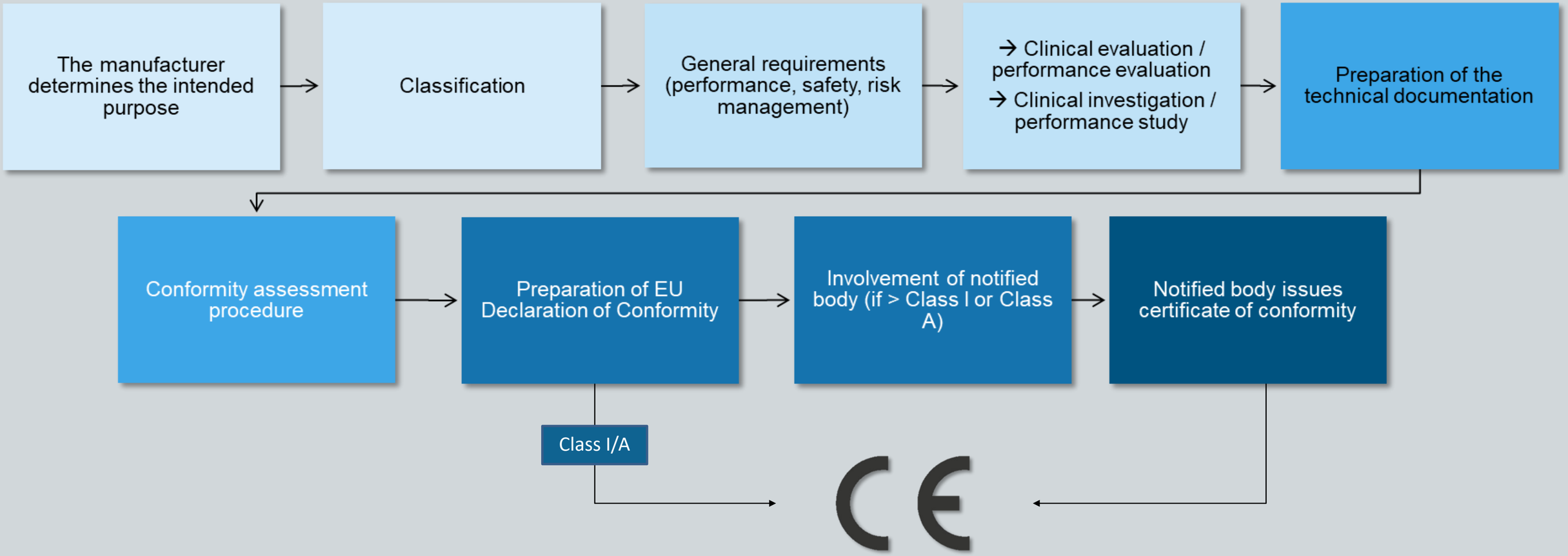
The road to CE marking is an on-going process



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‘putting into service’

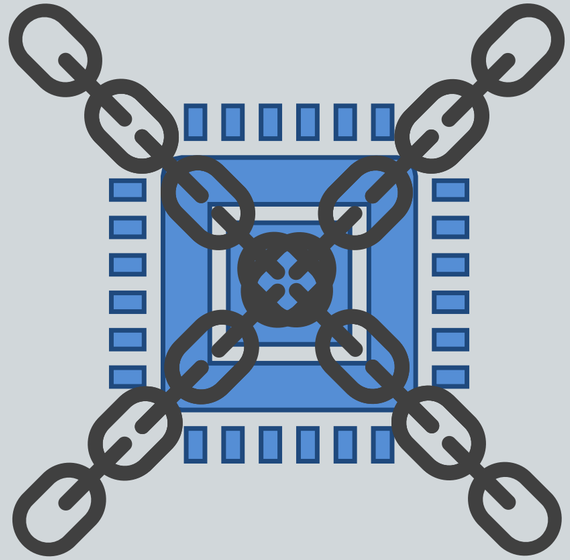
“the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose” – MDR article 2.29

“the supply of an AI system for first use directly to the deployer or for own use in the Union for its intended purpose” – AIA article 3.11

“Putting into service takes place at the moment of first use within the Union by the end user for the purposes for which it was intended” – The Blue Guide 2022, page 23

Current regulation of AI/ML

- Neither AI or ML is specified in regulations
  - Regulated as Medical Device Software (MDSW)
- MDSW is generally class IIa or higher
  - Requires third party assessment
- The requirements for notification on significant changes limits post-market learning



"Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment…" **- Annex IX, 4.10 MDR**

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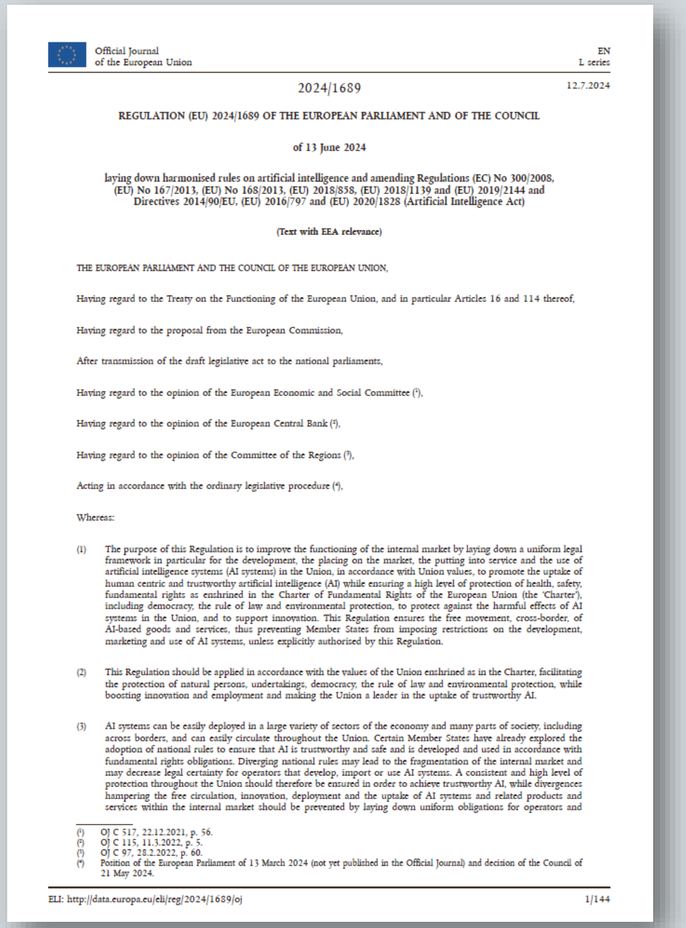
The EU AI Act - Scope



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REGULATION (EU) 2024/1689 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the European Central Bank (2),

Having regard to the opinion of the Committee of the Regions (3),

Acting in accordance with the ordinary legislative procedure (4),

Whereas:

(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union, in accordance with Union values, to promote the uptake of human centric and trustworthy artificial intelligence (AI) while ensuring a high level of protection of health, safety, fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter'), including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation. This Regulation ensures the free movement, cross-border, of AI-based goods and services, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

(2) This Regulation should be applied in accordance with the values of the Union enshrined as in the Charter, facilitating the protection of natural persons, undertakings, democracy, the rule of law and environmental protection, while boosting innovation and employment and making the Union a leader in the uptake of trustworthy AI.

(3) AI systems can be easily deployed in a large variety of sectors of the economy and many parts of society, including across borders, and can easily circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that AI is trustworthy and safe and is developed and used in accordance with fundamental rights obligations. Diverging national rules may lead to the fragmentation of the internal market and may decrease legal certainty for operators that develop, import or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured in order to achieve trustworthy AI, while divergences hampering the free circulation, innovation, deployment and the uptake of AI systems and related products and services within the internal market should be prevented by laying down uniform obligations for operators and

(1) OJ C 517, 22.12.2021, p. 56.
(2) OJ C 115, 11.3.2022, p. 5.
(3) OJ C 97, 28.2.2022, p. 60.
(4) Position of the European Parliament of 13 March 2024 (not yet published in the Official Journal) and decision of the Council of 21 May 2024.

ELI: http://data.europa.eu/eli/reg/2024/1689/oj — 1/144

- Posted in the Official Journey on the 12th July 2024
- Affecting all Medical device AI systems from the 2nd August 2027
- Regulates primarily ”High-risk” devices for our sector
  - High-risk are AI systems requiring certification under harmonized legislation (MDR & IVDR)
- Relies heavily on standards, which hopefully are internationally adopted

Definition

‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;

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High-risk AI exemptions (so far)

"With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met" – MDR, Article 5.5

"Irrespective of whether an AI system is placed on the market or ***put into service*** *independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:*

(a)
the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the ***Union harmonisation legislation listed in Annex I****;*

(b)
the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, ***is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.****"*

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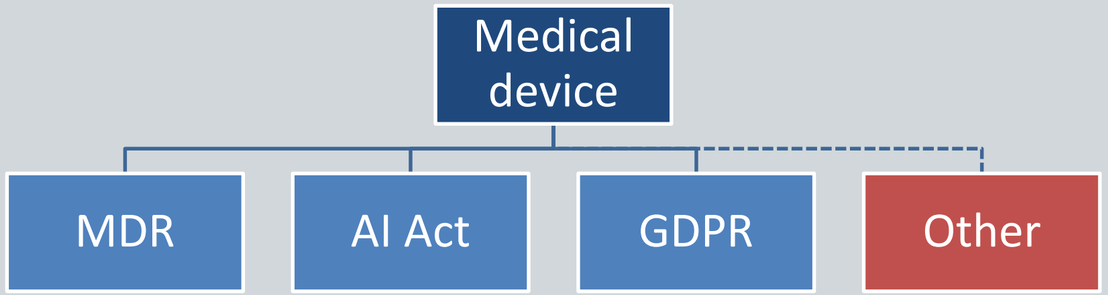
High-risk AI exemptions (so far)

“This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and development.” – AIA, Article 2.6

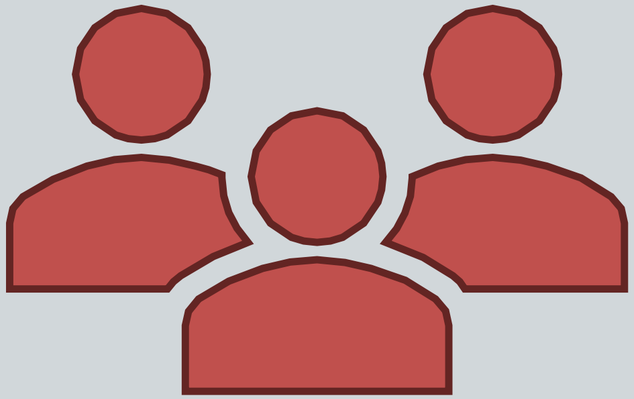
*“This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or **put into service**. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.” – AIA, Article 2.8*

The EU AI Act – Horizontal approach

- Adds additional requirements for sectorial legislation
- MDR & IVDR primarily regulates Medical devices
  - AI Act regulates the addition of AI
- GDPR (General Data Protection Regulation) regulates the data
  - Certain use-cases to avoid bias allows for exceptional data treatment



The EU AI Act – New requirements



- Transparency obligations
  - Information on AI interaction
  - Description of data sets
- Fundamental rights
  - Impact assessment
  - Infringement
- Post-market log generation for use and changes
- Human oversight features

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The EU AI Act – New posibilites

- ”Unlocked” learning of AI systems
- Locally adapted devices at different levels:
  - Regional
  - Hospital
  - Personal
- Transfer learning from existing models
  - Upstream providers role in compliance

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