Artificial Intelligence and Medical Devices: Opportunities and Challenges from a regulatory perspective

Folker Spitzenberger, PhD, M.D.R.A.
Department of Applied Natural Sciences
Centre for Regulatory Affairs in Biomedical Sciences
Technische Hochschule Lübeck University of Applied Sciences
Fraunhofer Einrichtung für Individualisierte und zellbasierte Medizintechnik - IMTE

27th DGRA Annual Congress, May 8th - 9th, 2025 in Bonn

AGENDA

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- Examples of AI applications for medical devices
- Opportunities and challenges
  - NLF regulatory approach
  - Definitions
  - Risk categorization/classification
  - Conformity assessment procedure
  - Interfaces: QMS, RMS & TD
  - Change management
  - Standardization in the field of AI
- “Take Home”

Examples of AI applications …

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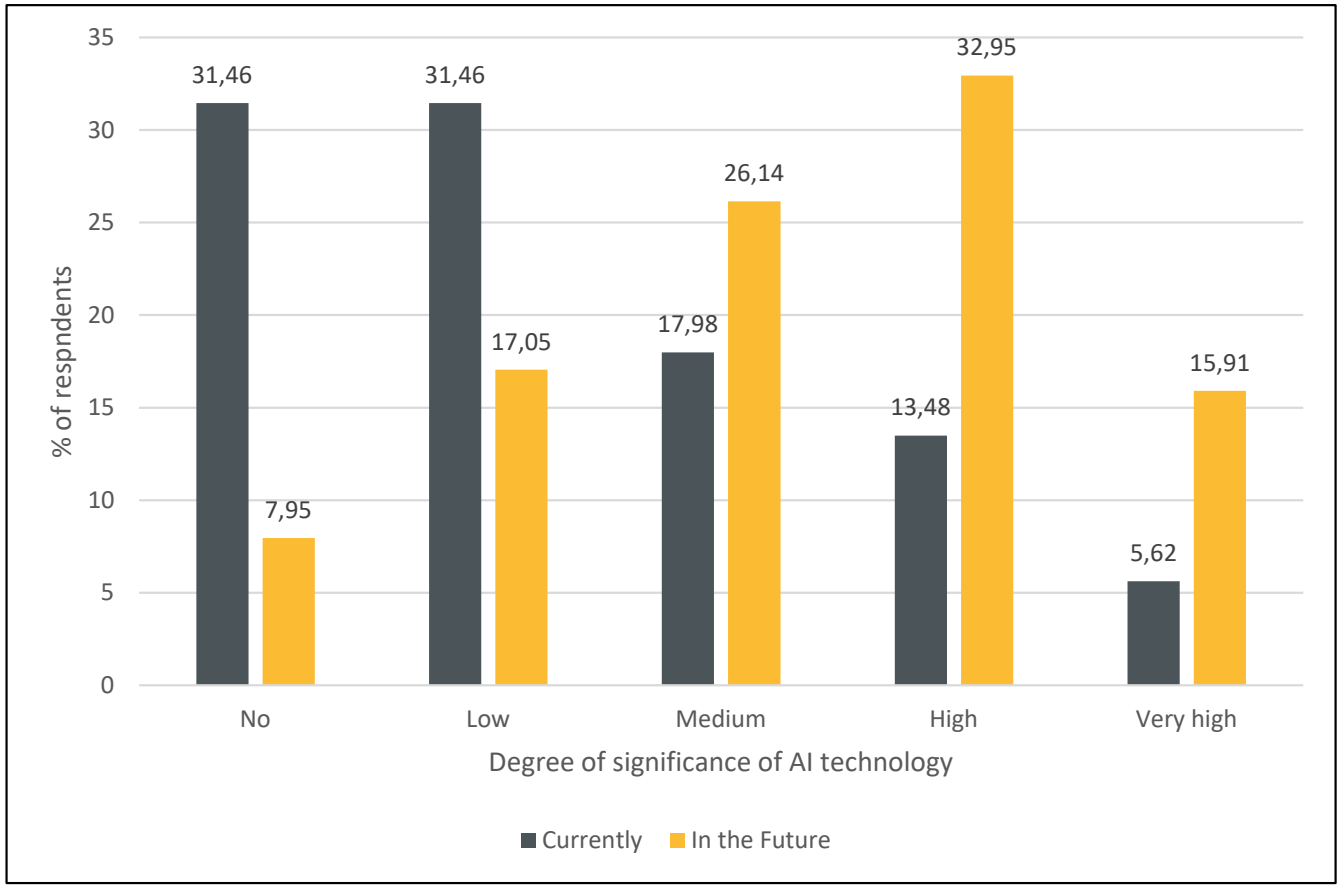
„What is the current and future significance of AI technology for the development, production and/or use of IVD products in your organization?“



Source: *Bajorat et al. 2021: KI-basierte In-vitro-Diagnostika vor dem Hintergrund der IVDR und dem europäischen KI-Konzept; MPJ – Medizinproduktejournal, 28. Jahrgang, Heft 4, 2021*

Examples of AI applications …

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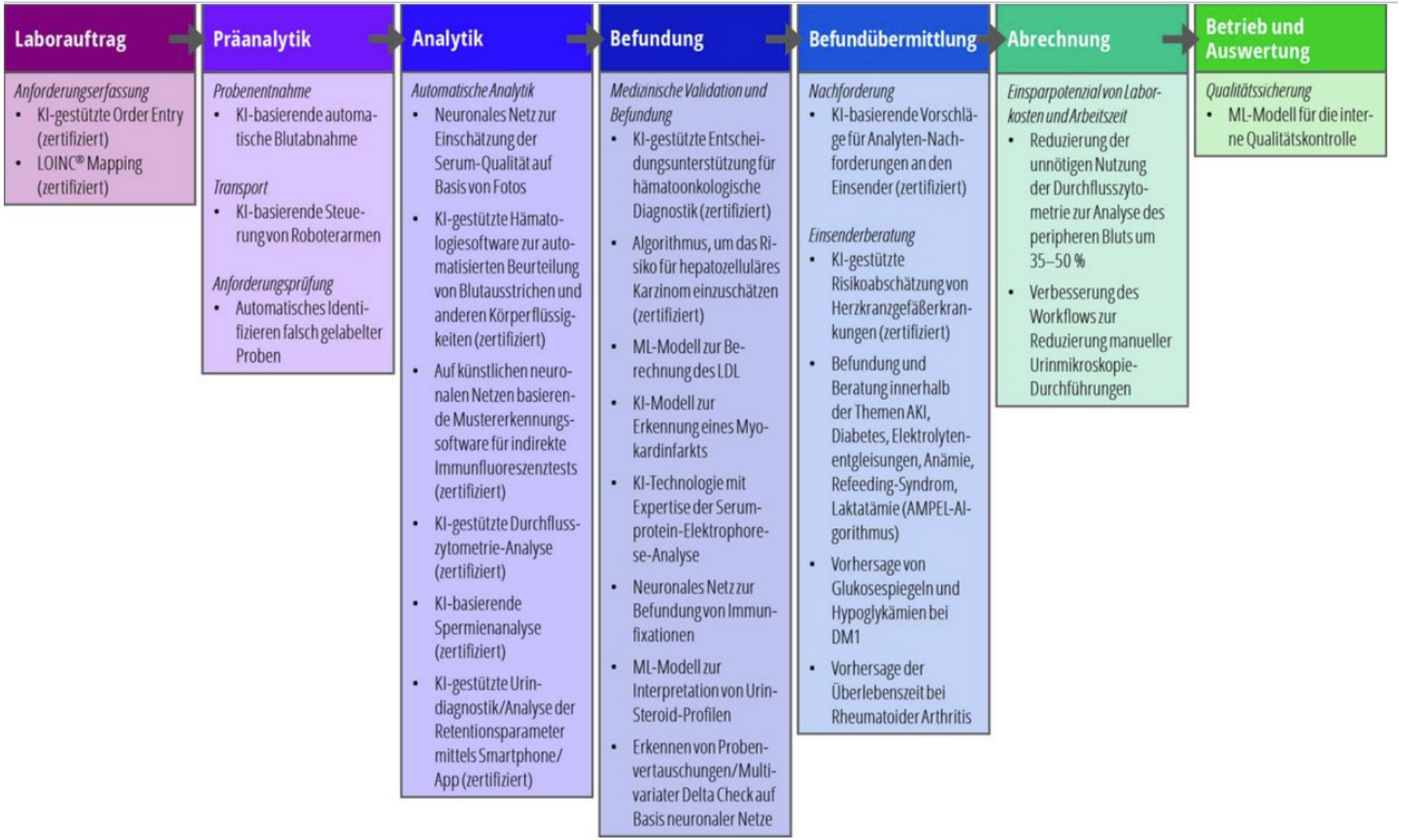

Source: *Mundorf & Ludwig 2024: Künstliche Intelligenz im medizinischen Labor: KI – aktueller Stand und Zukunftsperspektiven; Trillium Diagnostik, TD Heft 1/2024; DOI: https://doi.org/10.47184/td.2024.01.08*

Examples of AI applications …

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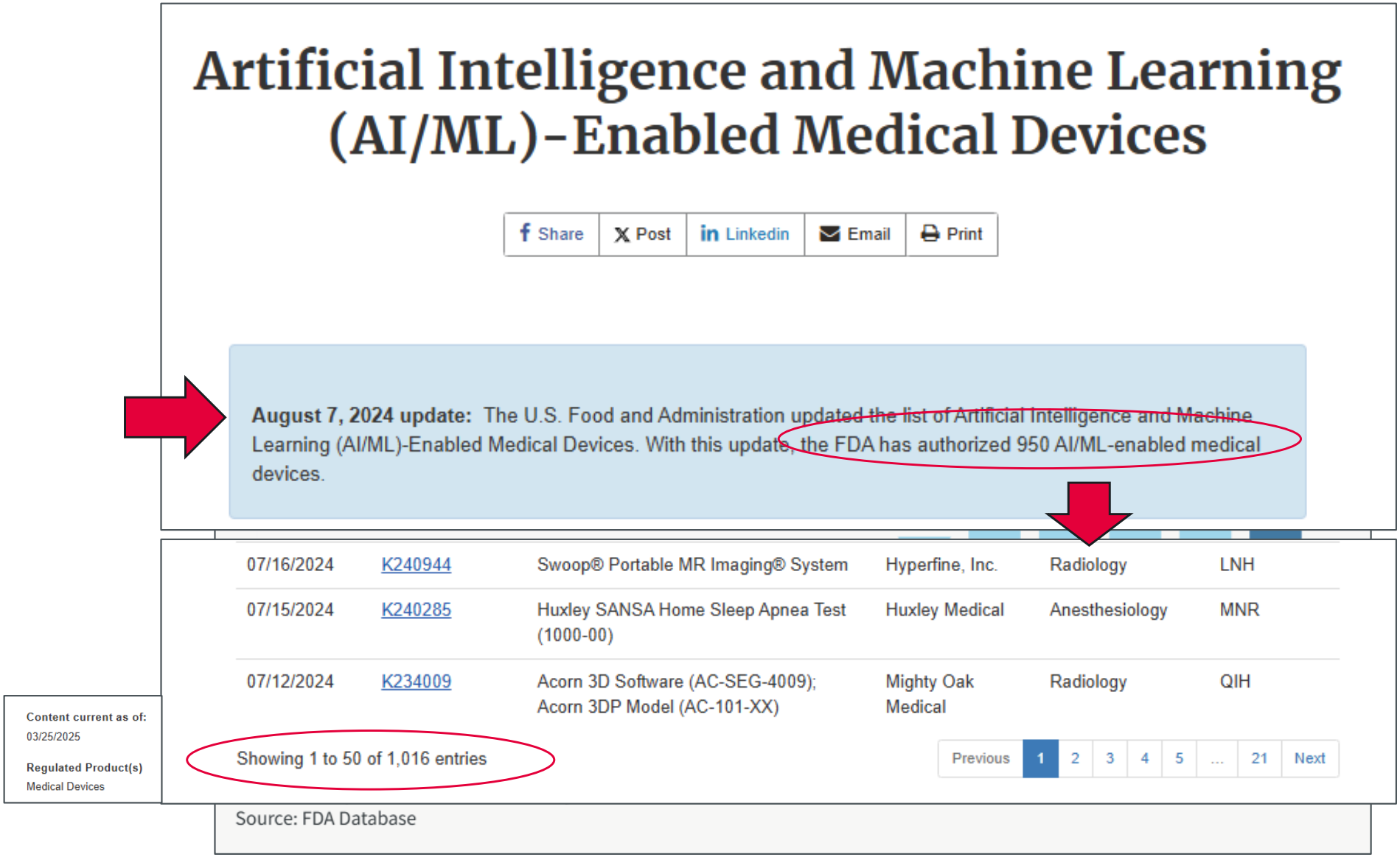

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices

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August 7, 2024 update: The U.S. Food and Administration updated the list of Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. With this update, the FDA has authorized 950 AI/ML-enabled medical devices.

07/16/2024	K240944	Swoop® Portable MR Imaging® System	Hyperfine, Inc.	Radiology	LNH
07/15/2024	K240285	Huxley SANSA Home Sleep Apnea Test (1000-00)	Huxley Medical	Anesthesiology	MNR
07/12/2024	K234009	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)	Mighty Oak Medical	Radiology	QIH

Showing 1 to 50 of 1,016 entries

Previous 1 2 3 4 5 … 21 Next

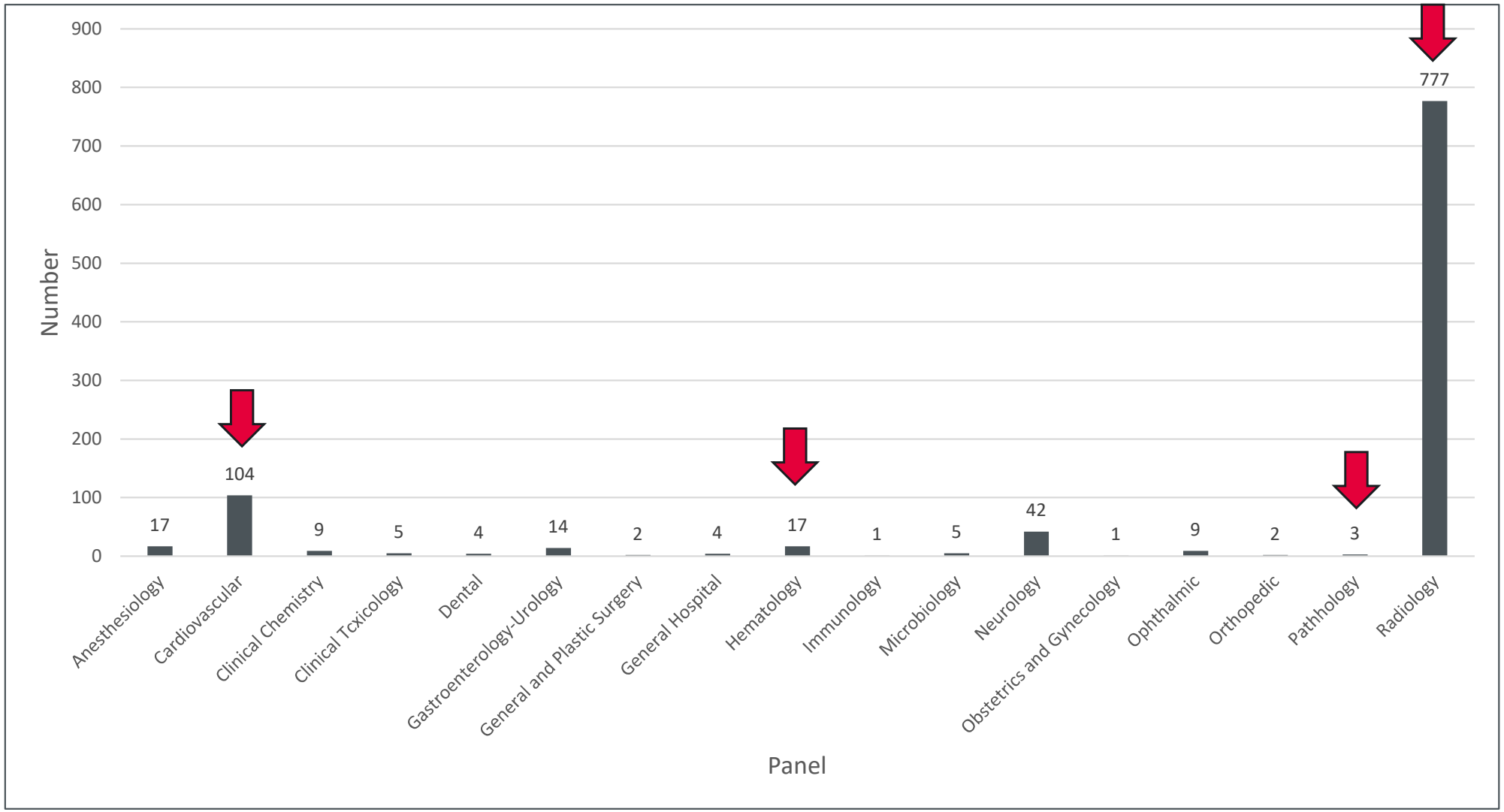
Content current as of: 03/25/2025

Regulated Product(s) Medical Devices

Source: FDA Database

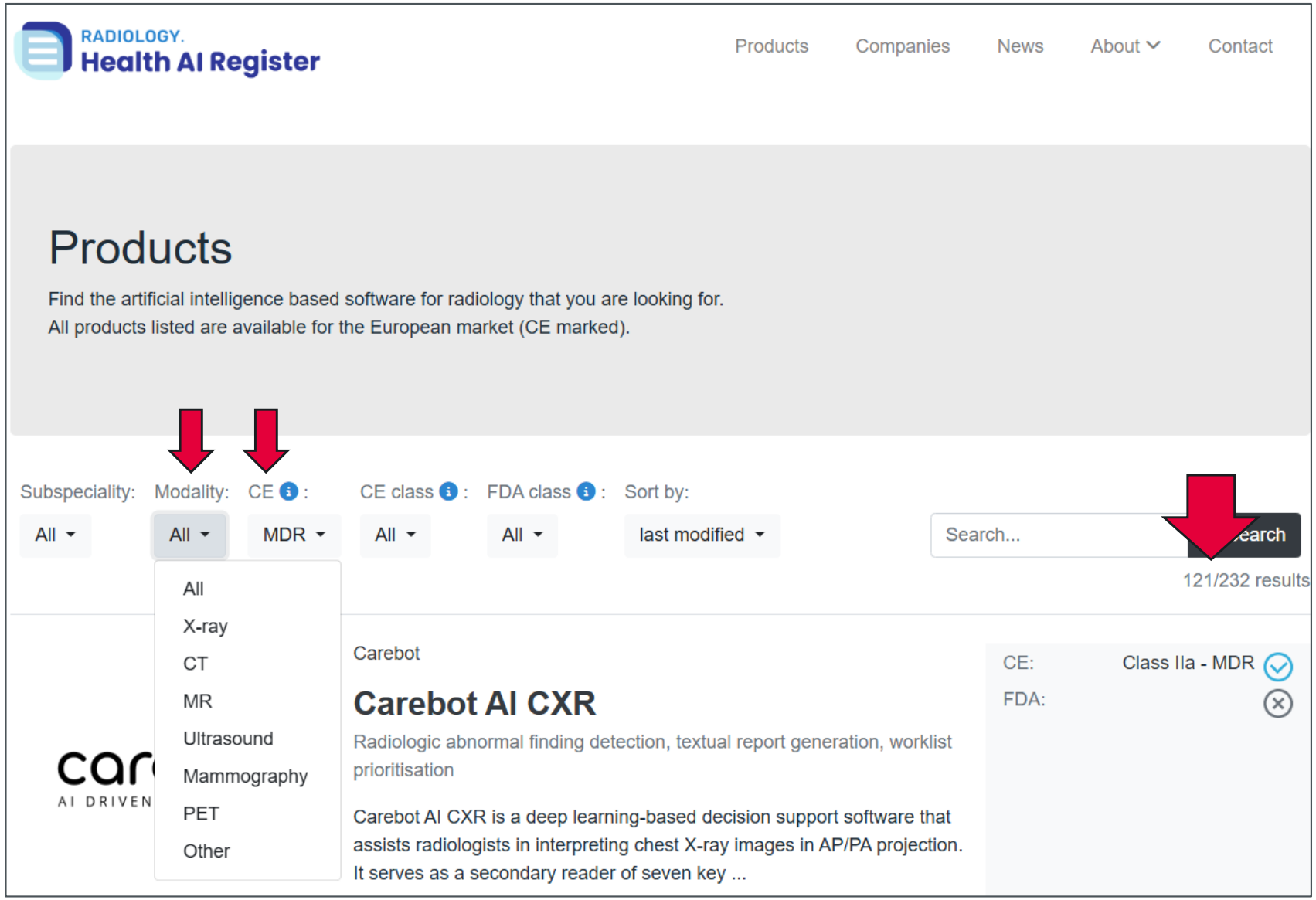
Source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Examples of AI applications …



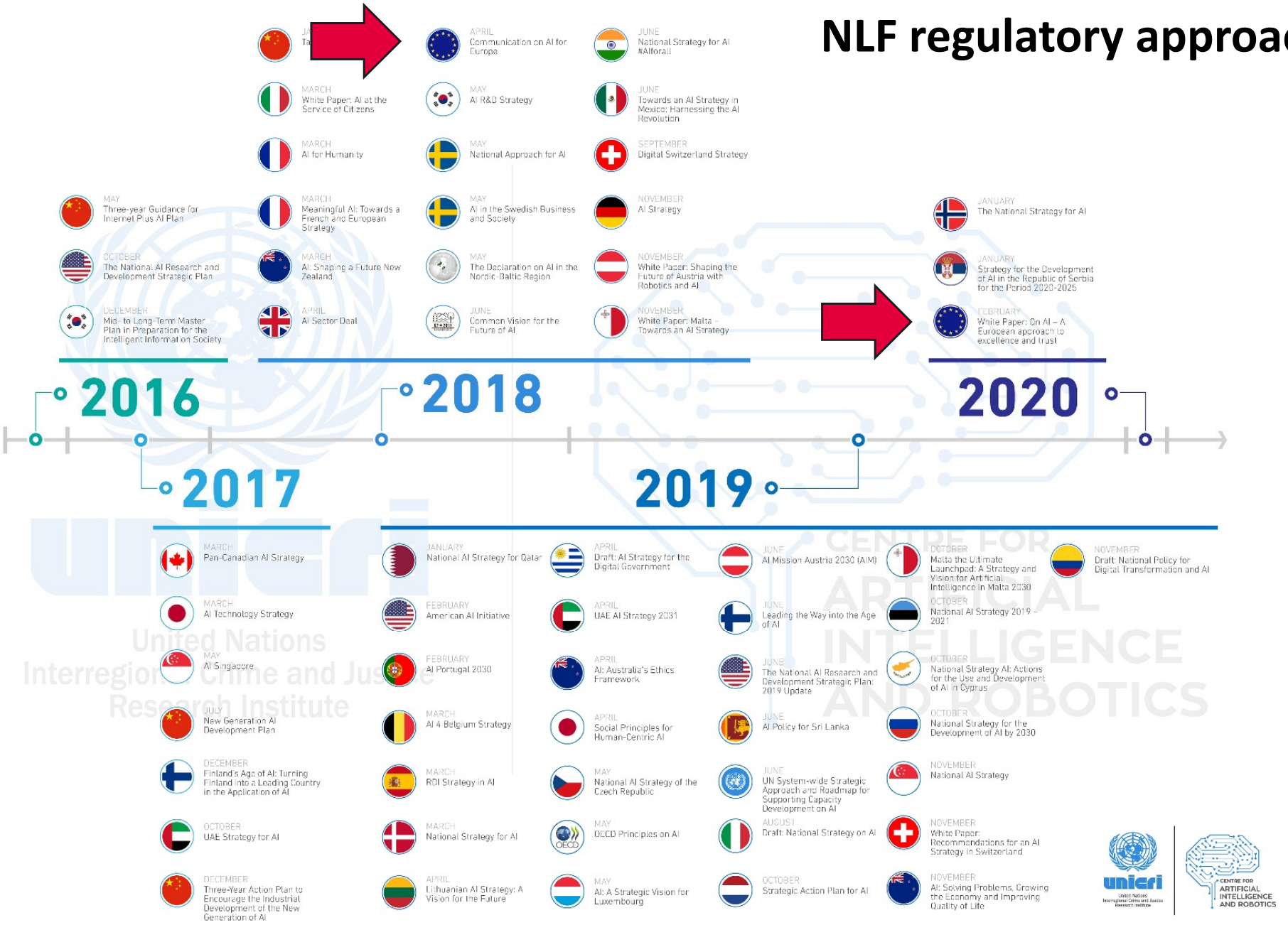
[Source: U.S. FDA – Database of Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices in the USA (Current as of 25.03.2025]

Examples of AI applications …



https://healthairegister.com/products/

NLF regulatory approach



Timeline of AI strategic documents, effective as of April 2020, Source: "UNICRI :: United Nations Interregional Crime and Justice Research Institute". www.unicri.it ., 10-09-2021

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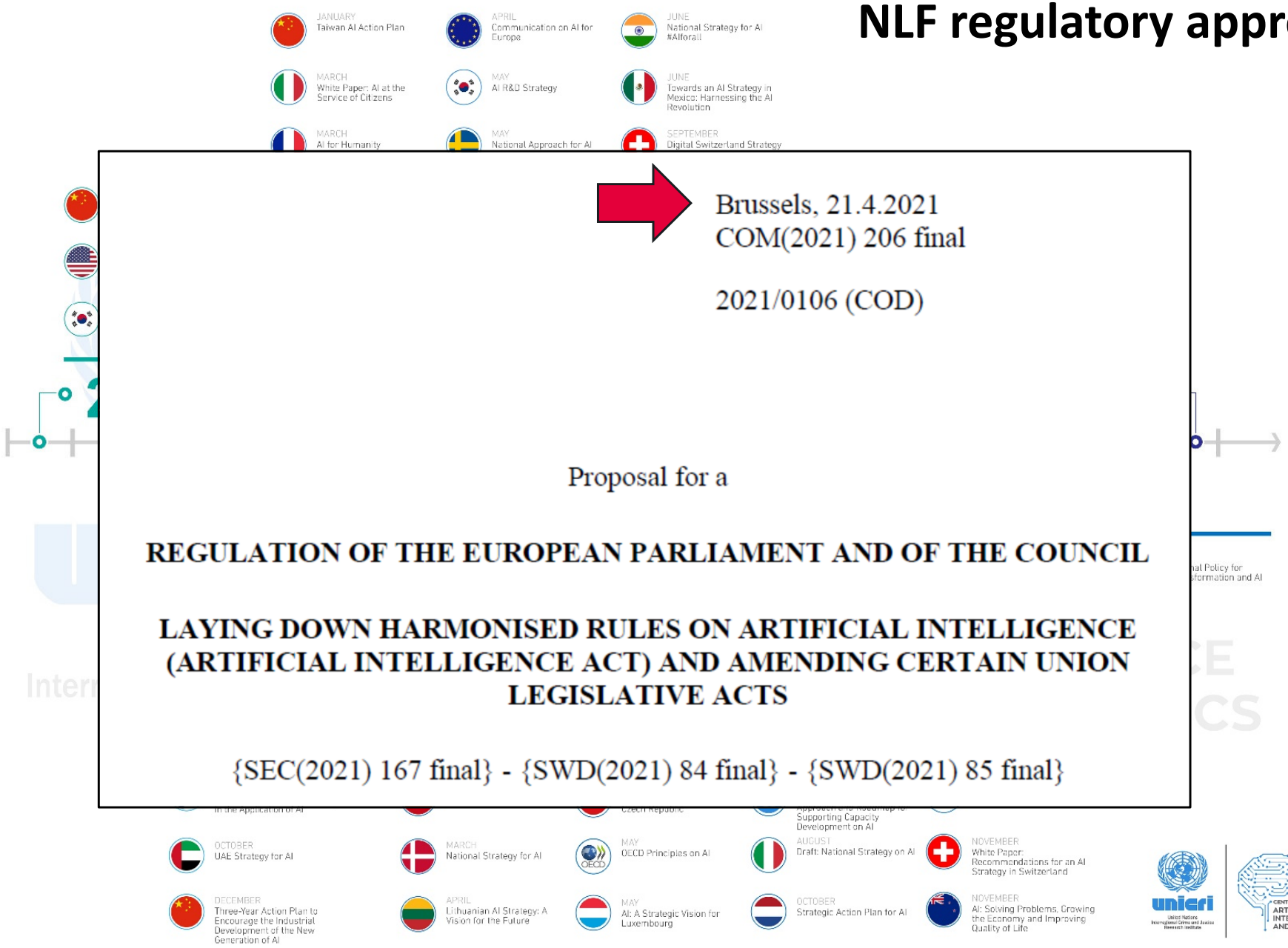
NLF regulatory approach



Timeline of AI strategic documents, effective as of April 2020, Source: "UNICRI :: United Nations Interregional Crime and Justice Research Institute". www.unicri.it ., 10-09-2021

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NLF regulatory approach

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2024/1689

12.7.2024

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)

NLF regulatory approach

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CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter`

1. The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

NLF regulatory approach

TECHNISCHE HOCHSCHULE LÜBECK

CHAPTER I

GENERAL PROVISIONS

… However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable **regulatory framework for medical devices** which **ensures a high level of safety and health whilst supporting innovation**.

This Regulation aims to ensure the **smooth functioning of the internal market** as regards medical devices, taking as a base a **high level of protection of health for patients and users**, ... At the same time, this Regulation sets **high standards of quality and safety for medical devices** in order to meet common safety concerns as regards such products. …

Excerpt from the **Recitals No. 1 and 2** of the **Regulation (EU) 2017/745** of the European Parliament and of the Council 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

NLF regulatory approach

Option 3+: **Horizontal EU legislative instrument** following a proportionate **risk-based approach plus codes of conduct for non-high-risk AI systems**:

"A **regulatory framework for high-risk AI systems only**, with **the possibility for all providers of non-high-risk AI systems to follow a code of conduct**. The requirements will concern data, documentation and traceability, provision of information and transparency, human oversight and robustness and accuracy and would be mandatory for high-risk AI systems. Companies that introduced codes of conduct for other AI systems would do so voluntarily."

"**AI systems** intended to be used as safety components of products that are **regulated under the New Legislative Framework legislation** (e.g. machinery, toys, medical devices, etc.) will **be subject to the same ex-ante and ex-post compliance and enforcement mechanisms** of the products of which they are a component. The key difference is that the ex-ante and ex-post mechanisms will ensure compliance **not only with the requirements established by sectorial legislation, but also with the requirements established by this regulation**."

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS, 2021/0106 (COD)

NLF regulatory approach

Option 3+: **Horizontal EU legislative instrument** following a proportionate **risk-based**

The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking. — The CE marking is affixed on products that will be placed on the EEA and Turkish market.

under the New Legislative Framework legislation (e.g. machinery, toys, medical devices, etc.) will **be subject to the same ex-ante and ex-post compliance and enforcement mechanisms** of the products of which they are a component. The key difference is that the ex-ante and ex-post mechanisms will ensure compliance **not only with the requirements established by sectorial legislation, but also with the requirements established by this regulation**."

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS, 2021/0106 (COD)

Definitions

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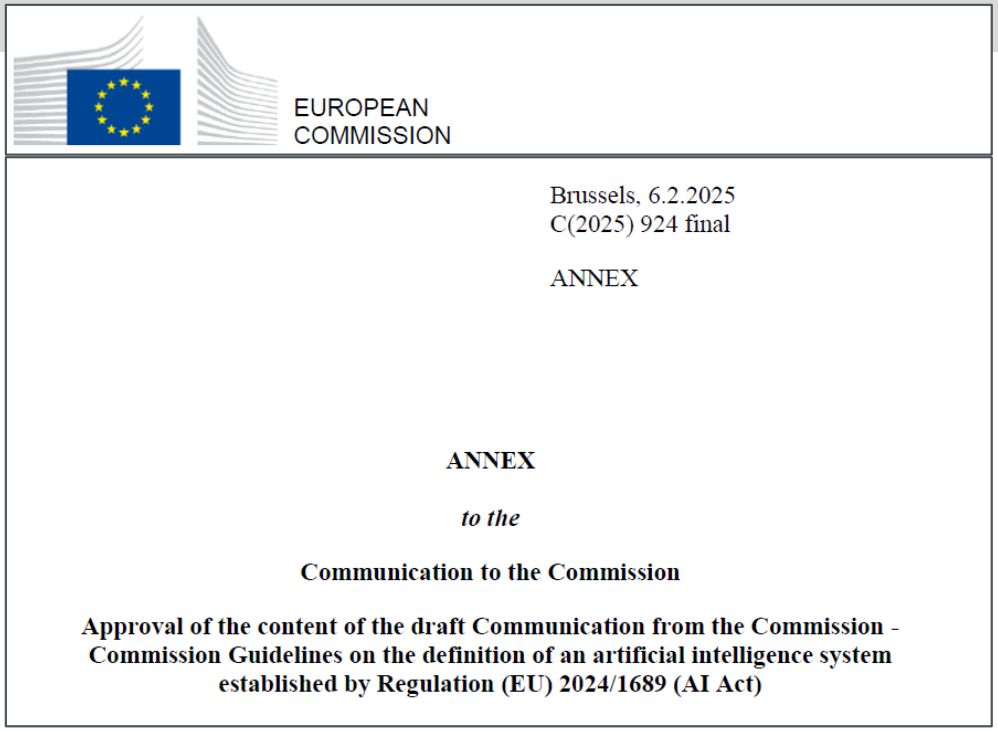
Definition „AI system“ (Art. 3 (1), AI Act)

‘**AI system’** means a machine-based system (1) that is designed to operate with varying levels of autonomy (2) and that may exhibit adaptiveness (3) after deployment, and that, for explicit or implicit objectives (4), infers (5), from the input it receives, how to generate outputs such as predictions, content (6), recommendations, or decisions that can influence (7) physical or virtual environments;



EUROPEAN COMMISSION

Brussels, 6.2.2025
C(2025) 924 final

ANNEX

ANNEX

to the

Communication to the Commission

Approval of the content of the draft Communication from the Commission - Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)

https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application

Definitions

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Definition „safety component“ (Art. 3 (14), AI Act)

‘safety component’ means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;

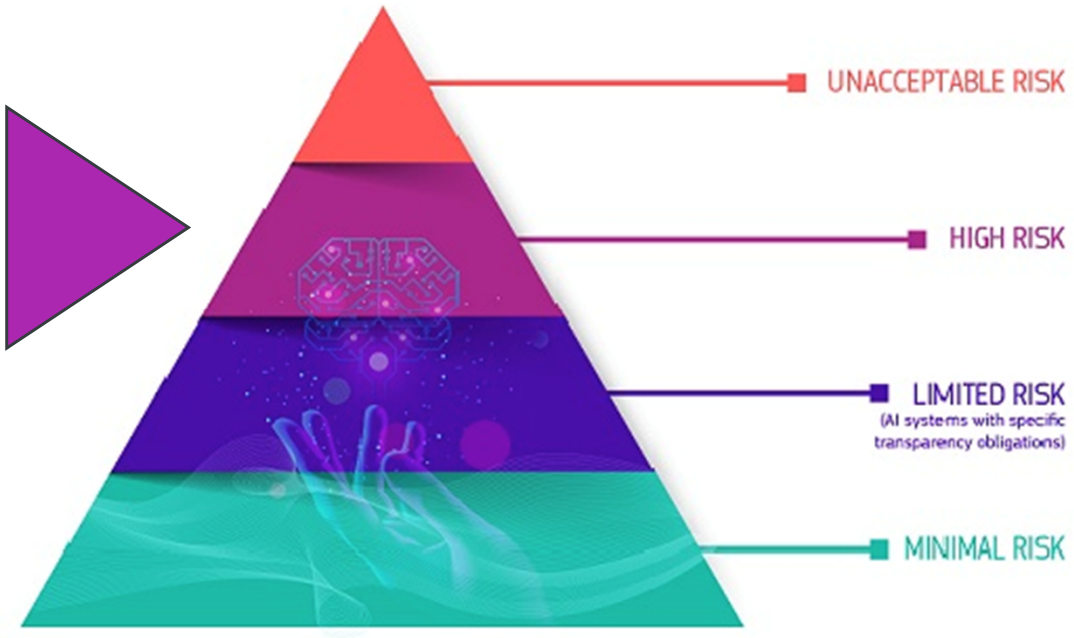
Definition „substantial modification“ (Art. 3 (23), AI Act)

‘substantial modification’ means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed;

AI Act – Risk categorization

(1) … 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. …
(2) **AI systems referred to in Annex III shall be considered to be high-risk** …

AI Act, Article 6 (1), (2), in extracts



Source: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

AI Act – Risk categorization

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ANNEX I

List of Union harmonisation legislation

Section A. List of Union harmonisation legislation based on the New Legislative Framework

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. 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 (OJ L 117, 5.5.2017, p. 1);

12. 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 (OJ L 117, 5.5.2017, p. 176).

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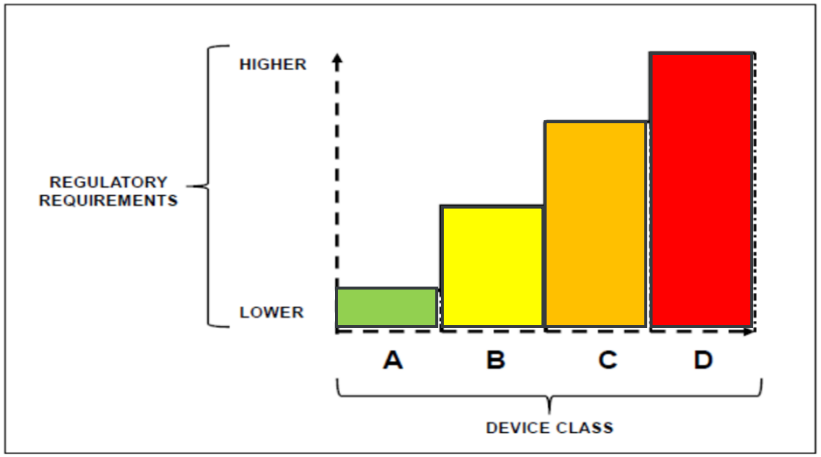
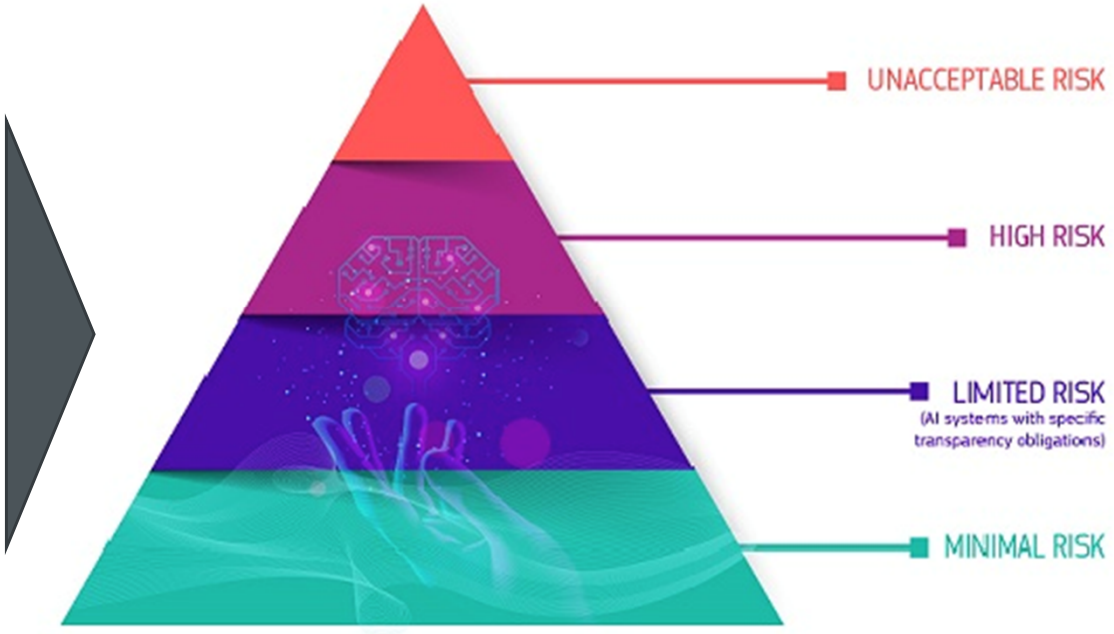
AI Act – Risk categorization

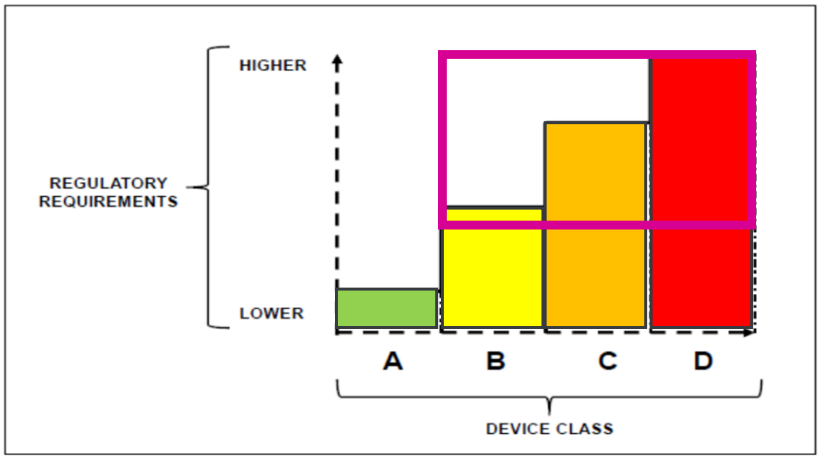


Source: WHO Global Model Regulatory Framework for Medical Devices including IVD Medical Devices (May 2017)

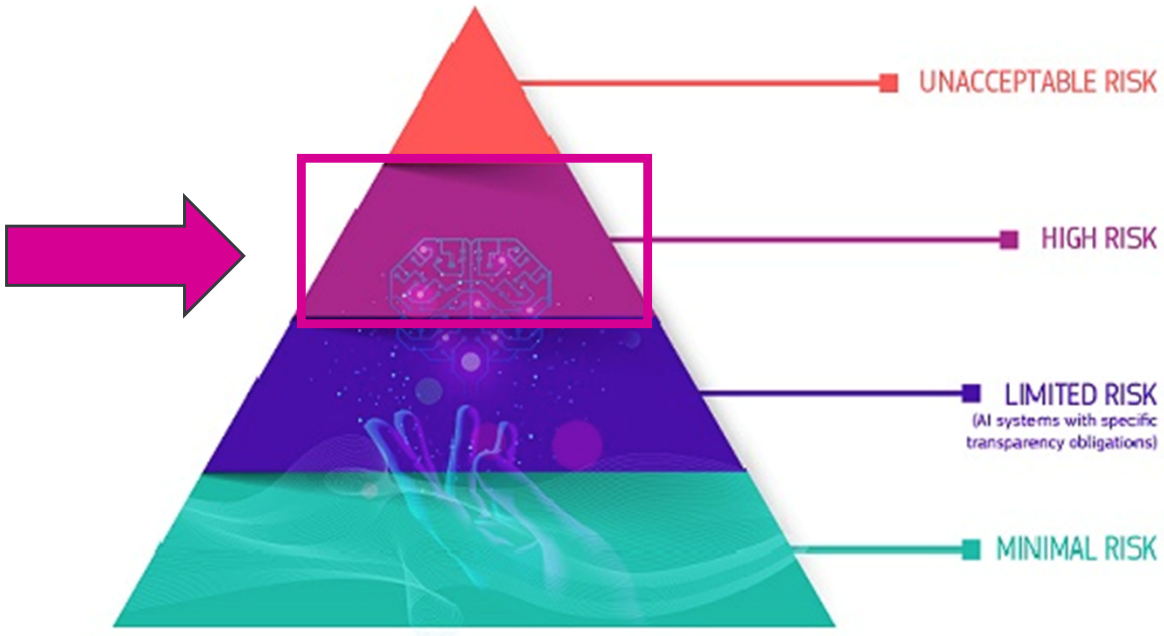


Source: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

AI Act – Risk categorization



Source: WHO Global Model Regulatory Framework for Medical Devices including IVD Medical Devices (May 2017)



Source: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

"The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered to be high-risk under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is, in particular, the case for Regulations (EU) 2017/745 and (EU) 2017/746, where a third-party conformity assessment is provided for medium-risk and high-risk products."
Recital 51, AI Act

Conformity assessment procedure (Art. 43)

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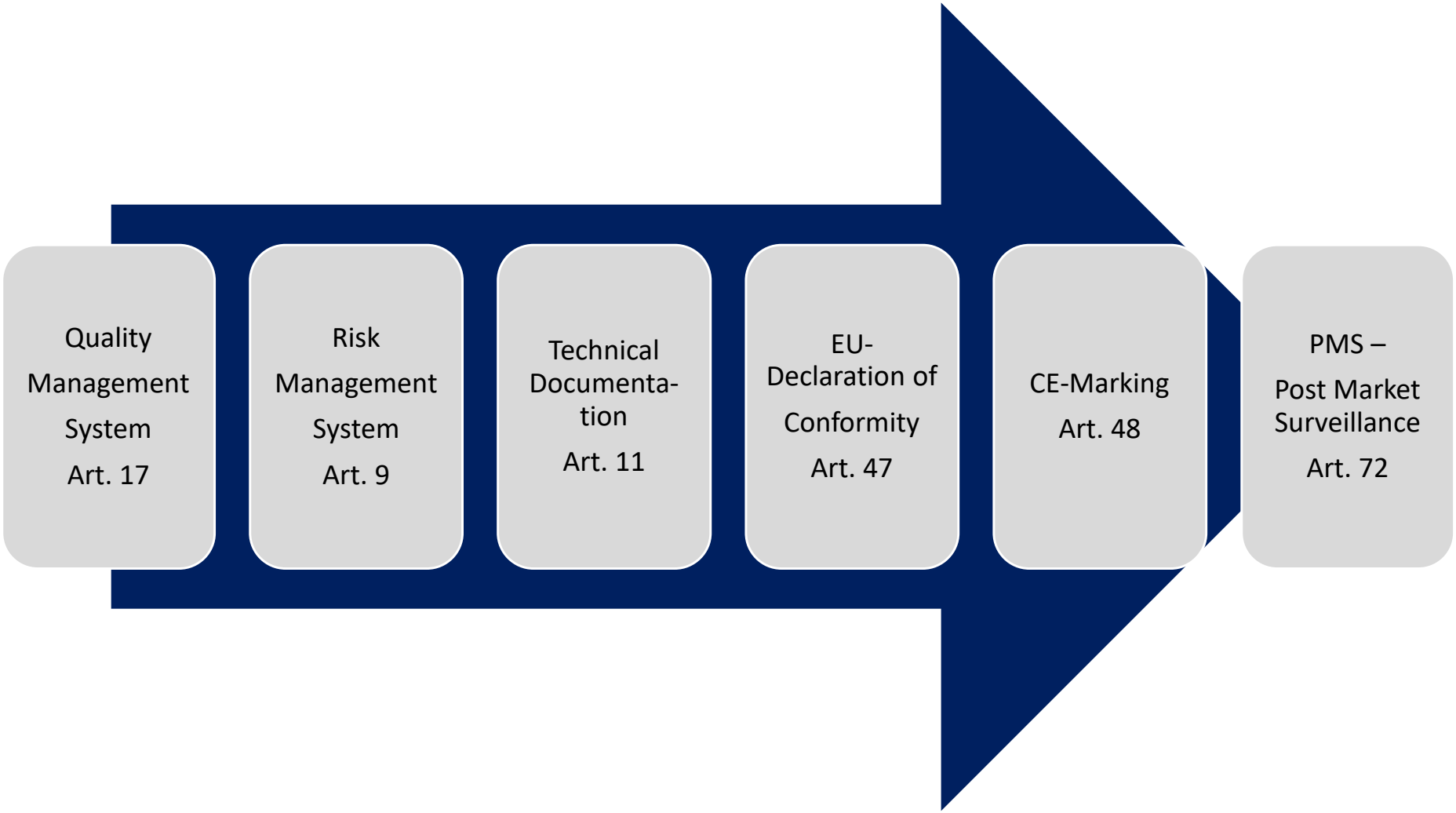
Basic elements of conformity assessment leading to CE marking



Conformity assessment procedure (Art. 43)

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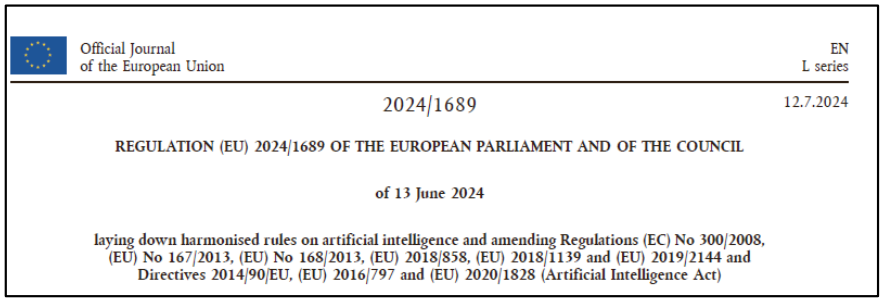
Additional elements of conformity assessment leading to CE marking

Interfaces: QMS, RMS & TD



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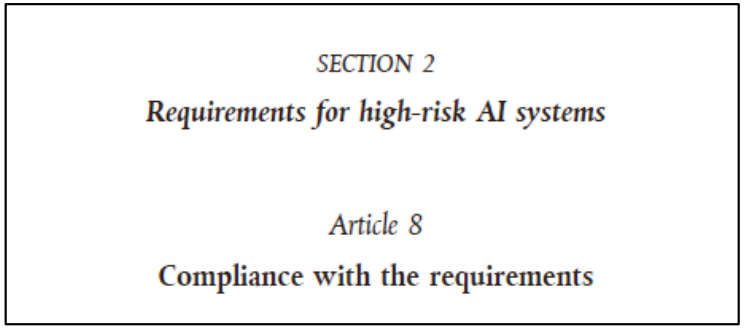


SECTION 2

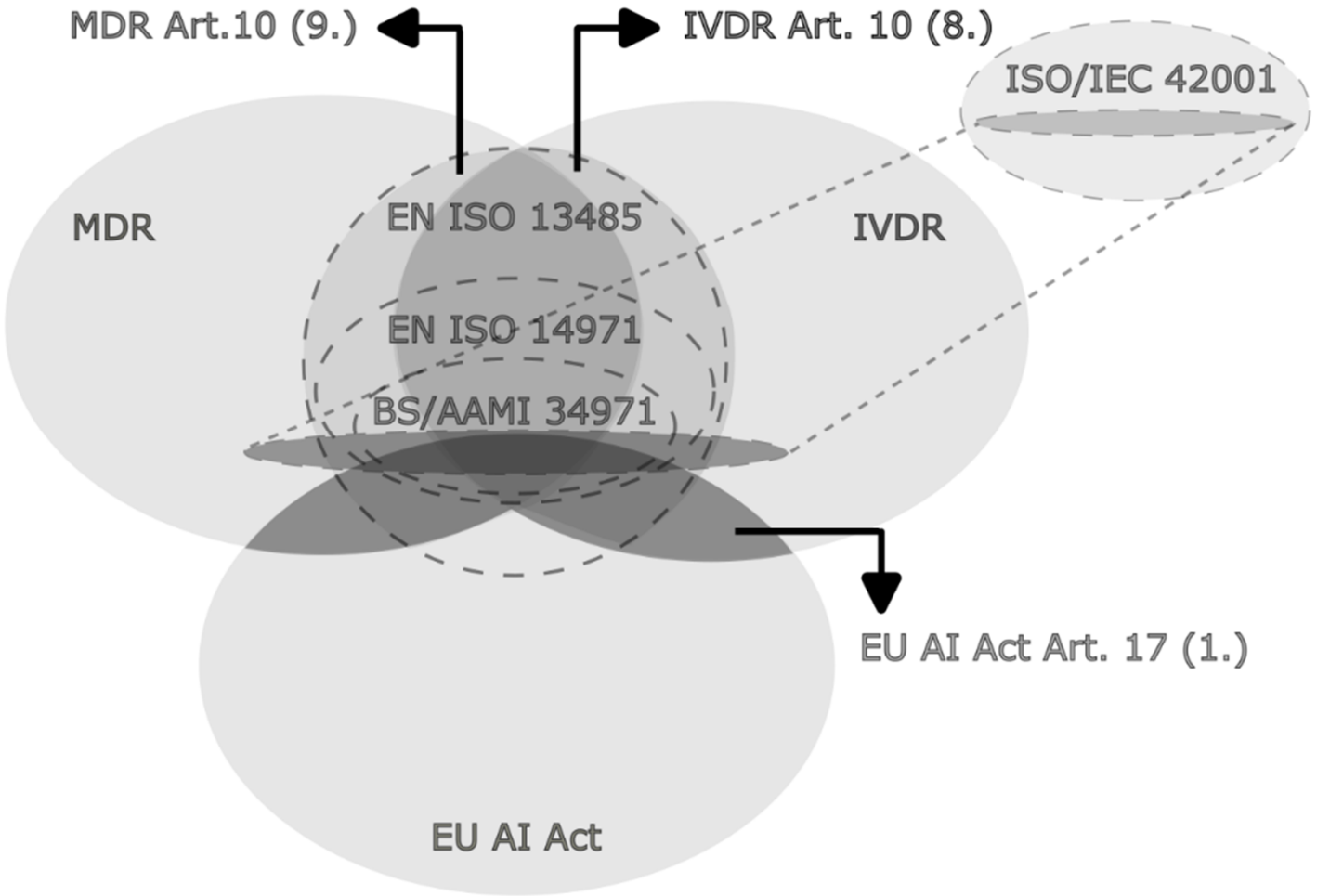
Requirements for high-risk AI systems

Article 8

Compliance with the requirements

(2) … In **ensuring the compliance of high-risk AI systems** referred to in paragraph 1 with the requirements set out in this Section, and in order to **ensure consistency**, **avoid duplication** and **minimise additional burdens**, **providers shall have a choice of integrating**, as appropriate, the necessary **testing and reporting processes**, **information** and **documentation** they provide with regard to their product **into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I**.

Interfaces: QMS, RMS & TD



Source: **Aykurt et al:** KI-basierte (IVD-)Medizinprodukte – Neue gesetzliche Anforderungen an das Qualitäts- und Risikomanagement im Zusammenspiel der MDR/IVDR und des EU AI Acts; in: Rethinking Quality – Wandel des Qualitätsmanagements durch Digitalisierung und Künstliche Intelligenz; Bericht zur GQW-Jahrestagung 2024 in Berlin, Springer Vieweg Verlag

Interfaces: QMS, RMS & TD

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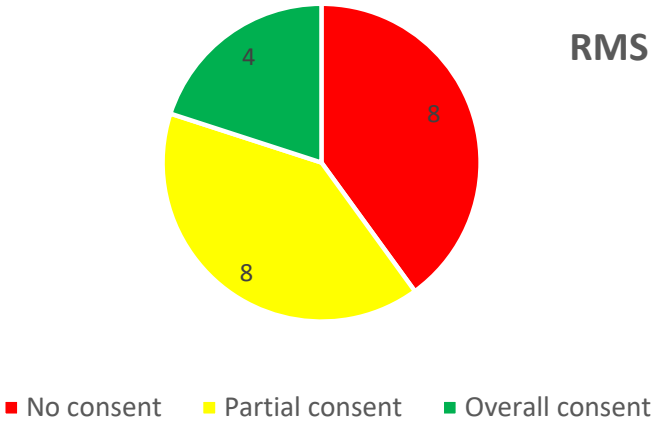
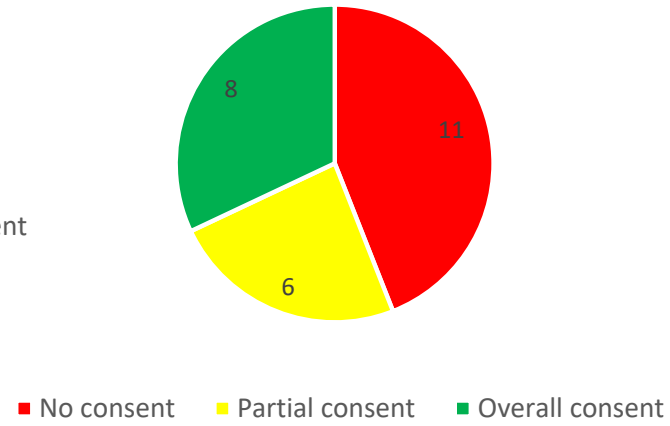
Comparison of the requirements for the quality management system, risk management system and technical documentation according to MDR and AIA

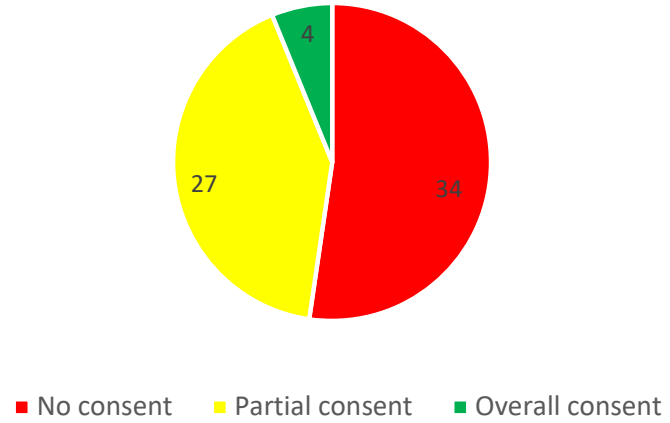
QMS [MDR, Art. 10 vs. AIA, Art. 17] - Comparison of 20 elements



RMS [MDR, Annex I, 2. - 5., 8. vs. AIA, Art. 9] - Comparison of 25 elements



TD [MDR, Annex II, III vs. AIA, Annex IV] - Comparison of 65 elements



Change management

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Rules-Based AI Systems	Data-Driven/Machine-Learning AI Systems	
	Locked Machine Learning Models	**Continuous Learning/Adaptive Models**
• Mimic human behavior-making decisions by applying static rules to arrive at predicable decisions.		
• Often visualized as a decision tree.	• Neither the internal algorithms nor system outputs change automatically.	• Utilize newly received data to test assumptions that underlie their operation in real-world use.
• May be originally developed based on a set of rules provided by human experts or can be based on training data.	• Further machine learning can be implemented through external approval, or in a stepwise manner.	• Programed to automatically modify internal algorithms and update external outputs in response to improvements being identified.
• The logic used to make decisions is usually clear and reproducible.		

Source: AAMI/BSI - Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance (2020)

Change management

TECHNISCHE HOCHSCHULE LÜBECK

Article 3 (23):
'substantial modification' means a **change to an AI system after its placing on the market** or putting into service **which is not foreseen or planned in the initial conformity assessment** carried out by the provider and as a result of which the **compliance of the AI system** with the requirements set out in Chapter III, Section 2 **is affected or results in a modification to the intended purpose** for which the AI system has been assessed;

Article 43 (4):
High-risk AI systems that have already been subject to a conformity assessment procedure **shall undergo a new conformity assessment procedure in the event of a substantial modification** … .
For **high-risk AI systems that continue to learn** after being placed on the market or put into service, **changes** to the high-risk AI system and its performance **that have been pre-determined by the provider at the moment of the initial conformity assessment** and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, **shall not constitute a substantial modification**.

Change management

TECHNISCHE HOCHSCHULE LÜBECK

Article 3 (23):

'substantial modification' means a **change to an AI system after its placing on the market** or putting **ned in the initial conformity assess**ment **sult of which the compliance of the** AI system with the requirements set out in Chap**ter III, Section 2 is affected or results** in a modification **hich the AI system** has been assessed

?

If a change in the intended purpose of an AI system was defined and foreseen in advance at the time of the original conformity assessment, is it considered a „substantial modification" or not?

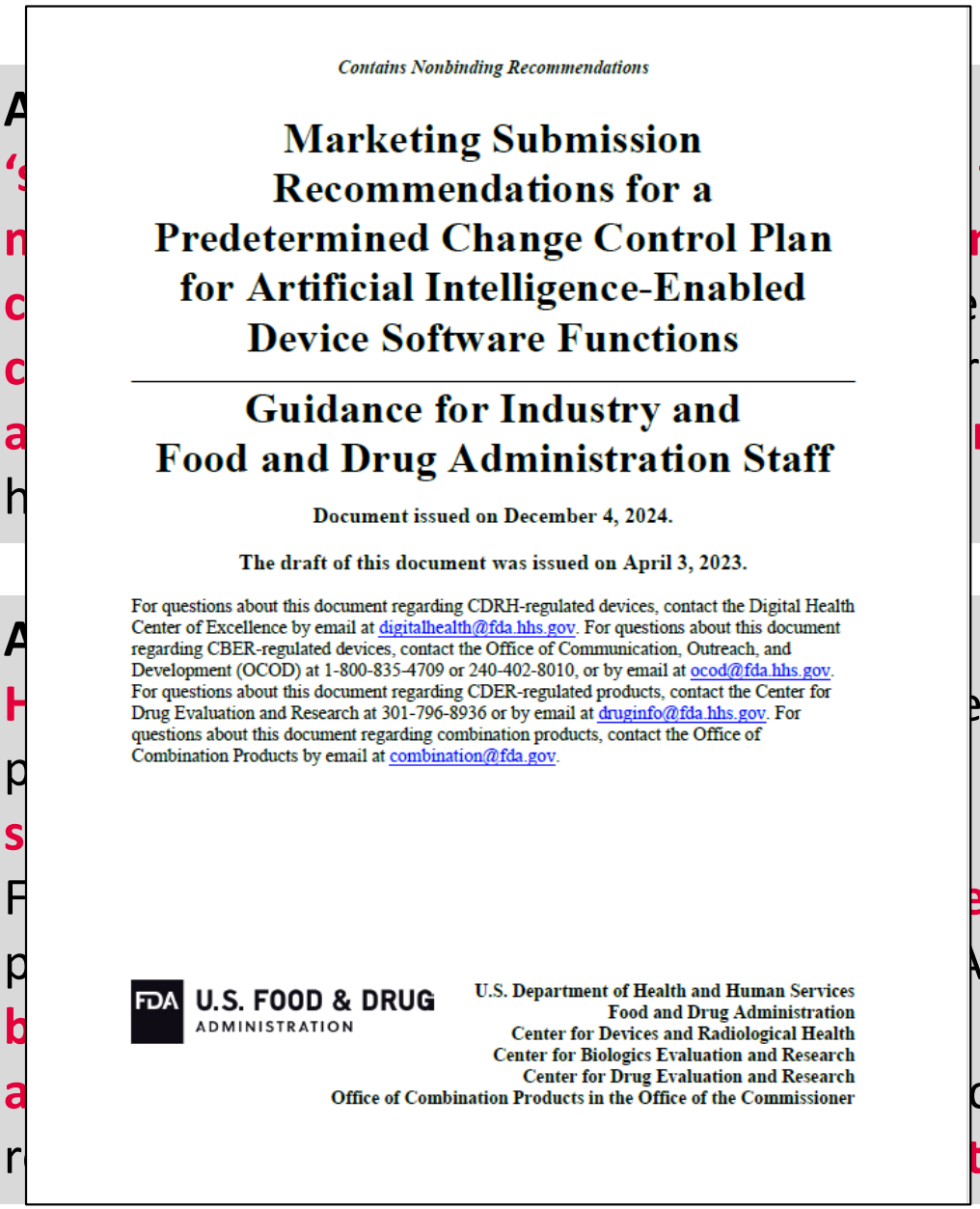
?

Article 43 (4):

High-risk AI systems which underwent a new conformity assessment procedure **shall ur** **in the event of a substantial modifi**cation.

For **high-risk AI sy**stems that continue learning after being placed on the market or put into service, **changes** to the high-risk AI system and its performance **that have been pre-determined by the provider at the moment of the initial conformity assessment** and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, **shall not constitute a substantial modification**.

Change management



Contains Nonbinding Recommendations

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

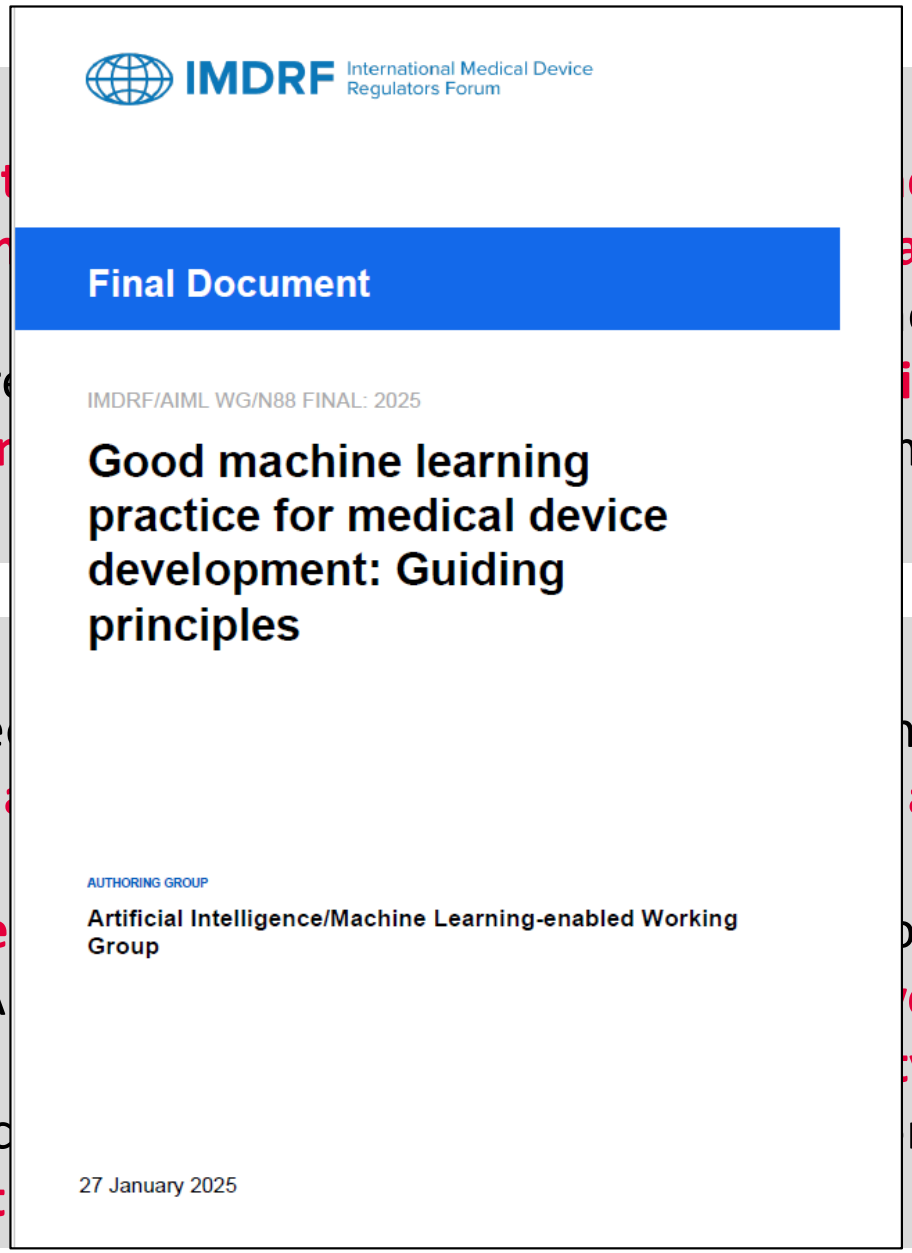
Document issued on December 4, 2024.

The draft of this document was issued on April 3, 2023.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health Center of Excellence by email at digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research at 301-796-8936 or by email at druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products by email at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner



IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/AIML WG/N88 FINAL: 2025

Good machine learning practice for medical device development: Guiding principles

AUTHORING GROUP

Artificial Intelligence/Machine Learning-enabled Working Group

27 January 2025

Standardization in the field of AI

TECHNISCHE HOCHSCHULE LÜBECK

EUROPEAN COMMISSION

Brussels, 22.5.2023
C(2023) 3215 final

COMMISSION IMPLEMENTING DECISION

of 22.5.2023

on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence

Article 1
Requested standardisation activities

The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are requested to draft the new European standards or European standardisation deliverables, as listed in Annex I, in support of Union policy on artificial intelligence by 30 April 2025.

The European standards or European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.

ANNEX I

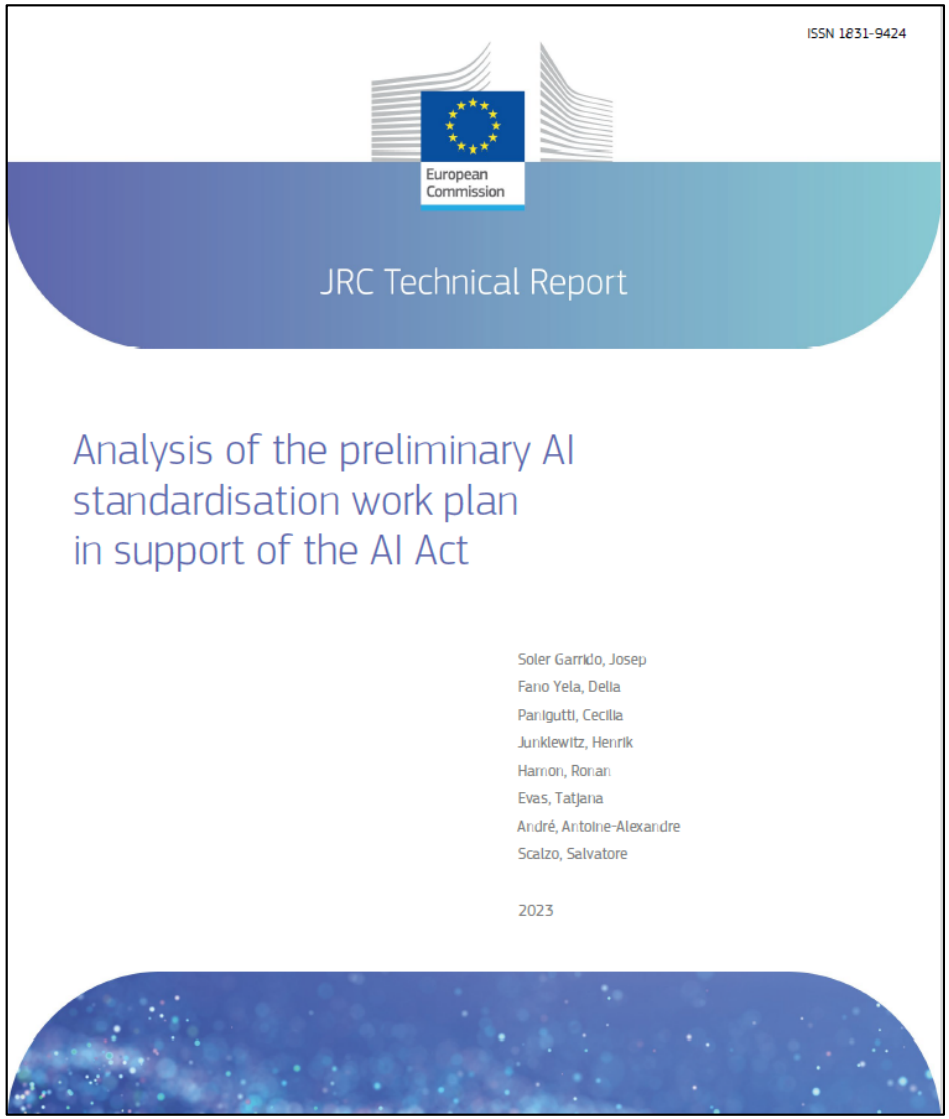
List of new European Standards and European standardisation deliverables to be drafted

	Reference information
1.	European standard(s) and/or European standardisation deliverable(s) on risk management systems for AI systems
2.	European standard(s) and/or European standardisation deliverable(s) on governance and quality of datasets used to build AI systems
3.	European standard(s) and/or European standardisation deliverable(s) on record keeping through logging capabilities by AI systems
4.	European standard(s) and/or European standardisation deliverable(s) on transparency and information provisions for users of AI systems
5.	European standard(s) and/or European standardisation deliverable(s) on human oversight of AI systems
6.	European standard(s) and/or European standardisation deliverable(s) on accuracy specifications for AI systems
7.	European standard(s) and/or European standardisation deliverable(s) on robustness specifications for AI systems
8.	European standard(s) and/or European standardisation deliverable(s) on cybersecurity specifications for AI systems
9.	European standard(s) and/or European standardisation deliverable(s) on quality management systems for providers of AI systems, including post-market monitoring processes
10.	European standard(s) and/or European standardisation deliverable(s) on conformity assessment for AI systems

Source: Standardisation request to the European Standardisation Organisations in support of Union policy on artificial intelligence (22.05.2023; C(2023) 3215 final)

Standardization in the field of AI

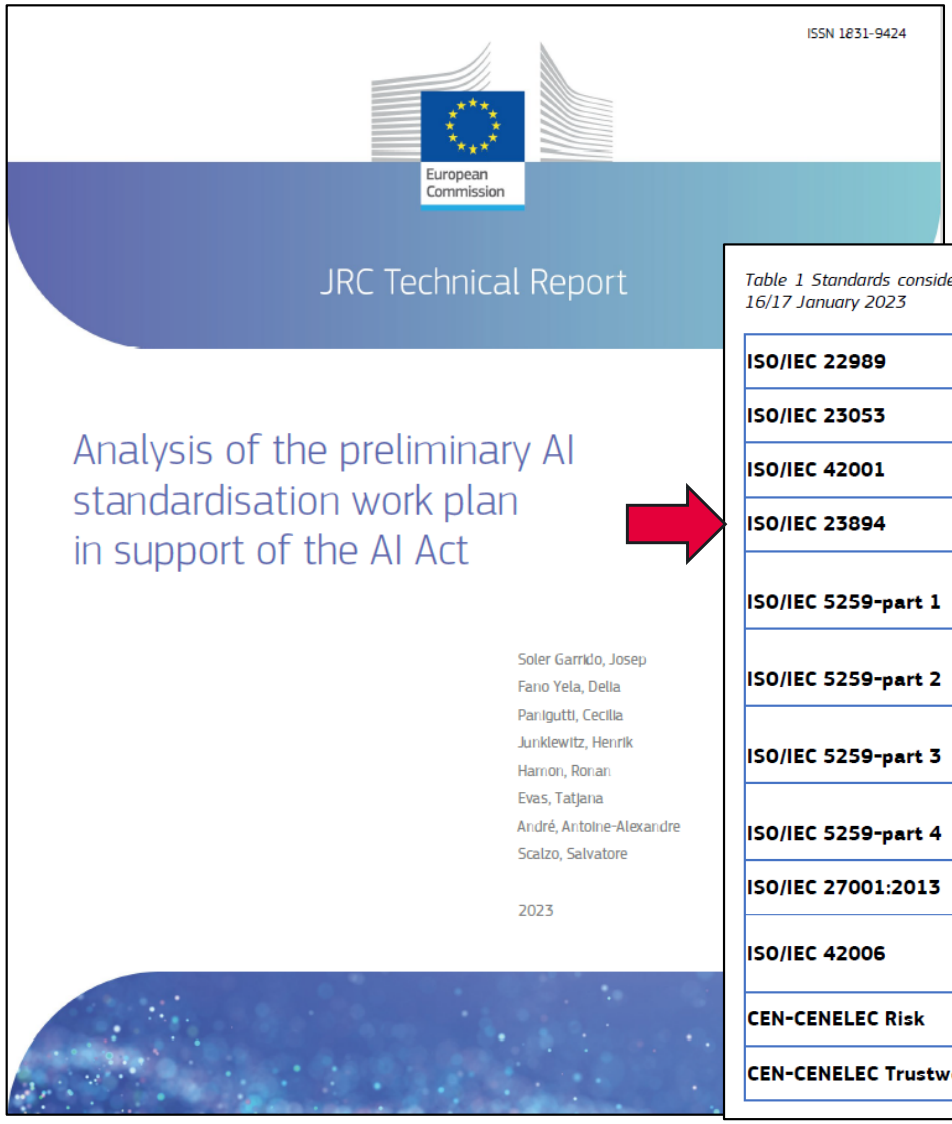
TECHNISCHE HOCHSCHULE LÜBECK



https://ai-watch.ec.europa.eu/topics/ai-standards_en

https://publications.jrc.ec.europa.eu/repository/handle/JRC139430

Standardization in the field of AI



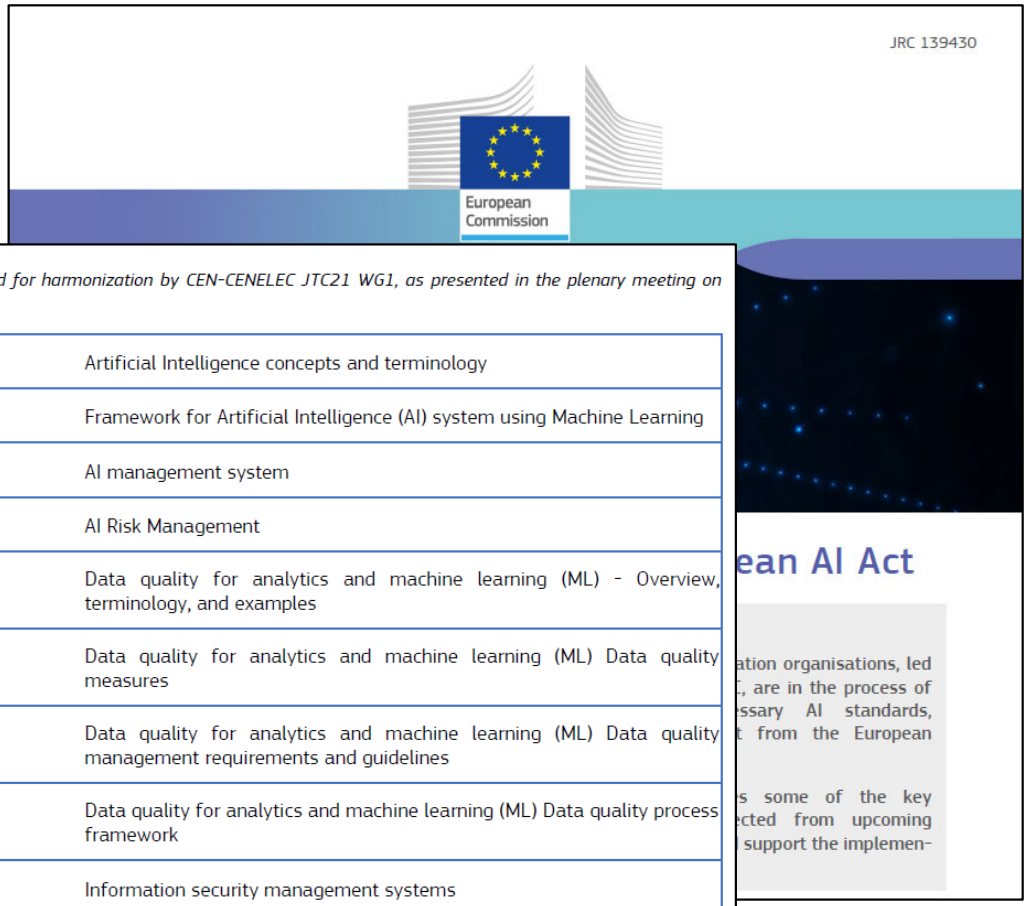


Table 1 Standards considered for harmonization by CEN-CENELEC JTC21 WG1, as presented in the plenary meeting on 16/17 January 2023

ISO/IEC 22989	Artificial Intelligence concepts and terminology
ISO/IEC 23053	Framework for Artificial Intelligence (AI) system using Machine Learning
ISO/IEC 42001	AI management system
ISO/IEC 23894	AI Risk Management
ISO/IEC 5259-part 1	Data quality for analytics and machine learning (ML) - Overview, terminology, and examples
ISO/IEC 5259-part 2	Data quality for analytics and machine learning (ML) Data quality measures
ISO/IEC 5259-part 3	Data quality for analytics and machine learning (ML) Data quality management requirements and guidelines
ISO/IEC 5259-part 4	Data quality for analytics and machine learning (ML) Data quality process framework
ISO/IEC 27001:2013	Information security management systems
ISO/IEC 42006	Requirements on bodies performing audit and certification of AI management systems
CEN-CENELEC Risk	AI Risk catalogue and management
CEN-CENELEC Trustworthiness	AI trustworthiness characterisation

handle/JRC139430

https://ai-watch.ec.europa.eu/topics/ai-standards_en

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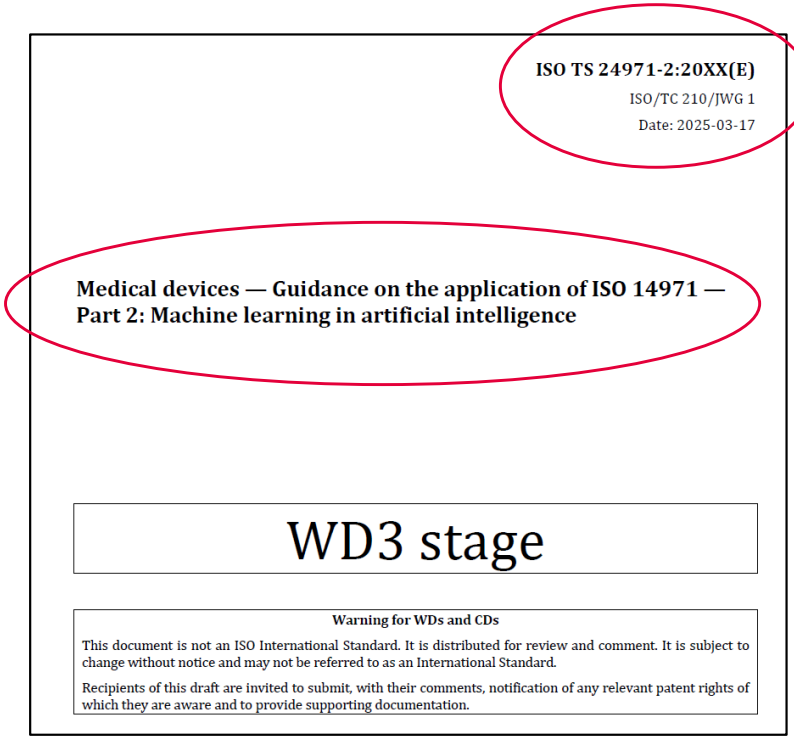


ISO TS 24971-2:20XX(E)
ISO/TC 210/JWG 1
Date: 2025-03-17

Medical devices — Guidance on the application of ISO 14971 — Part 2: Machine learning in artificial intelligence

WD3 stage

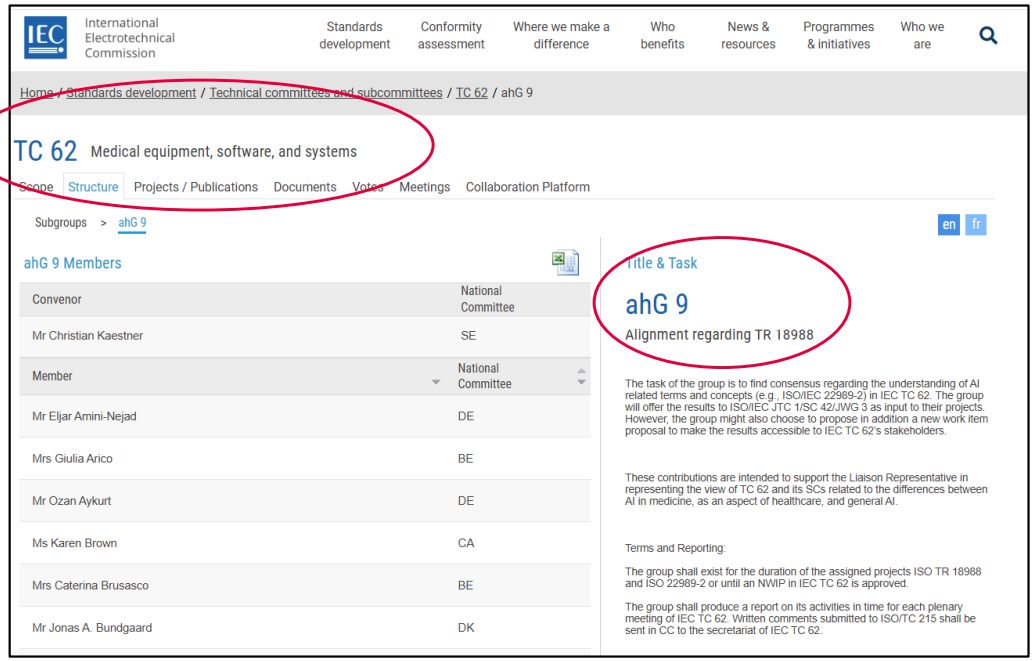
Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

„… ISO/IEC 22989 [3] and ISO/IEC 23894 [5] provide general guidance on AI concepts, terminology and *risk management*, but they do not specifically address the application of AI to *medical devices*. It must be noted that "risk" is defined in these documents as the effect of uncertainties on objectives (see also ISO 31000 [2]). This definition is useful for organizational or business *risk management*. The term "*risk*" used in the healthcare sector is different and is defined in ISO 14971:2019 as the combination of the probability of occurrence of *harm* and the *severity* of that *harm*. …"

Standardization in the field of AI



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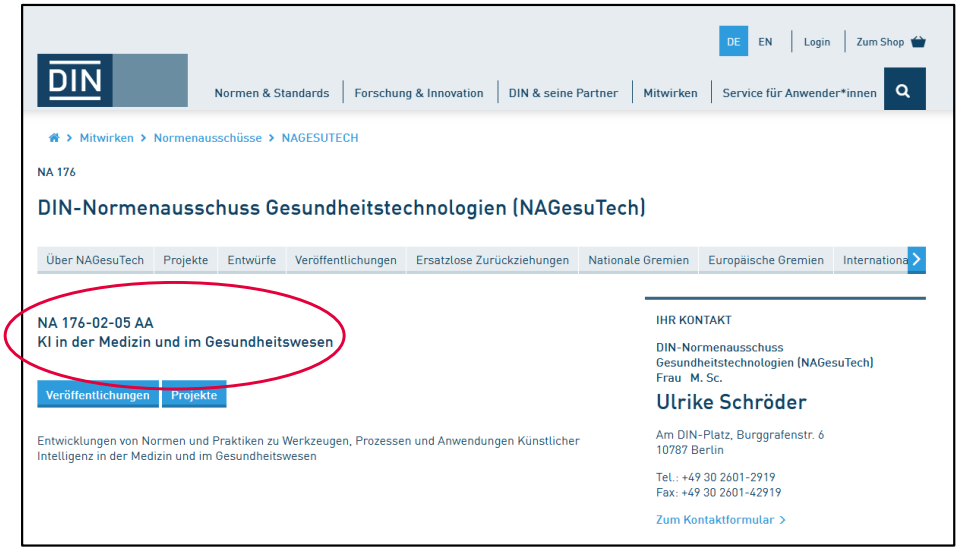

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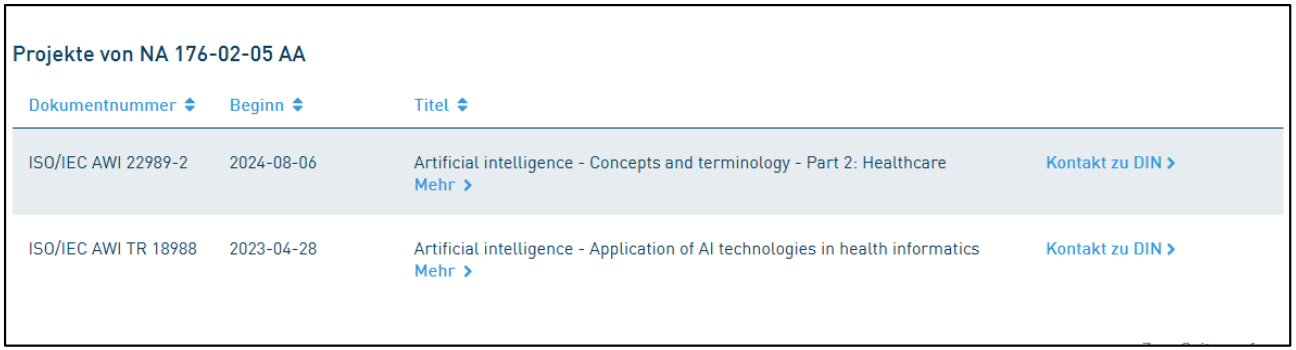

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Activities of implementation

Tasks in 2024-2025

See a timeline of all key tasks required by the EU AI Act in 2024 and 2025, with references to the sources.

Tasks: AI Office | Tasks: EU Member States

https://artificialintelligenceact.eu/

Official Journal of the European Union — EN, L series

2025/454 — 10.3.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/454

of 7 March 2025

laying down the rules for the application of Regulation (EU) 2024/1689 of the European Parliament and of the Council as regards the establishment of a scientific panel of independent experts in the field of artificial intelligence

(Text with EEA relevance)

MDCG:

Interplay between the MDR[1] & IVDR[2] and the AIA[3]

Bearbeitungsstand: 04.12.2024 17:14

Referentenentwurf

des Bundesministeriums für Wirtschaft und Klimaschutz und des Bundesministeriums der Justiz

Entwurf eines Gesetzes zur Durchführung der Verordnung (EU) 2024/1689 des Europäischen Parlaments und des Rates vom 13. Juni 2024 zur Festlegung harmonisierter Vorschriften für künstliche Intelligenz und zur Änderung der Verordnungen (EG) Nr. 300/2008, (EU) Nr. 167/2013, (EU) Nr. 168/2013, (EU) 2018/858, (EU) 2018/1139 und (EU) 2019/2144 sowie der Richtlinien 2014/90/EU, (EU) 2016/797 und (EU) 2020/1828 (Verordnung über künstliche Intelligenz)

(Gesetz zur Durchführung der KI-Verordnung)

Gesetzentwurf

der Bundesregierung

Entwurf eines Gesetzes zur Verbesserung der Rahmenbedingungen für die Erprobung von Innovationen in Reallaboren und zur Förderung des regulatorischen Lernens

„Take home“: Opportunities / Challenges

TECHNISCHE HOCHSCHULE LÜBECK

Opportunities (+)	Challenges/Risks (-)
Promoting confidence to embrace human-centric AI-based solutions by all stakeholders	AI Act may bring too strict and non-flexible requirements that prevent from innovation in the IT sector
Supporting the continuity of access to safe products such as medical devices on the basis of the NLF conformity assessment regulatory approach	AI Act may still risk creating two- or even multiple-track systems, if unclear definitions and concepts are not resolved
Basic and horizontal elements of conformity assessment such as QMS, RMS, technical documentation etc. allow for integration of requirements from sectorial legislation, such as MDR/IVDR	Conflicting requirements must be resolved, for example with regard to risk management, quality management and change management concepts in different product sectors
AI Act includes the EU principle of presumption of conformity by application of harmonised standards	Lacking, unclear or non-appropriate standard requirements will delay the implementation process and will put the EU behind with regard to innovative products

Fraunhofer IMTE

Thank you.

TECHNISCHE HOCHSCHULE LÜBECK

Ozan Aykurt

Pauline Kaufmann

Folker Spitzenberger

Centre for Regulatory Affairs in Biomedical Sciences
Technische Hochschule Lübeck
Mönkhofer Weg 239
23562 Lübeck
Tel. +49 451 300 5372
E-Mail folker.spitzenberger@th-luebeck.de; folker.spitzenberger@imte.fraunhofer.de
Website www.th-luebeck.de