Herausforderungen und Lösungsansätze für die Normung zur künstlichen Intelligenz in der Medizintechnik –

Update zur europäischen und internationalen Standardisierung

Challenges and Solutions for Standardization in Artificial Intelligence in Medical Technology – Update on European and International Standardization

Lübeck Summer Academy – 16.06.2026

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Centre for Regulatory Affairs in Biomedical Sciences - CRABS
Technische Hochschule Lübeck University of Applied Sciences

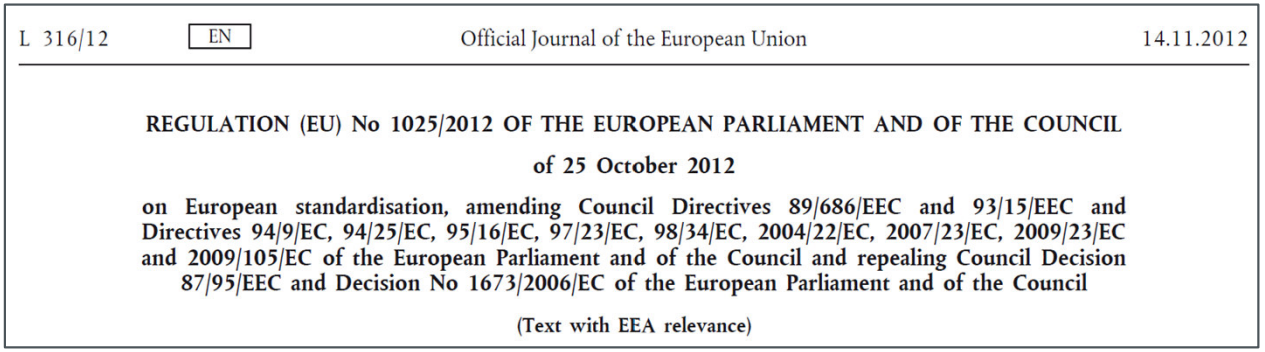
TECHNISCHE HOCHSCHULE LÜBECK

AGENDA

- Background and Relevance of Standardization
- EU AI Act, MDR & IVDR
- Standarization Committees in AI/Medical Technology & current Status of Standardization Activities
- Challenges in Standardization in the field of AI in Medical Technology
- Conclusions and Options for Standardization in the field of AI in Medical Technology

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK



L 316/12 EN Official Journal of the European Union 14.11.2012

REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 October 2012

on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

(Text with EEA relevance)

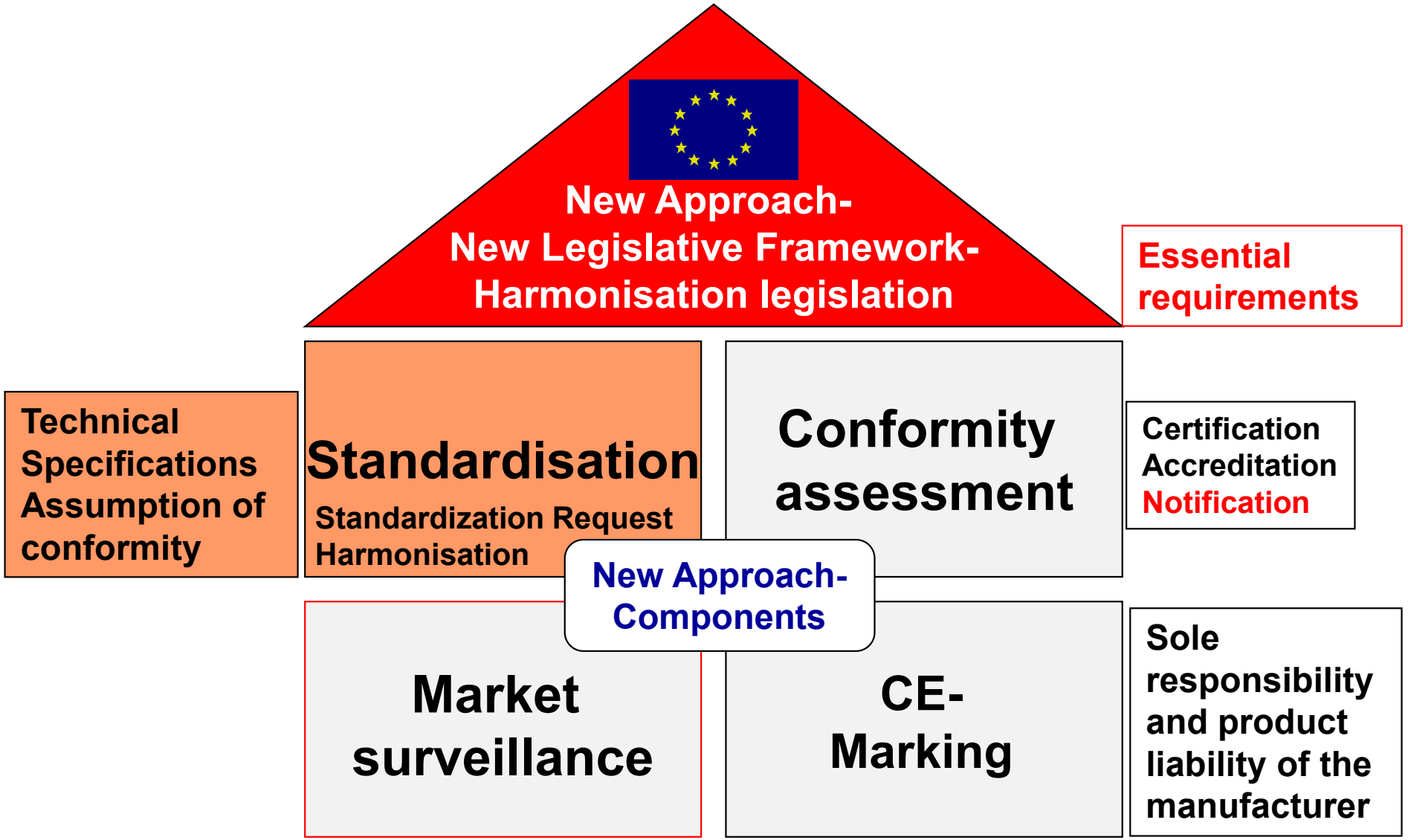
*The **primary objective of standardisation** is the **definition of voluntary technical or quality specifications** with which current or future products, production processes or services may comply. …*

***standardisation** … is **founded on the principles** recognised **by the World Trade Organisation** (WTO) in the field of standardisation, namely **coherence, transparency, openness, consensus, voluntary application, independence** from special interests and efficiency …*

Excerpt from Recitals 1, 2, Regulation (EU) 1025/2012

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK



Compare: KAN-Report 47, 2011: „Accreditation of conformity assessment bodies“

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK

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

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').

Official Journal of the European Union EN L series

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)

Article 40

Harmonised standards and standardisation deliverables

1. High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.

2. In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.

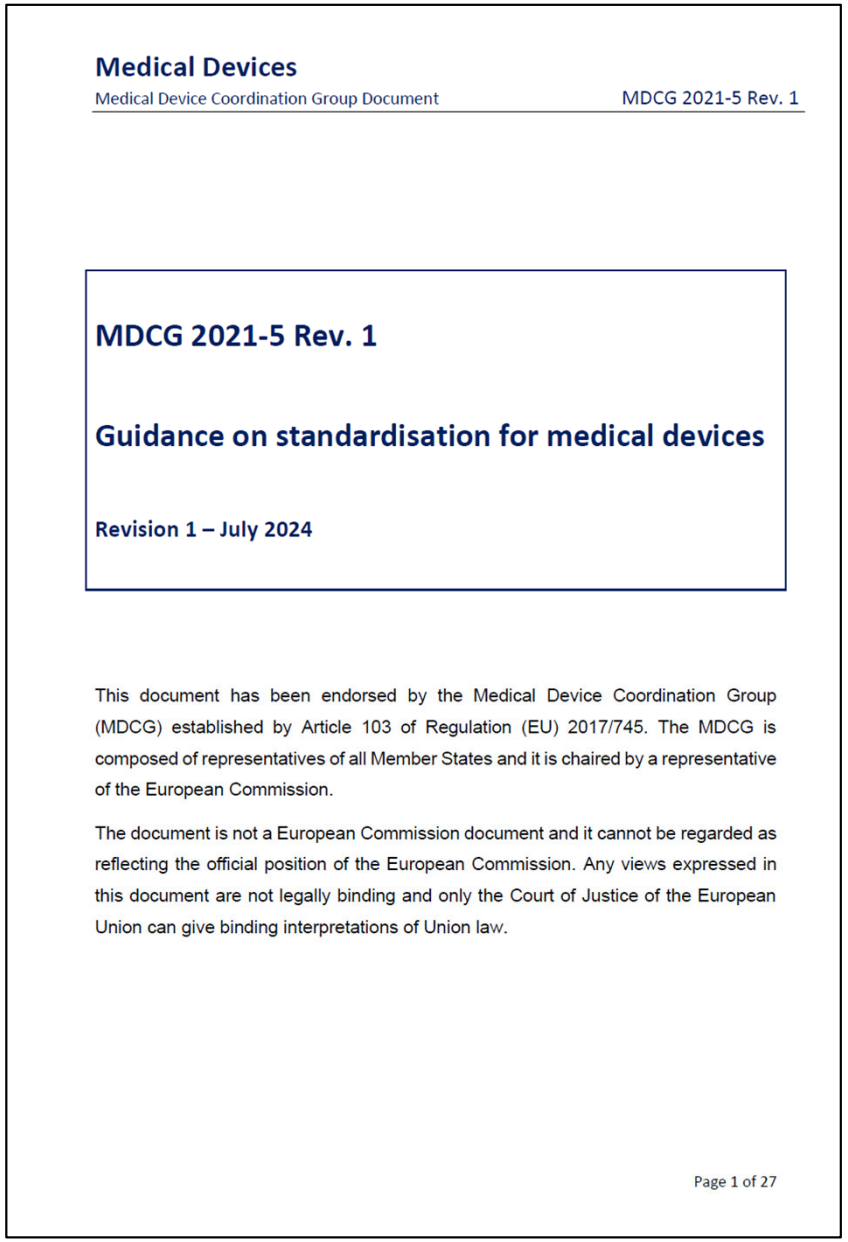
When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation.

The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

3. The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK



Medical Devices

Medical Device Coordination Group Document MDCG 2021-5 Rev. 1

MDCG 2021-5 Rev. 1

Guidance on standardisation for medical devices

Revision 1 – July 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Page 1 of 27

IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

Background and relevance of standardization

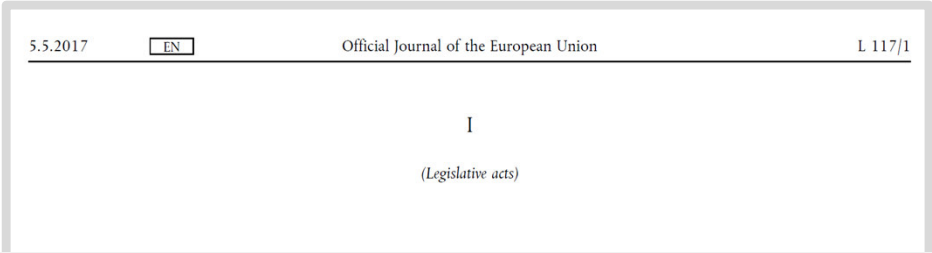
TECHNISCHE HOCHSCHULE LÜBECK

Official Journal of the European Union — EN L series

2024/1689 — 12.7.2024

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

of 13 June 2024



5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

"… When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I …"

Article 40, EU AI Act

When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation.

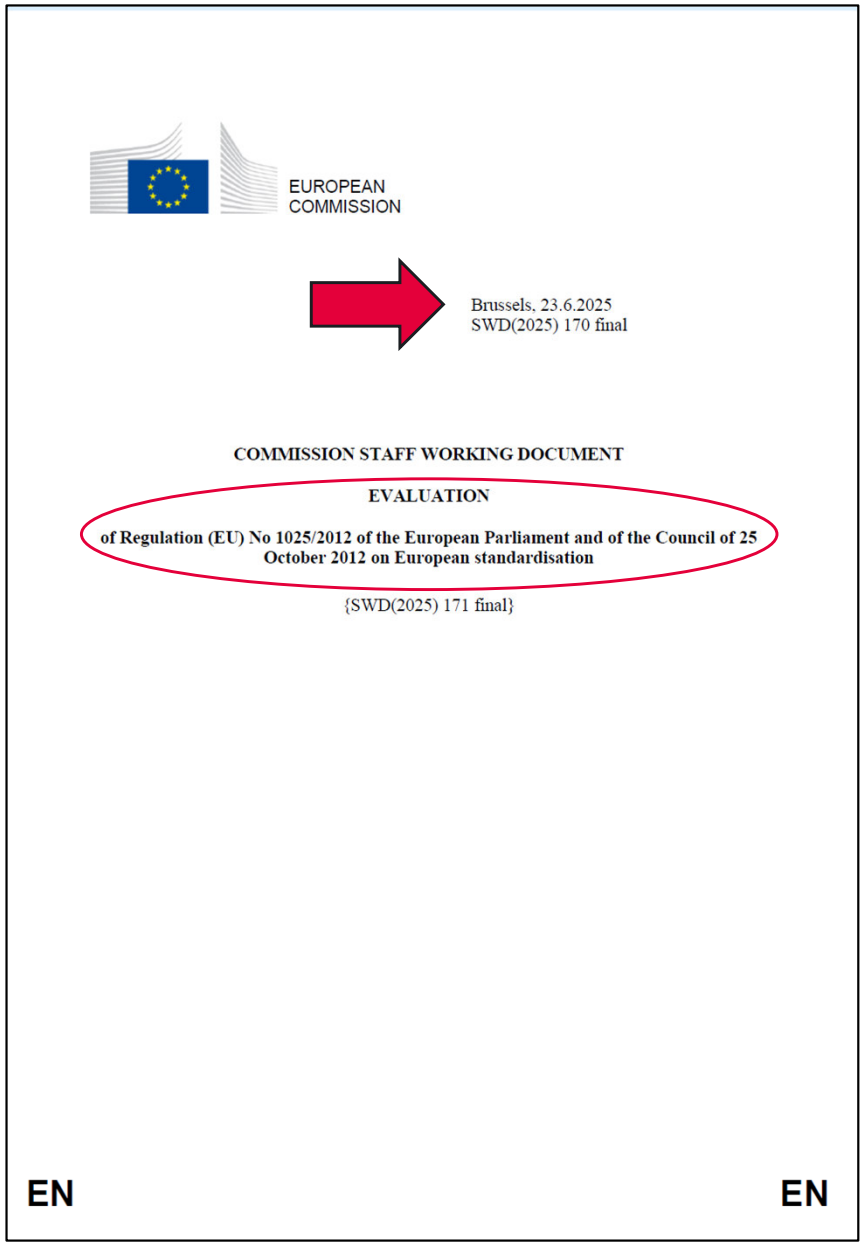
The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

3. The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

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').

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK



EUROPEAN COMMISSION

Brussels, 23.6.2025
SWD(2025) 170 final

COMMISSION STAFF WORKING DOCUMENT

EVALUATION

of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation

{SWD(2025) 171 final}

EN **EN**

Table of contents

Background and relevance of standardization

TECHNISCHE HOCHSCHULE LÜBECK


EUROPEAN COMMISSION

Brussels, 23.6.2025
SWD(2025) 171 final

Effectiveness: *"… with a total average duration of six years (three of which for the drafting and consensus-building stage), the* ***standardisation process is still considered to be much too slow****, in particular in relation to legislative requirements, market needs and global competition …"*

Relevance: *"…****Weaknesses in the current framework*** *have been made more evident by external factors, such as (i)* ***accelerated technology cycles in the digital and green fields;*** *(ii) an ageing population of technical experts; (iii)* ***geo-economic developments;*** *(iv) the* ***increased assertiveness of non-EU countries in international standardisation****; and (v) CJEU case law. In particular,* ***the framework struggles to deliver in emerging technology areas, including those that are key to the EU's policy priorities and the competitiveness of its businesses*** *…"*

EU AI Act, MDR & IVDR

TECHNISCHE HOCHSCHULE LÜBECK

EUROPEAN COMMISSION

Brussels, 22.5.2023
C(2023) 3215 final

COMMISSION

on a standardisation request to the European Committee for Electrotech

Brussels, 23.6.2025
C(2025) 3871 final

COMMISSION IMPLEMENTING DECISION

of 23.6.2025

on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215

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.

Article 1

Requested standardisation activities

1. The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are requested to draft the [new] harmonised standards and European standardisation deliverables listed in Annex I to this Decision, in support of Regulation (EU) 2024/1689, by 31 August 2025.
2. The harmonised standards and 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) and (23.6.2025; C(2025) 3871 final)

European Commission

EN

Public Health

Home > Medical Devices - Topics of Interest > Harmonised standards

Harmonised standards

Harmonised standards under the Regulations on medical devices and in vitro diagnostic medical devices are developed by CEN and CENELEC as European standardisation organisations, on the basis of a standardisation request issued by the Commission according to Regulation (EU) No 1025/2012.

Once their references are published by the Commission in the Official Journal of the European Union, the voluntary use of those standards confer presumption of conformity with the requirements of the Regulations they aim to cover.

The Commission issued a standardisation request to CEN and CENELEC on 14 April 2021. It is available in the "eNorm Platform - European Commission standardisation requests" as M/575 (EN version - FR and DE available, clicking on the linguistic icon).

A first amendment to the standardisation request was adopted on 31 January 2023, available as M/575 Amd 1 in the EN, FR and DE versions. A second amendment to the standardisation request was adopted on 27 May 2024, available as M/575 Amd 2 in the EN, FR and DE versions.

A consolidated version of the standardisation request M/575, for information purposes only, is available here.

https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

EU AI Act, **MDR & IVDR**

TECHNISCHE HOCHSCHULE LÜBECK

For Regulation (EU) 2017/745 on medical devices:

- Commission Implementing Decision (EU) 2026/760 of 1 April 2026
- Commission Implementing Decision (EU) 2026/193 of 28 January 2026
- Commission Implementing Decision (EU) 2025/2078 of 17 October 2025
- Commission Implementing Decision (EU) 2025/681 of 8 April 2025
- Commission Implementing Decision (EU) 2024/2631 of 8 October 2024
- Commission Implementing Decision (EU) 2024/815 of 6 March 2024
- Commission Implementing Decision (EU) 2023/1410 of 4 July 2023
- Commission Implementing Decision (EU) 2022/757 of 11 May 2022
- Commission Implementing Decision (EU) 2022/6 of 4 January 2022
- Commission Implementing Decision (EU) 2021/1182 of 16 July 2021

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

- Commission Implementing Decision (EU) 2026/197 of 28 January 2026
- Commission Implementing Decision (EU) 2025/679 of 8 April 2025
- Commission Implementing Decision (EU) 2024/2625 of 8 October 2024
- Commission Implementing Decision (EU) 2024/817 of 6 March 2024
- Commission Implementing Decision (EU) 2023/1411 of 4 July 2023
- Commission Implementing Decision (EU) 2022/729 of 11 May 2022
- Commission Implementing Decision (EU) 2022/15 of 6 January 2022
- Commission Implementing Decision (EU) 2021/1195 of 19 July 2021

EU AI Act, **MDR & IVDR**

TECHNISCHE HOCHSCHULE LÜBECK

DE ABl. L vom 30.1.2026

ANHANG

Im Anhang des Durchführungsbeschlusses (EU) 2021/1182 werden folgende Einträge angefügt:

Nr.	Fundstelle der Norm
„37.	EN ISO 7197:2024 Neurochirurgische Implantate — Sterile Hydrozephalus-Shunts zum Einmalgebrauch (ISO 7197:2024)
38.	EN ISO 10993-4:2017 Biologische Beurteilung von Medizinprodukten — Teil 4: Auswahl von Prüfungen zur Wechselwirkung mit Blut (ISO 10993-4:2017) EN ISO 10993-4:2017/A1:2025
39.	EN ISO 14155:2020 Klinische Prüfung von Medizinprodukten an Menschen — Gute klinische Praxis (ISO 14155:2020) EN ISO 14155:2020/A11:2024
40.	EN ISO 14630:2024 Nichtaktive chirurgische Implantate — Allgemeine Anforderungen (ISO 14630:2024)
41.	EN ISO 17665:2024 Sterilisation von Produkten für die Gesundheitsfürsorge — Feuchte Hitze — Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665:2024)
42.	EN ISO 18562-1:2024 Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen — Teil 1: Beurteilung und Prüfung innerhalb eines Risikomanagement-Prozesses (ISO 18562-1:2024)
43.	EN ISO 18562-2:2024 Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen — Teil 2: Prüfungen für Emissionen von Partikeln (ISO 18562-2:2024)
44.	EN ISO 18562-3:2024 Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen — Teil 3: Prüfungen für Emissionen von flüchtigen organischen Stoffen (ISO 18562-3:2024)
45.	EN ISO 18562-4:2024 Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen — Teil 4: Prüfungen für herauslösbare Substanzen in Kondensaten (ISO 18562-4:2024)
46.	EN ISO 21535:2024 Nichtaktive chirurgische Implantate — Implantate zum Gelenkersatz — Besondere Anforderungen an Implantate für den Hüftgelenkersatz (ISO 21535:2023)
47.	EN ISO 21536:2024 Nichtaktive chirurgische Implantate — Implantate zum Gelenkersatz — Besondere Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2023)
48.	EN ISO 80369-2:2024 Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen — Teil 2: Verbindungsstücke für respiratorische Anwendungen (ISO 80369-2:2024, berichtigte Fassung 2025-06)“

ABl. L vom 7.4.2026 DE

ANHANG

Im Anhang des Durchführungsbeschlusses (EU) 2021/1182 werden die folgenden Einträge angefügt:

Nr.	Norm
„49.	EN 13060:2025 Sterilisatoren für medizinische Zwecke — Dampf-Klein-Sterilisatoren — Anforderungen und Prüfung
50.	EN 14222:2021 + A1:2025 Edelstahl-Dampfkessel
51.	EN IEC 60118-0:2024 Akustik — Hörgeräte — Teil 0: Messung der Leistungsmerkmale von Hörgeräten“

2026: + 12 + 3 Standards MDR-Scope (Total: 52)

ABl. L vom 30.1.2026 DE

ANHANG

Im Anhang des Durchführungsbeschlusses (EU) 2021/1195 werden folgende Einträge angefügt:

Nr.	Fundstelle der Norm
„18.	EN ISO 17665:2024 Sterilisation von Produkten für die Gesundheitsfürsorge — Feuchte Hitze — Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665:2024)
19.	EN ISO 18113-1:2024 In-vitro-Diagnostika — Bereitstellung von Informationen durch den Hersteller (Kennzeichnung) — Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2022)
20.	EN ISO 18113-2:2024 In-vitro-Diagnostika — Bereitstellung von Informationen durch den Hersteller (Kennzeichnung) — Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO 18113-2:2022)
21.	EN ISO 18113-3:2024 In-vitro-Diagnostika — Bereitstellung von Informationen durch den Hersteller (Kennzeichnung) — Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal (ISO 18113-3:2022)
22.	EN ISO 18113-4:2024 In-vitro-Diagnostika — Bereitstellung von Informationen durch den Hersteller (Kennzeichnung) — Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-4:2022)
23.	EN ISO 18113-5:2024 In-vitro-Diagnostika — Bereitstellung von Informationen durch den Hersteller (Kennzeichnung) — Teil 5: Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-5:2022)“

2026: + 6 Standards IVDR-Scope (Total: 24)

Prof. Dr. Folker Spitzenberger

EU AI Act, **MDR & IVDR**

TECHNISCHE HOCHSCHULE LÜBECK

Generated 7/4/2026

Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	Withdrawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers	17.05.2022	OJ L 138	2022/757	17.05.2022				
2017/745 - Medical Devices	CEN	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom of holes	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 1865-2:2024 Patient handling equipment used in ambulances - Part 2: Power assisted stretcher	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 1865-6:2024 Patient handling equipment used in ambulances - Part 6: Powered chairs	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 13060:2025 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing	07.04.2026	OJ L	2026/760	07.04.2026				

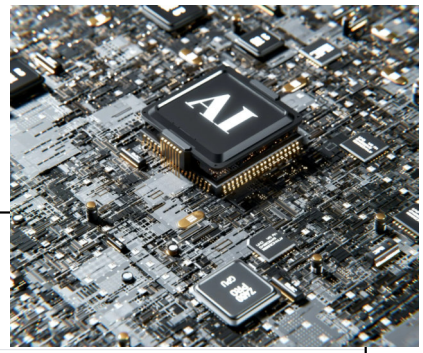
Generated on 30.1.2026

Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	Withdrawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	10.04.2025	OJ L	2025/679	10.04.2025				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	10.04.2025	OJ L	2025/679	10.04.2025				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) EN ISO 11135:2014/A1:2019	20.07.2021	OJ L 258	2021/1195	20.07.2021				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019	20.07.2021	OJ L 258	2021/1195	20.07.2021				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013) EN ISO 11137-2:2015/A1:2023	08.03.2024	OJ L	2024/817	08.03.2024				

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

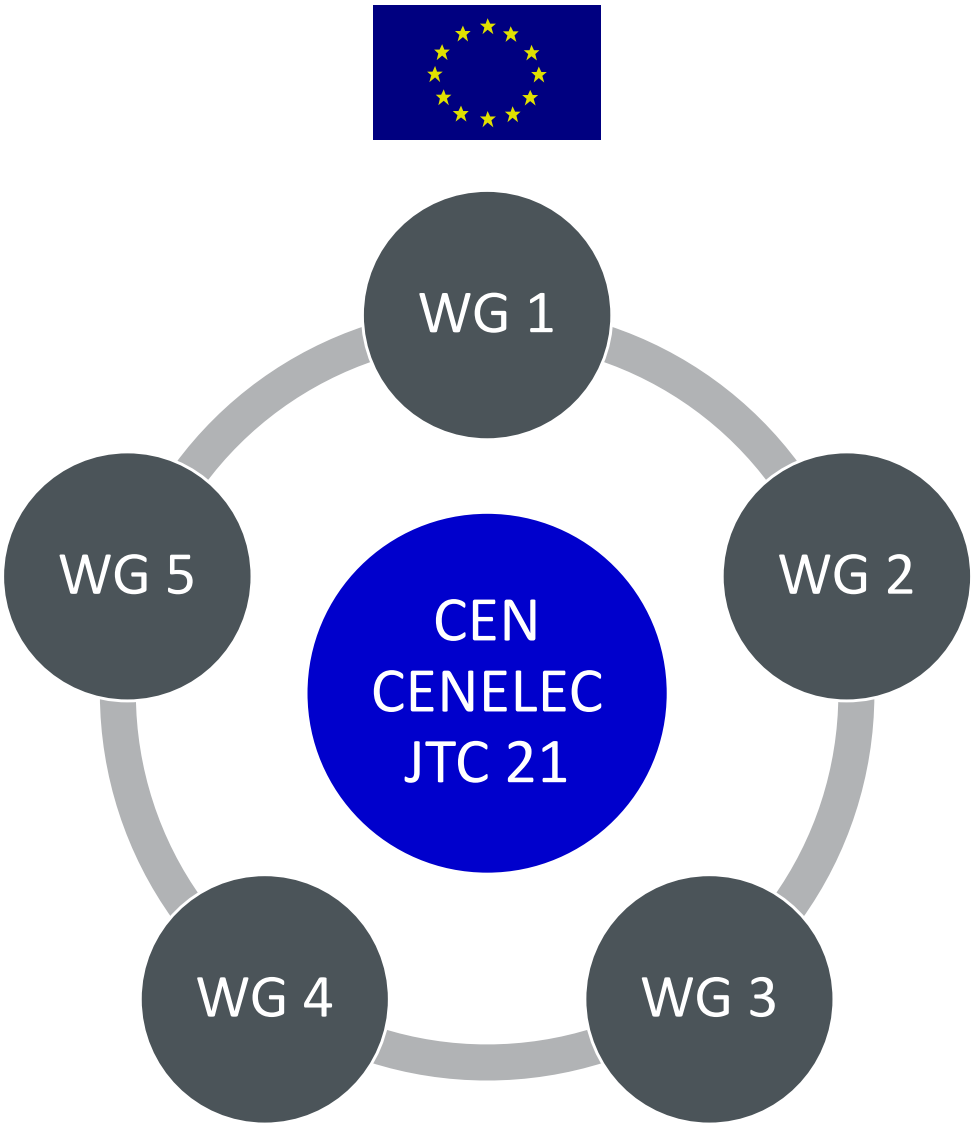


JTC 21 Artificial Intelligence | CEN CENELEC

Shaping the Future of Artificial Intelligence: CEN-CENELEC JTC 21

CEN-CENELEC Joint Technical Committee 21 (JTC 21) is a dedicated body focused on standardization in the field of Artificial Intelligence (AI). This committee plays a crucial role in developing European Standards for AI technologies, addressing the unique needs and requirements of the European market and societal context.

The committee's work is particularly important as AI technologies continue to evolve and impact various sectors across Europe. By developing harmonized standards, JTC 21 aims to support the implementation of AI systems that are not only technologically advanced but also align with European values and regulatory frameworks like the AI Act.



https://jtc21.eu/

CEN-CENELEC JTC 21

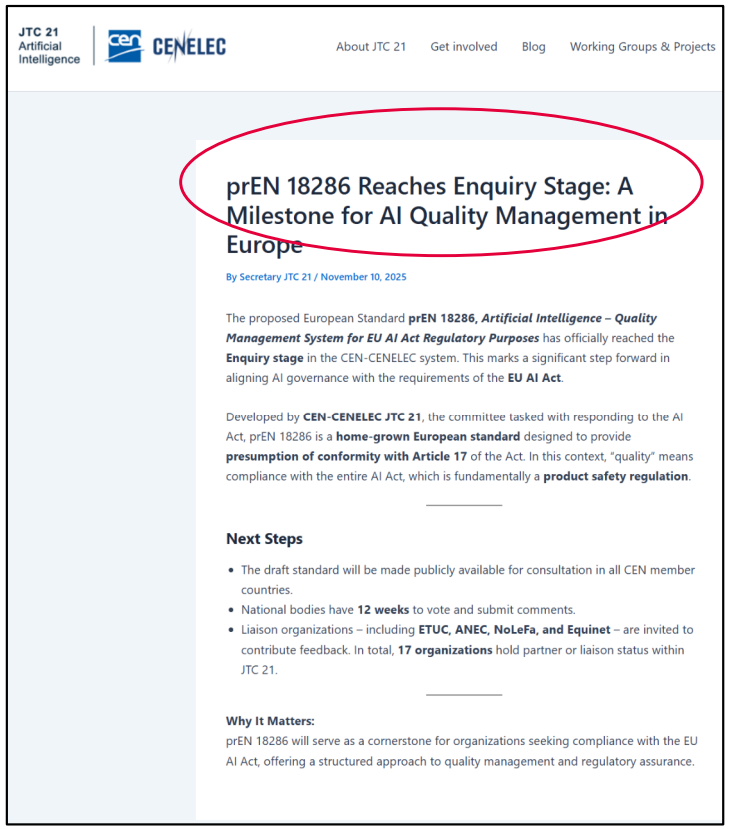
WG 1	WG 2	WG 3	WG 4	WG 5
• Strategic Advisory Group • Monitor AI developments & innovations • Coordination of all WGs • Interface with international standardization	• Operational aspects of AI • QMS (prEN 18286) • RMS (prEN 18228) • Conformity assessment (prEN 18285)	• Engineering aspects of AI • Quality and governance of datasets (prEN 18284) • Managing bias (prEN 18283) • Evaluation methods for accurate computer vision systems (prEN 18281) • Natural Language Processing (prEN ISO/IEC 23828) • Logging (prEN ISO/IEC 24970)	• Foundational and societal aspects of AI • AI trustworthiness framework – Part 1: Logging, transparency and human oversight (prEN 18229-1) • AI trustworthiness framework – Part 1: Accuracy and robustness (prEN 18229-2)	• Cybersecurity for AI systems • Cybersecurity specifications for AI systems (prEN 18282)

https://jtc21.eu/

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

CEN-CENELEC JTC 21



JTC 21 Artificial Intelligence | CEN CENELEC

About JTC 21 | Get involved | Blog | Working Groups & Projects

prEN 18286 Reaches Enquiry Stage: A Milestone for AI Quality Management in Europe

By Secretary JTC 21 / November 10, 2025

The proposed European Standard **prEN 18286**, ***Artificial Intelligence – Quality Management System for EU AI Act Regulatory Purposes*** has officially reached the **Enquiry stage** in the CEN-CENELEC system. This marks a significant step forward in aligning AI governance with the requirements of the **EU AI Act**.

Developed by **CEN-CENELEC JTC 21**, the committee tasked with responding to the AI Act, prEN 18286 is a **home-grown European standard** designed to provide **presumption of conformity with Article 17** of the Act. In this context, "quality" means compliance with the entire AI Act, which is fundamentally a **product safety regulation**.

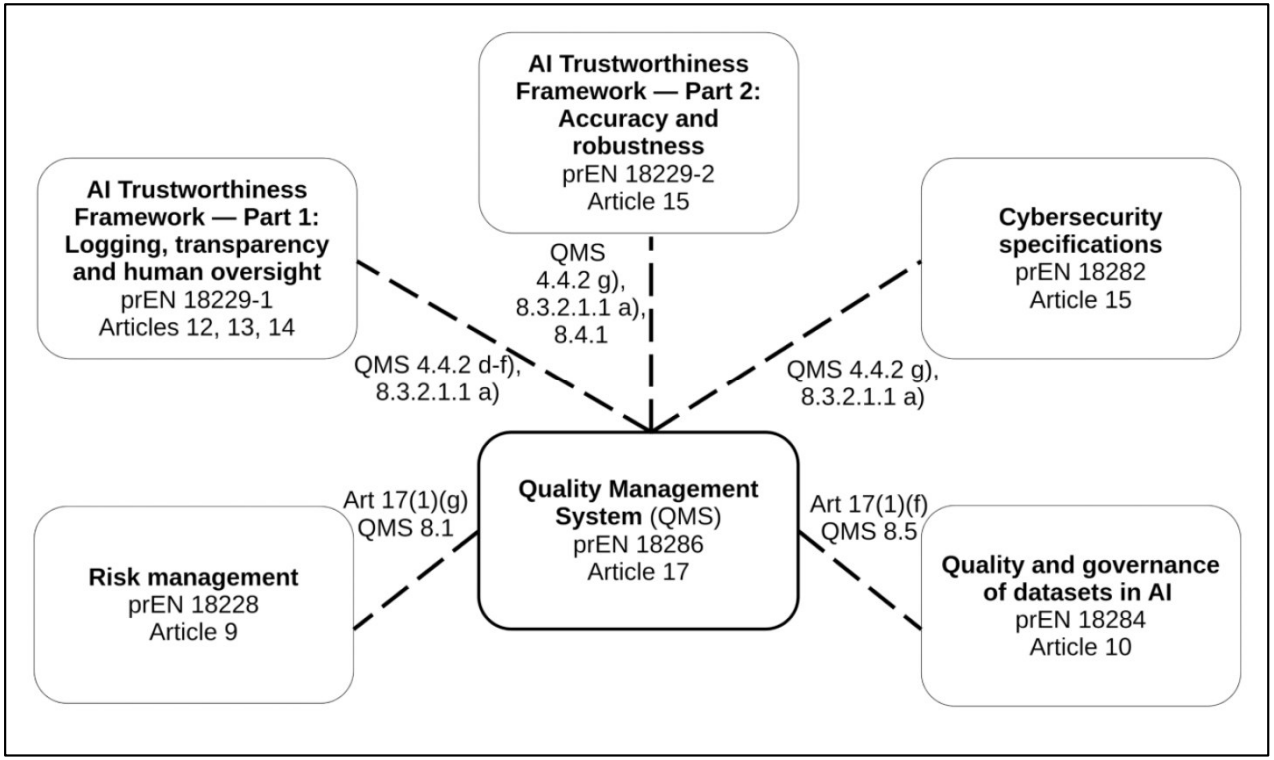
Next Steps

- The draft standard will be made publicly available for consultation in all CEN member countries.
- National bodies have **12 weeks** to vote and submit comments.
- Liaison organizations – including **ETUC, ANEC, NoLeFa, and Equinet** – are invited to contribute feedback. In total, **17 organizations** hold partner or liaison status within JTC 21.

Why It Matters:

prEN 18286 will serve as a cornerstone for organizations seeking compliance with the EU AI Act, offering a structured approach to quality management and regulatory assurance.

https://jtc21.eu/pren-18286-reaches-enquiry-stage-a-milestone-for-ai-quality-management-in-europe/



Source: Artificial intelligence – Quality management system for EU AI Act regulatory purposes; English version prEN 18286:2025; Figure B.1 — Relationship between harmonised standards

TECHNISCHE HOCHSCHULE LÜBECK

CEN-CENELEC JTC 21

ANNEX I

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

	Reference information
	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

- The current Standardization Request is valid until **February 28, 2027**.
- The agreement is to adhere to clear deadlines with the aim of making all standards available by **November 2026** or **March 2027**.

Standardization Committees and Status of Standardization

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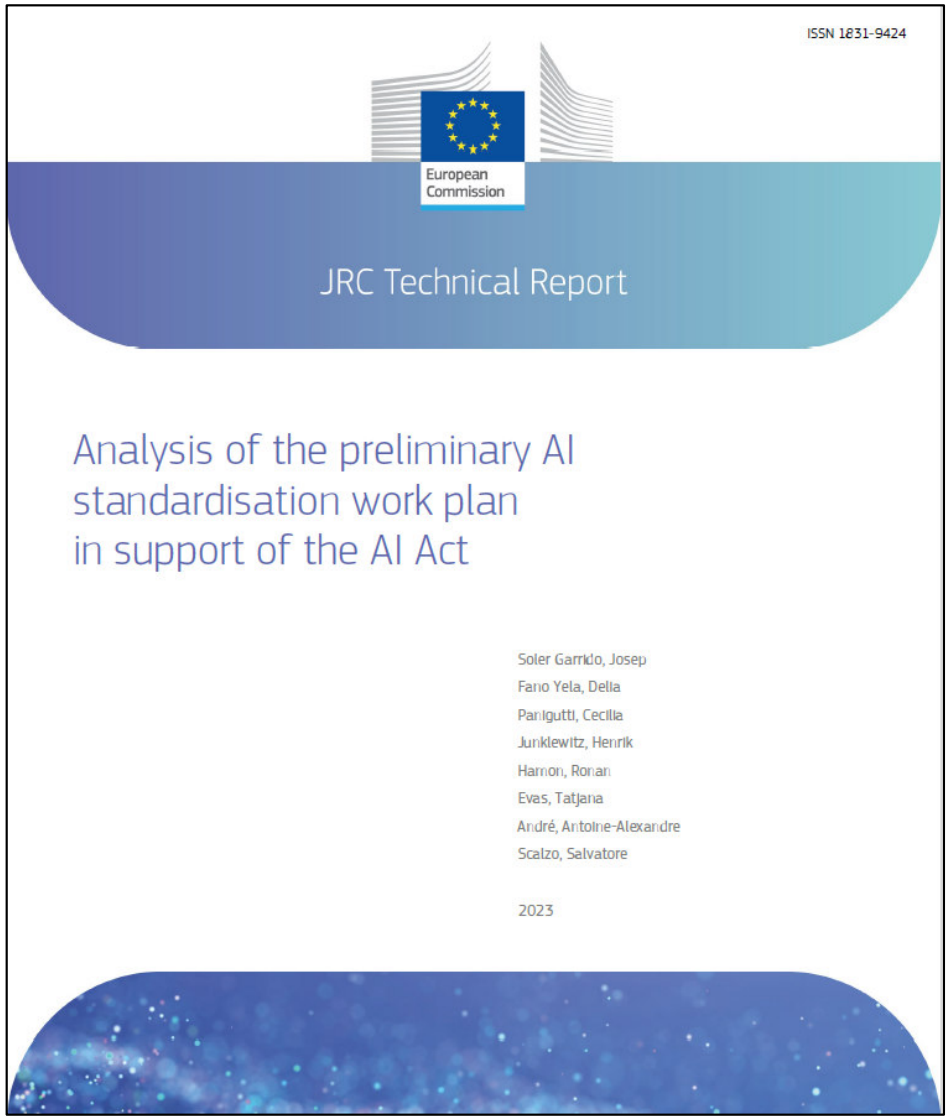

https://ai-watch.ec.europa.eu/topics/ai-standards_en

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

Standardization Committees and Status of Standardization

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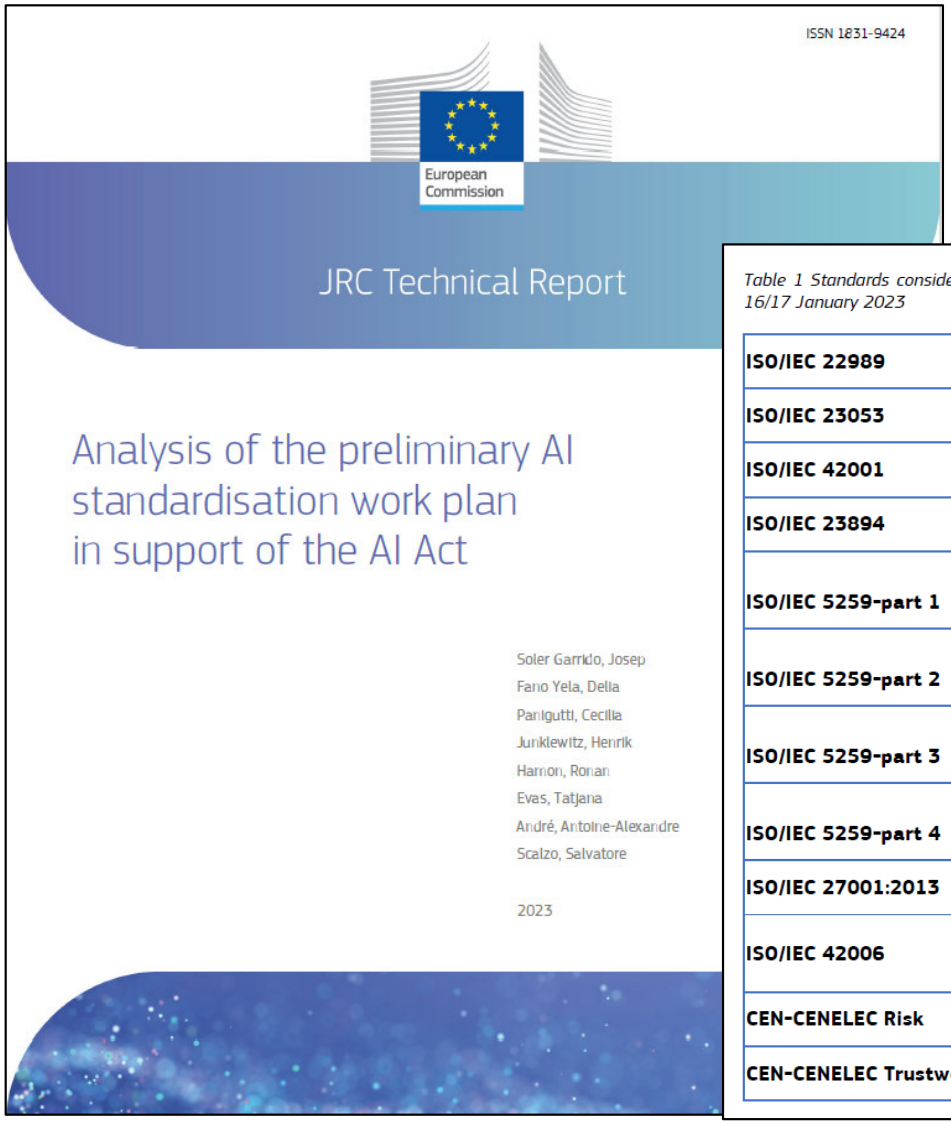

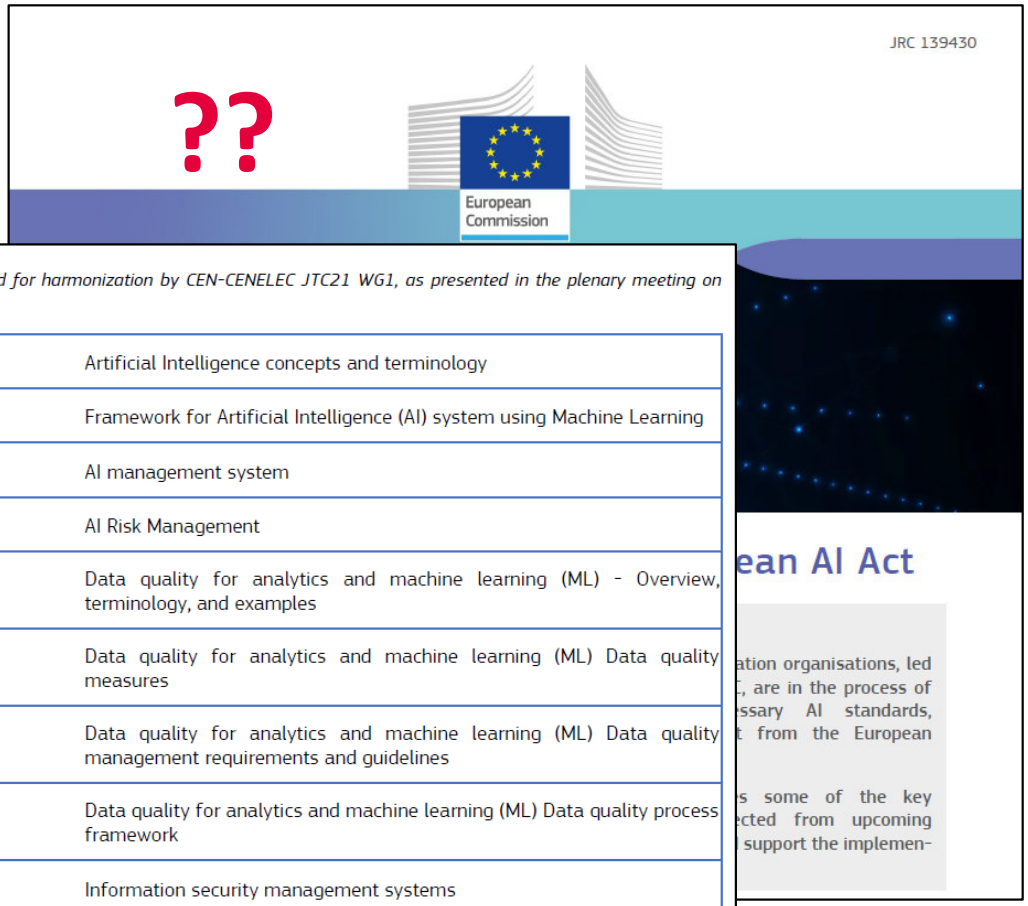

Table 1 Standards considered for harmonization by CEN-CENELEC JTC21 WG1, as presented in the plenary meeting on 16/17 January 2023

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

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

ISO IEC

International
ISO/IEC JCT 1/SC 42
Artificial Intelligence

European Commission

Eu Commission
Standardization
Requests

JTC 21
Artificial
Intelligence

CEN CENELEC

Europa
CEN-CENELEC JCT 21
AI – WG 1 - 5

DIN DKE

National
DIN/DKE NA 043-01-42 GA
„Künstliche Intelligenz“
AK – 2, 3, 4, 5

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

ISO IEC

International
ISO/IEC JCT 1/SC 42
Artificial Intelligence

ISO

International
ISO TC 215
Health informatics

248
Published ISO standards *
of which 221 under the direct responsibility of ISO/TC 215

65
ISO standards under development *
of which 61 under the direct responsibility of ISO/TC 215

39
Participating members

32
Observing members

European Commission

Eu Commission Standardization Requests

JTC 21 Artificial Intelligence | CEN CENELEC

Europa
CEN-CENELEC JCT 21
AI – WG 1 - 5

DIN DKE

National
DIN/DKE NA 043-01-42 GA
„Künstliche Intelligenz“
AK – 2, 3, 4, 5

Liaison Committees to ISO/TC 215

The committees below can access the documents of ISO/TC 215:

Reference	Title	ISO/IEC
IEC/SC 62A	Common aspects of medical equipment, software, and systems	IEC
IEC/ISO JSyC BDC	IEC/ISO Joint Systems Committee on Bio-digital convergence (IEC/ISO JSyC BDC)	ISO/IEC
IEC/SyC AAL	Active Assisted Living	IEC
IEC/SyC Smart Cities	Electrotechnical aspects of Smart Cities	IEC
IEC/TC 62	Medical equipment, software, and systems	IEC
ISO/IEC JTC 1	Information technology	ISO/IEC
ISO/IEC JTC 1/SC 6	Telecommunications and information exchange between systems	ISO/IEC
ISO/IEC JTC 1/SC 7	Software and systems engineering	ISO/IEC
ISO/IEC JTC 1/SC 17	Cards and security devices for personal identification	ISO/IEC
ISO/IEC JTC 1/SC 24	Computer graphics, image processing and environmental data representation	ISO/IEC
ISO/IEC JTC 1/SC 27	Information security, cybersecurity and privacy protection	ISO/IEC
ISO/IEC JTC 1/SC 29	Coding of audio, picture, multimedia and hypermedia information	ISO/IEC
ISO/IEC JTC 1/SC 32	Data management and interchange	ISO/IEC
ISO/IEC JTC 1/SC 36	Information technology for learning, education and training	ISO/IEC
ISO/IEC JTC 1/SC 41	Internet of things and digital twin	ISO/IEC
ISO/IEC JTC 1/SC 42	Artificial intelligence	ISO/IEC
ISO/IEC JTC 1/SC 43	Brain-computer interfaces	ISO/IEC
ISO/IEC JTC 1/SC 44	Consumer protection in the field of privacy by design	ISO/IEC
ISO/TC 12	Quantities and units	ISO
ISO/TC 37	Language and terminology	ISO
ISO/TC 46	Information and documentation	ISO
ISO/TC 106	Dentistry	ISO
ISO/TC 106/SC 3	Terminology	ISO
ISO/TC 121	Anaesthetic and respiratory equipment	ISO
ISO/TC 145	Graphical symbols	ISO
ISO/TC 154	Processes, data elements and documents in commerce, industry and administration	ISO
ISO/TC 170	Surgical instruments	ISO
ISO/TC 210	Quality management and corresponding general aspects for products with a health purpose including medical devices	ISO
ISO/TC 212	Medical laboratories and in vitro diagnostic systems	ISO
ISO/TC 249	Traditional medicine	ISO
ISO/TC 249/SC 1	Traditional Chinese medicine	ISO
ISO/TC 268/SC 1	Smart community infrastructures	ISO
ISO/TC 276	Biotechnology	ISO
ISO/TC 307	Blockchain and distributed ledger technologies	ISO
ISO/TC 314	Ageing societies	ISO

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

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International
ISO/IEC JCT 1/SC 42
Artificial Intelligence

ISO

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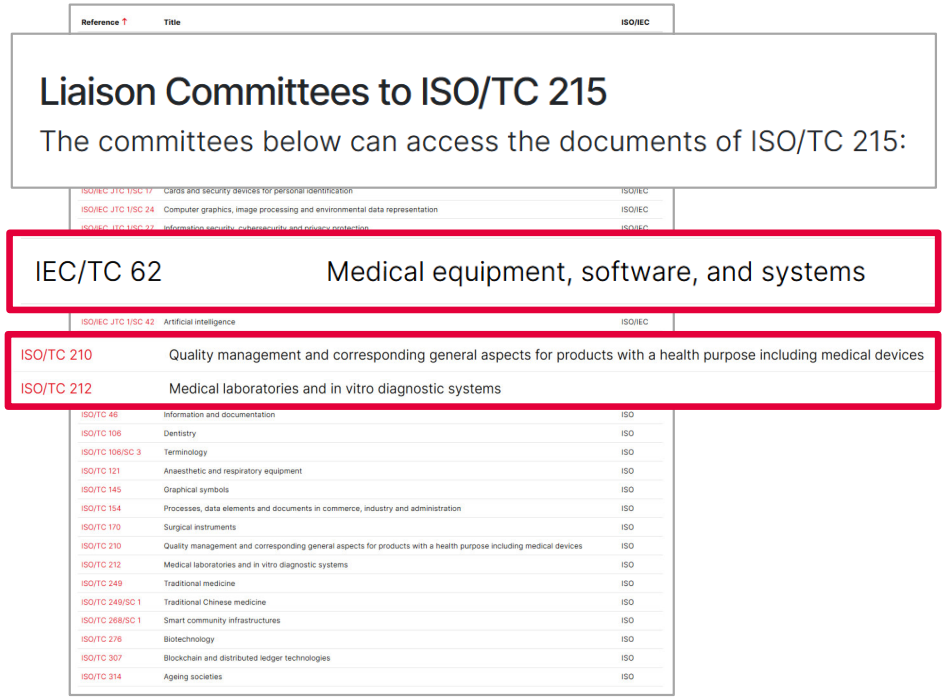
JTC 21 Artificial Intelligence | CEN CENELEC

Europa
CEN-CENELEC JCT 21
AI – WG 1 - 5

DIN DKE

National
DIN/DKE NA 043-01-42 GA
„Künstliche Intelligenz“
AK – 2, 3, 4, 5



Prof. Dr. Folker Spitzenberger

Standardization Committees and Status of Standardization

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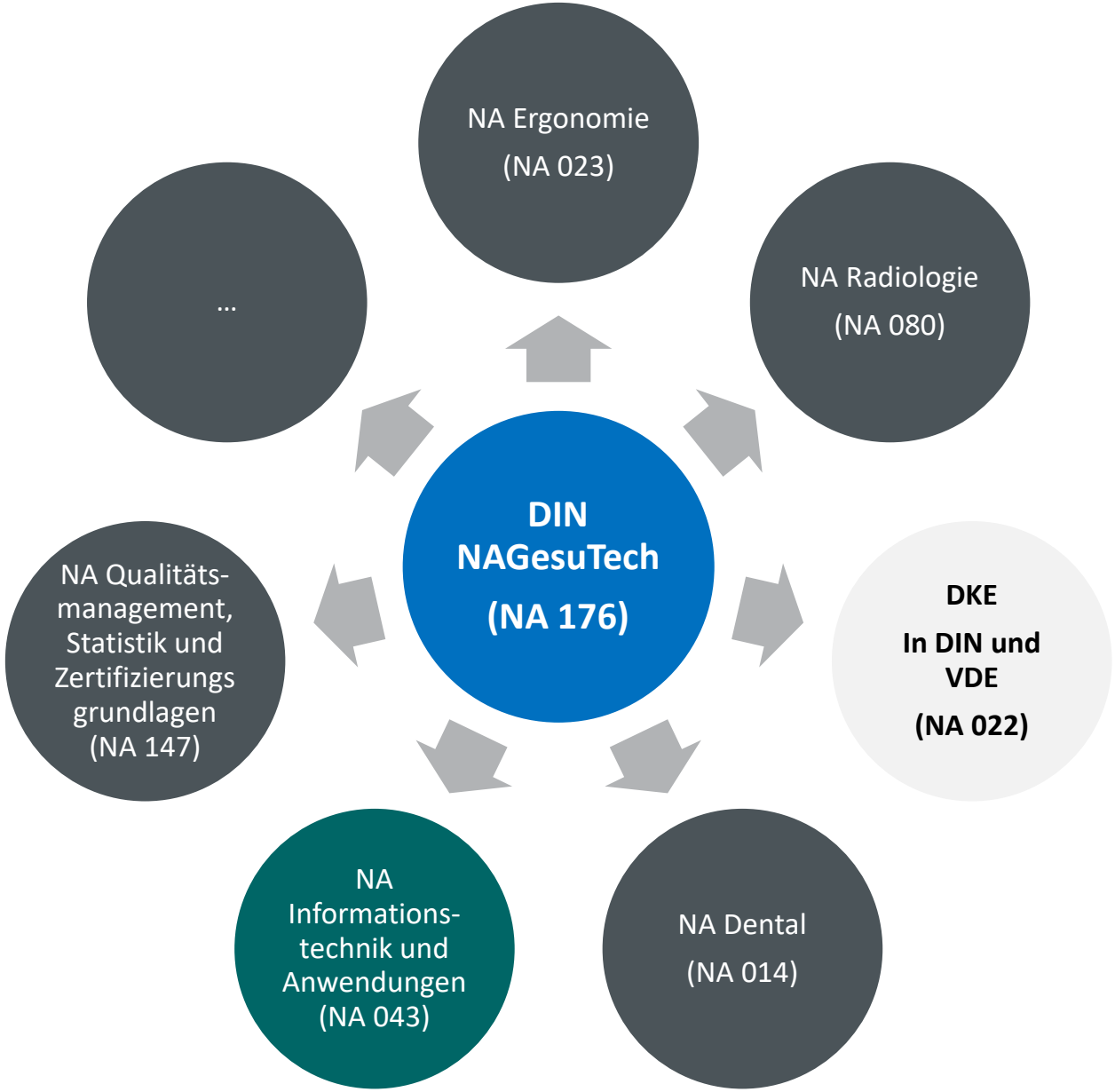

Standardization Committees and Status of Standardization

TECHNISCHE HOCHSCHULE LÜBECK

NA 176

DIN-Normenausschuss Gesundheitstechnologien (NAGesuTech)

Über NAGesuTech | Projekte | Entwürfe | Veröffentlichungen | Ersatzlose Zurückziehungen | Nationale Gremien | Europäische Gremien | Internationa

Nationale Gremien von NA 176

Anzahl: 11

Kurzbezeichnung	Name	Untergremien
NA 176 BR	Beirat des DIN-Normenausschuss Gesundheitstechnologien	0
NA 176-01 FB	Fachbereich Systeme und Prozesse im Gesundheitswesen	8
NA 176-02 FB	Fachbereich Medizinische Informatik	6
NA 176-03 FB	Fachbereich Produkte und Verfahren für die Reinigung, Desinfektion, Sterilisation und Aseptik	11
NA 176-04 FB	Fachbereich Systeme für Infusion, Wundversorgung sowie Prävention	11
NA 176-05 FB	Fachbereich Respiratorische Produkte und Anlagen	6
NA 176-06 FB	Fachbereich Hilfen für Menschen mit Behinderungen sowie Produkte und Systeme zur Teilhabe am Alltag	10
NA 176-07 FB	Fachbereich Rettungsdienstliche Systeme	3
NA 176-08 FB	Fachbereich Labor und Diagnostik	8
NA 176-09 FB	Fachbereich Biotechnologie	3

Standardization Committees and Status of Standardization

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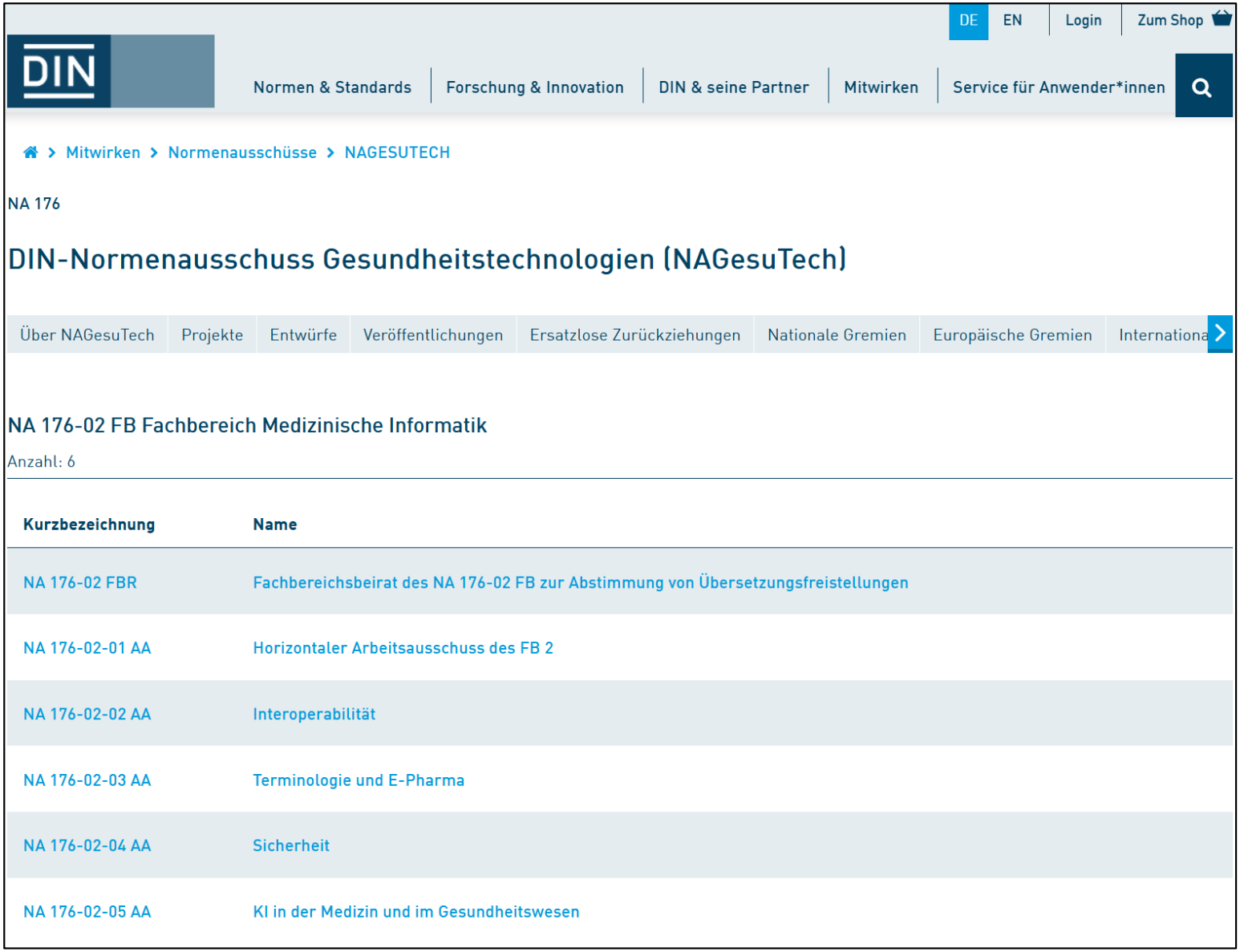

Standardization Committees and Status of Standardization

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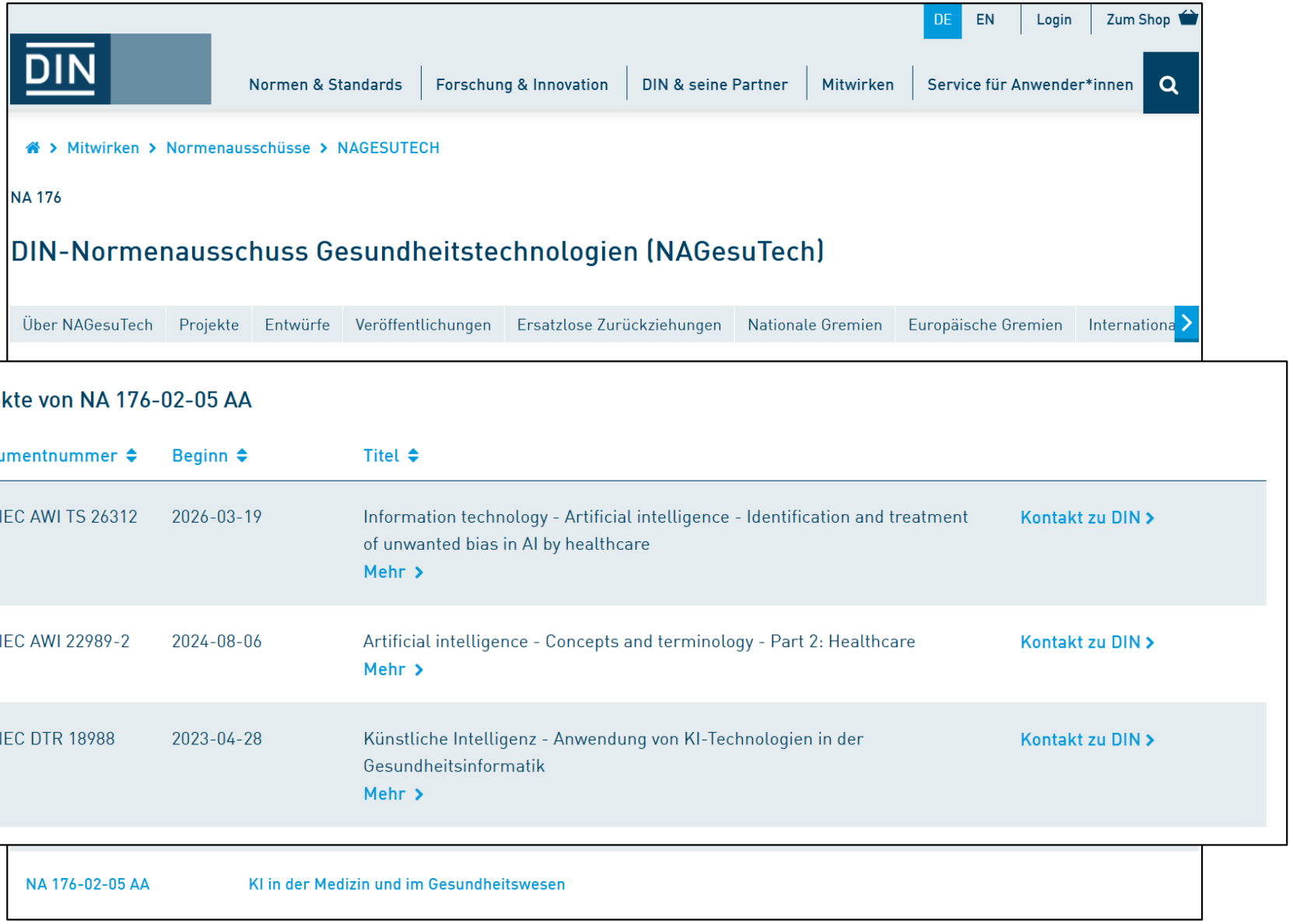

Challenges in standardization

TECHNISCHE HOCHSCHULE LÜBECK

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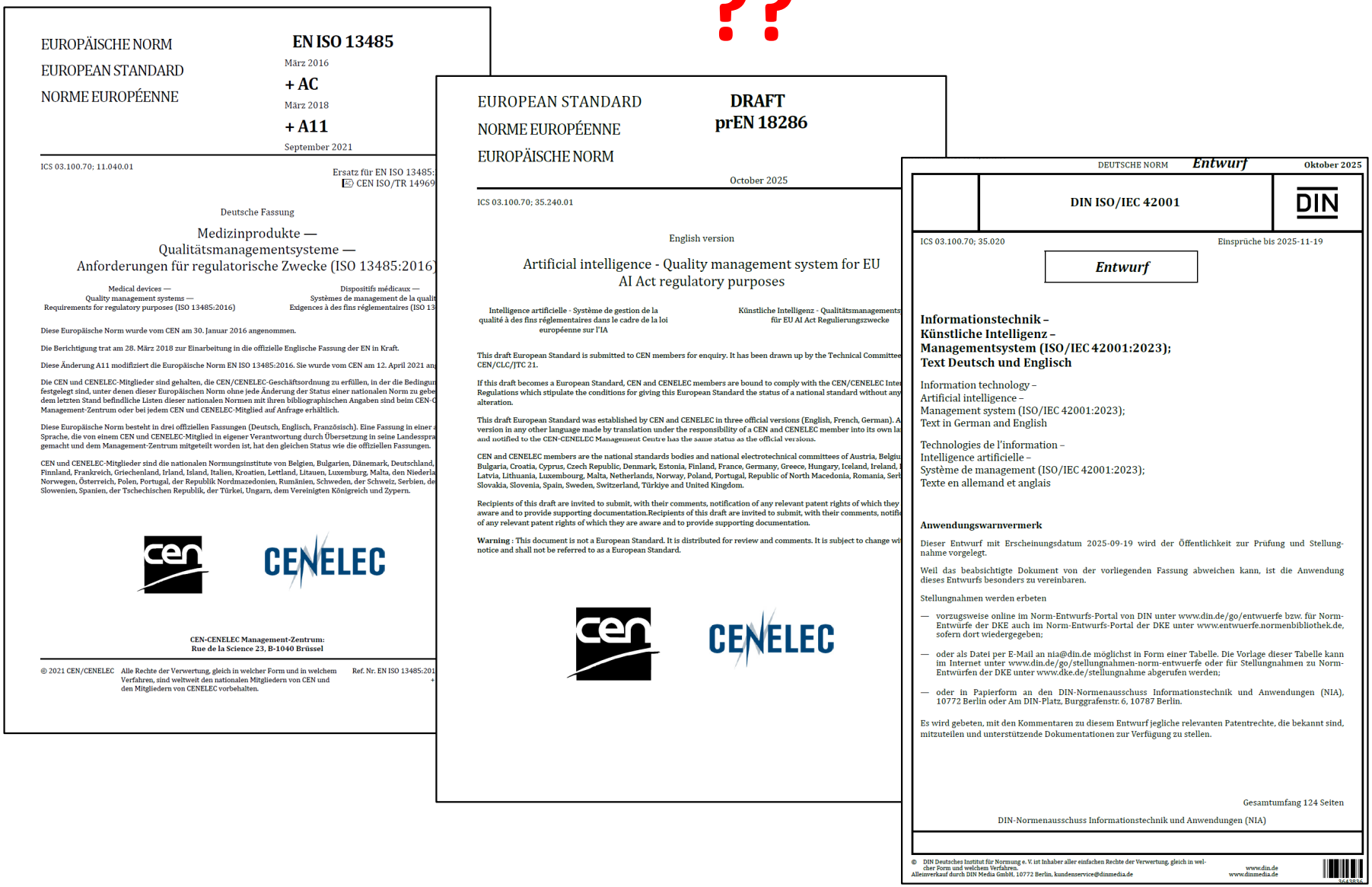

EUROPÄISCHE NORM
EUROPEAN STANDARD
NORME EUROPÉENNE

EN ISO 13485
März 2016
+ AC
März 2018
+ A11
September 2021

ICS 03.100.70; 11.040.01

Ersatz für EN ISO 13485:
CEN ISO/TR 14969

Deutsche Fassung

Medizinprodukte —
Qualitätsmanagementsysteme —
Anforderungen für regulatorische Zwecke (ISO 13485:2016)

Medical devices —
Quality management systems —
Requirements for regulatory purposes (ISO 13485:2016)

Dispositifs médicaux —
Systèmes de management de la qualit
Exigences à des fins réglementaires (ISO 13

Diese Europäische Norm wurde vom CEN am 30. Januar 2016 angenommen.

Die Berichtigung trat am 28. März 2018 zur Einarbeitung in die offizielle Englische Fassung der EN in Kraft.

Diese Änderung A11 modifiziert die Europäische Norm EN ISO 13485:2016. Sie wurde vom CEN am 12. April 2021 an

Die CEN und CENELEC-Mitglieder sind gehalten, die CEN/CENELEC-Geschäftsordnung zu erfüllen, in der die Bedingur festgelegt sind, unter denen dieser Europäischen Norm ohne jede Änderung der Status einer nationalen Norm zu gebe dem letzten Stand befindliche Listen dieser nationalen Normen mit ihren bibliographischen Angaben sind beim CEN-C Management-Zentrum oder bei jedem CEN und CENELEC-Mitglied auf Anfrage erhältlich.

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CEN-CENELEC Management-Zentrum:
Rue de la Science 23, B-1040 Brüssel

Ref. Nr. EN ISO 13485:201

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 18286

October 2025

ICS 03.100.70; 35.240.01

English version

Artificial intelligence - Quality management system for EU AI Act regulatory purposes

Intelligence artificielle - Système de gestion de la qualité à des fins réglementaires dans le cadre de la loi européenne sur l'IA

Künstliche Intelligenz - Qualitätsmanagements für EU AI Act Regulierungszwecke

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/CLC/JTC 21.

If this draft becomes a European Standard, CEN and CENELEC members are bound to comply with the CEN/CENELEC Inte Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN and CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own la and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgiu Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serb Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change wi notice and shall not be referred to as a European Standard.

DEUTSCHE NORM ***Entwurf*** **Oktober 2025**

DIN ISO/IEC 42001

DIN

ICS 03.100.70; 35.020

Einsprüche bis 2025-11-19

Entwurf

Informationstechnik –
Künstliche Intelligenz –
Managementsystem (ISO/IEC 42001:2023);
Text Deutsch und Englisch

Information technology –
Artificial intelligence –
Management system (ISO/IEC 42001:2023);
Text in German and English

Technologies de l'information –
Intelligence artificielle –
Système de management (ISO/IEC 42001:2023);
Texte en allemand et anglais

Anwendungswarnvermerk

Dieser Entwurf mit Erscheinungsdatum 2025-09-19 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil das beabsichtigte Dokument von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

Stellungnahmen werden erbeten

— vorzugsweise online im Norm-Entwurfs-Portal von DIN unter www.din.de/go/entwuerfe bzw. für Norm-Entwürfe der DKE auch im Norm-Entwurfs-Portal der DKE unter www.entwuerfe.normenbibliothek.de, sofern dort wiedergegeben;

— oder als Datei per E-Mail an nia@din.de möglichst in Form einer Tabelle. Die Vorlage dieser Tabelle kann im Internet unter www.din.de/go/stellungnahmen-norm-entwuerfe oder für Stellungnahmen zu Norm-Entwürfen der DKE unter www.dke.de/stellungnahme abgerufen werden;

— oder in Papierform an den DIN-Normenausschuss Informationstechnik und Anwendungen (NIA), 10772 Berlin oder Am DIN-Platz, Burggrafenstr. 6, 10787 Berlin.

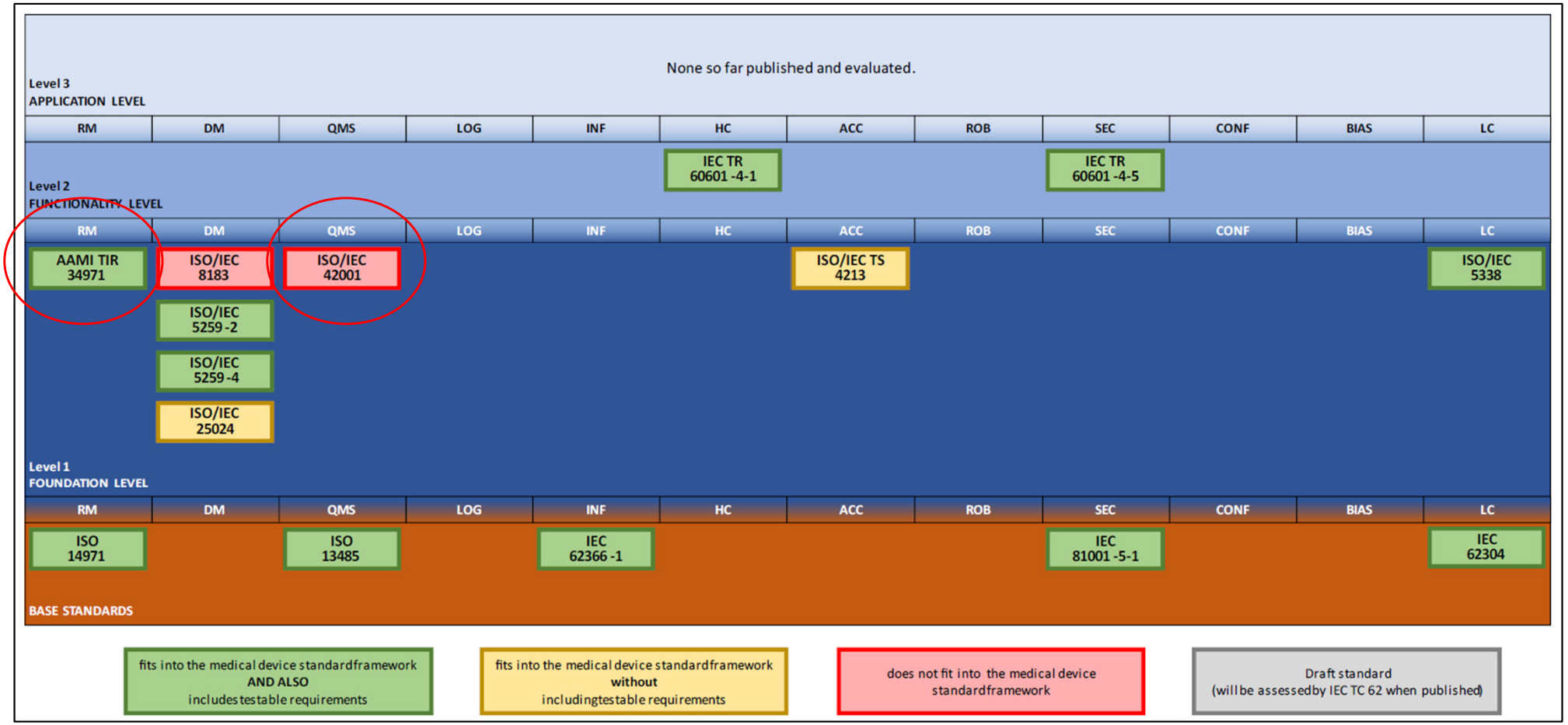
Es wird gebeten, mit den Kommentaren zu diesem Entwurf jegliche relevanten Patentrechte, die bekannt sind, mitzuteilen und unterstützende Dokumentationen zur Verfügung zu stellen.

Gesamtumfang 124 Seiten

DIN-Normenausschuss Informationstechnik und Anwendungen (NIA)

...

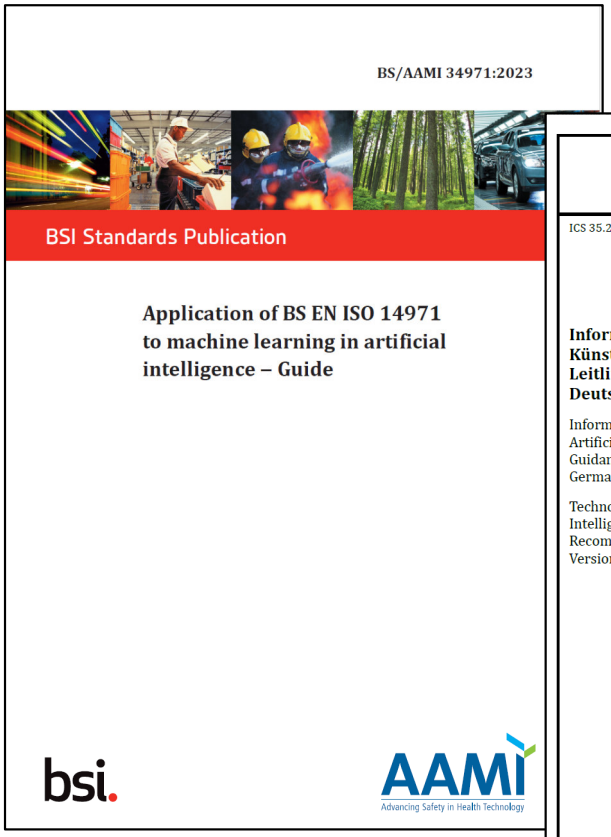
Challenges in standardization



Source: IEC TECHNICAL COMMITTEE 62: Standards suitable to be used for the development of AI/ML standards in the medical area (confirmed by IEC TC 62 "Medical equipment, software and systems"); Document 62/502A/INF, 2024-09-13, developed by SNAIG (Software Network and Artifical Intelligence advisory Group)

Challenges in standardization

TECHNISCHE HOCHSCHULE LÜBECK



BS/AAMI 34971:2023

BSI Standards Publication

Application of BS EN ISO 14971 to machine learning in artificial intelligence – Guide

bsi.

AAMI
Advancing Safety in Health Technology

DEUTSCHE NORM

DIN EN ISO/IEC 23894

ICS 35.240.01

**Informationstechnik –
Künstliche Intelligenz –
Leitlinien für Risikomanagement (ISO/IEC 23894:2023);
Deutsche Fassung EN ISO/IEC 23894:2024**

Information technology –
Artificial intelligence –
Guidance on risk management (ISO/IEC 23894:2023);
German version EN ISO/IEC 23894:2024

Technologies de l'information –
Intelligence artificielle –
Recommandations relatives au management du risque (ISO/IEC 23894:2023);
Version allemande EN ISO/IEC 23894:2024

Gesamtumfang

DIN-Normenausschuss Informationstechnik und Anwendungen (NIA)

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www.din.de
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3525013

ISO IEC

FINAL DRAFT
Technical Specification

ISO/DTS 24971-2

Medical devices — Guidance on the application of ISO 14971 —

Part 2:
Machine learning in artificial intelligence

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2025-08-28

Voting terminates on:
2025-11-20

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DTS 24971-2:2025(en)

EUROPÄISCHE NORM
EUROPEAN STANDARD
NORME EUROPÉENNE

EN ISO 14971
Dezember 2019
+ A11
Dezember 2021

ICS 11.040.01

Ersetzt EN ISO 14971:2012

Deutsche Fassung

Medizinprodukte —
Anwendung des Risikomanagements auf Medizinprodukte
(ISO 14971:2019)

Medical devices —
Application of risk management to medical devices
(ISO 14971:2019)

Dispositifs médicaux —
Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)

Diese Europäische Norm wurde vom CEN am 5. August 2019 angenommen. Die Änderung A11 modifiziert die Europäische Norm EN ISO 14971:2019. Sie wurde vom CEN am 27. Oktober 2021 angenommen.

Die CEN- und CENELEC-Mitglieder sind gehalten, die CEN/CENELEC-Geschäftsordnung zu erfüllen, in der die Bedingungen festgelegt sind, unter denen dieser Europäischen Norm ohne jede Änderung der Status einer nationalen Norm zu geben ist. Auf dem letzten Stand befindliche Listen dieser nationalen Normen mit ihren bibliographischen Angaben sind beim CEN-CENELEC-Management-Zentrum oder bei jedem CEN- und CENELEC-Mitglied auf Anfrage erhältlich.

Diese Europäische Norm besteht in drei offiziellen Fassungen (Deutsch, Englisch, Französisch). Eine Fassung in einer anderen Sprache, die von einem CEN- und CENELEC-Mitglied in eigener Verantwortung durch Übersetzung in seine Landessprache gemacht und dem CEN-CENELEC-Management-Zentrum mitgeteilt worden ist, hat den gleichen Status wie die offiziellen Fassungen.

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cen CENELEC

EUROPÄISCHES KOMITEE FÜR NORMUNG
EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION

CEN-CENELEC Management-Zentrum: Rue de la Science 23, B-1040 Brüssel

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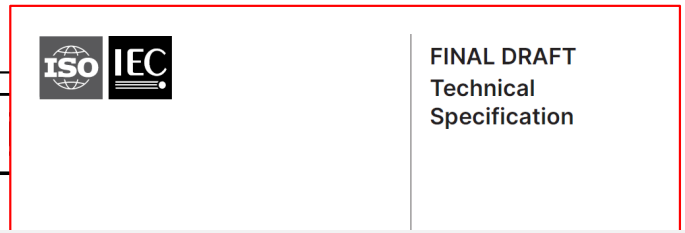
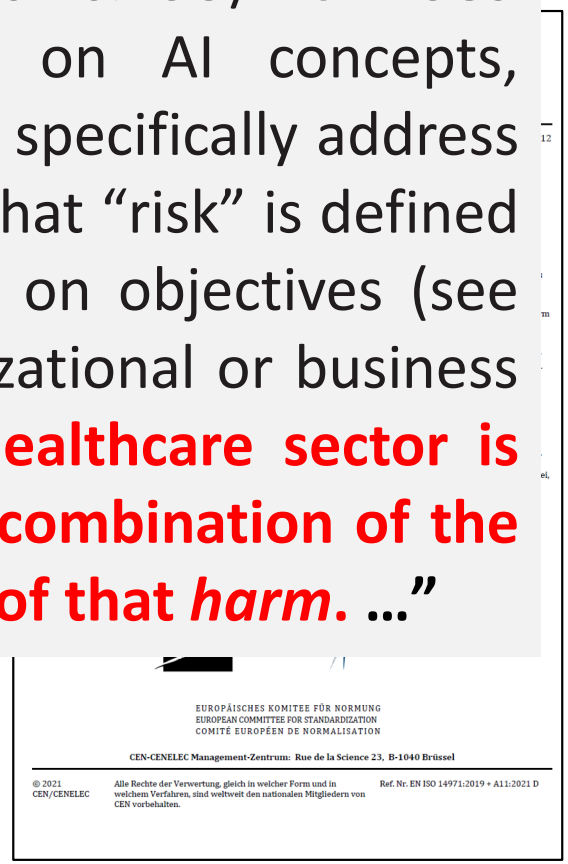
Ref. Nr. EN ISO 14971:2019 + A11:2021 D

Challenges in standardization

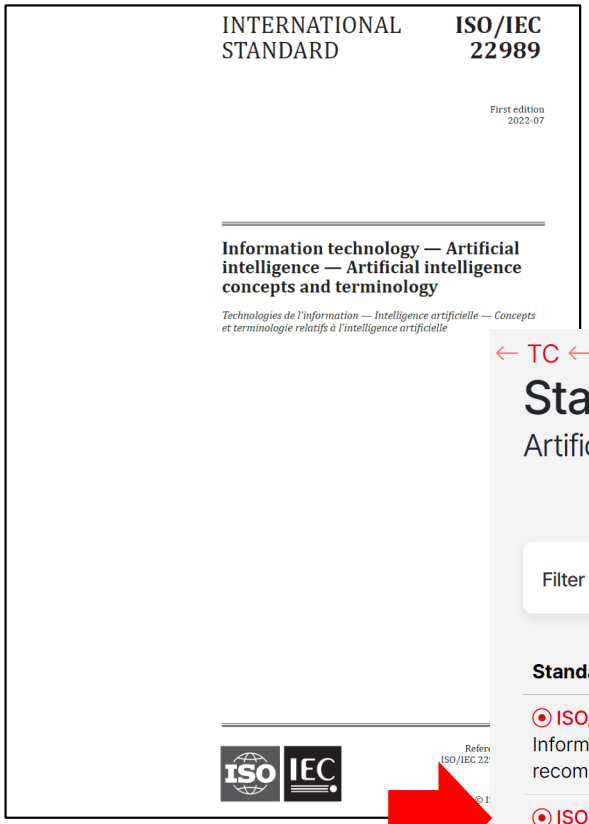
TECHNISCHE HOCHSCHULE LÜBECK



"… Many different AI-based technologies and algorithms exist today, including decision trees, genetic algorithms and deep learning-based technologies such as generative AI and neural networks. ISO/IEC 22989 and ISO/IEC 23894 provide general guidance on AI concepts, terminology and *risk management*, but they do not specifically address the application of AI to *medical devices*. It is noted that "risk" is defined in these documents as the effect of uncertainties on objectives (see also ISO 31000). 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*. …"**



Challenges in standardization



INTERNATIONAL STANDARD **ISO/IEC 22989**

First edition
2022-07

Information technology — Artificial intelligence — Artificial intelligence concepts and terminology

Technologies de l'information — Intelligence artificielle — Concepts et terminologie relatifs à l'intelligence artificielle

ISO IEC

← TC ← ISO/IEC JTC 1

Standards by ISO/IEC JTC 1/SC 42

Artificial intelligence

Filter [48] : Published | Under development | Withdrawn | Deleted | Search in the list

Standard and/or project under the direct responsibility of ISO/IEC JTC 1/SC 42 Secretariat ↑	Stage	ICS
ISO/IEC DIS 4213 [Under development] Information technology — Artificial Intelligence — Performance measurement for AI classification, regression, clustering and recommendation tasks	40.00	35.240.01
ISO/IEC DTR 18988 [Under development] Artificial intelligence — Application of AI technologies in health informatics	50.00	35.240.80
ISO/IEC CD TS 22440-1 [Under development] Artificial intelligence — Functional safety and AI systems — Part 1: Requirements	30.60	
ISO/IEC CD TS 22440-2 [Under development] Artificial intelligence — Functional safety and AI systems — Part 2: Guidance	30.60	
ISO/IEC CD TS 22440-3 [Under development] Artificial intelligence — Functional safety and AI systems — Part 3: Examples of application	30.60	
ISO/IEC DTS 22443 [Under development] Information technology — Artificial intelligence — Guidance on addressing societal concerns and ethical considerations	50.00	35.020
ISO/IEC AWI 22989-2 [Under development] Artificial intelligence — Concepts and terminology — Part 2: Healthcare	20.00	
ISO/IEC 22989:2022/DAmd 1 [Under development] Information technology — Artificial intelligence — Artificial intelligence concepts and terminology — Amendment 1: Generative AI	40.60	35.020 01.040.35

Challenges in standardization

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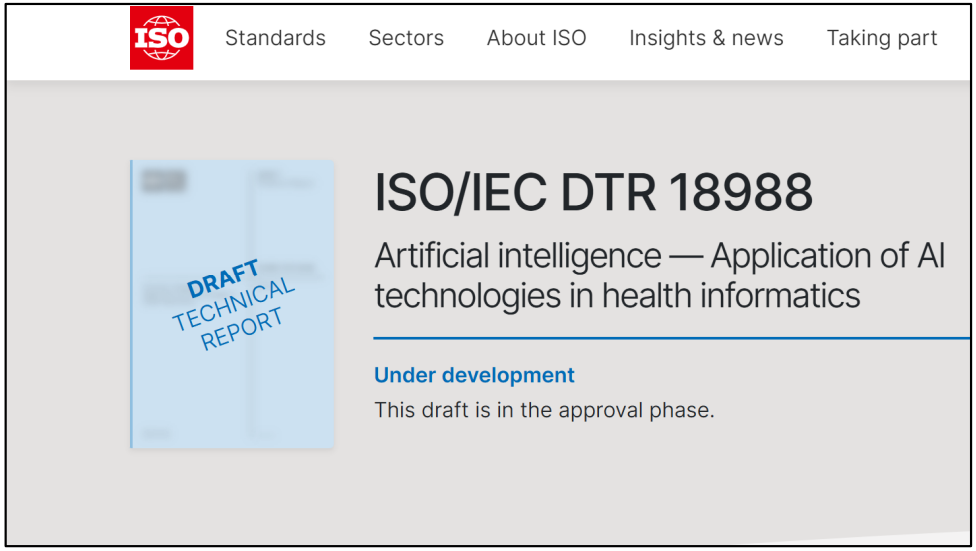

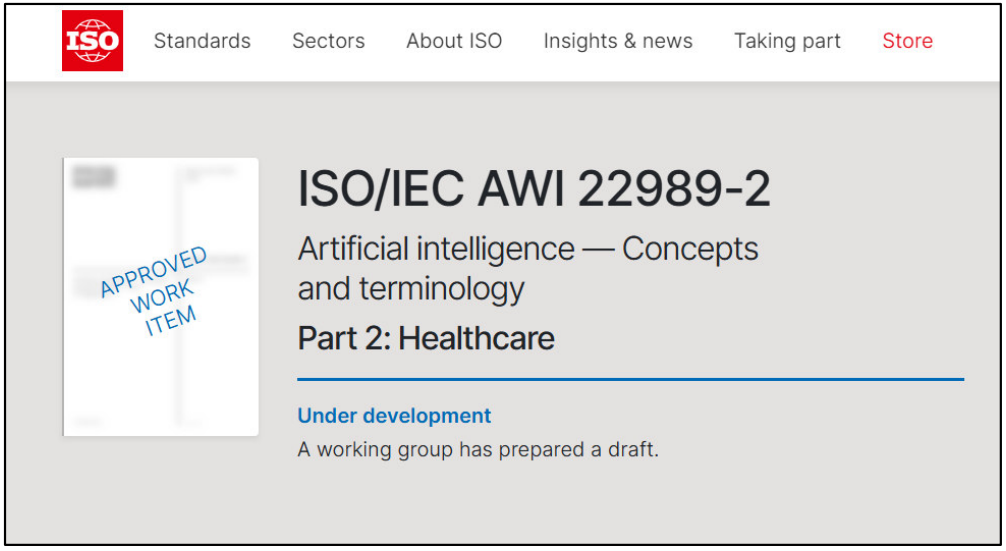

„… This document will describe the properties, factors, available methods and processes relating to the use of AI in health informatics to effectively realize the potential benefits for healthcare use cases. This document will identify use of AI in healthcare, for purposes of developing AIHI related standards, such as mapping and categorization, and point out the differences to generic AI …“

https://www.iso.org/standard/85602.html

„This document establishes terminology for AI and describes concepts in the field of AI for healthcare. This document can be used in the development of other standards and in support of communications among diverse, interested parties or stakeholders. This document is applicable to all types of organizations … .“

https://www.iso.org/standard/89456.html

Challenges in standardization

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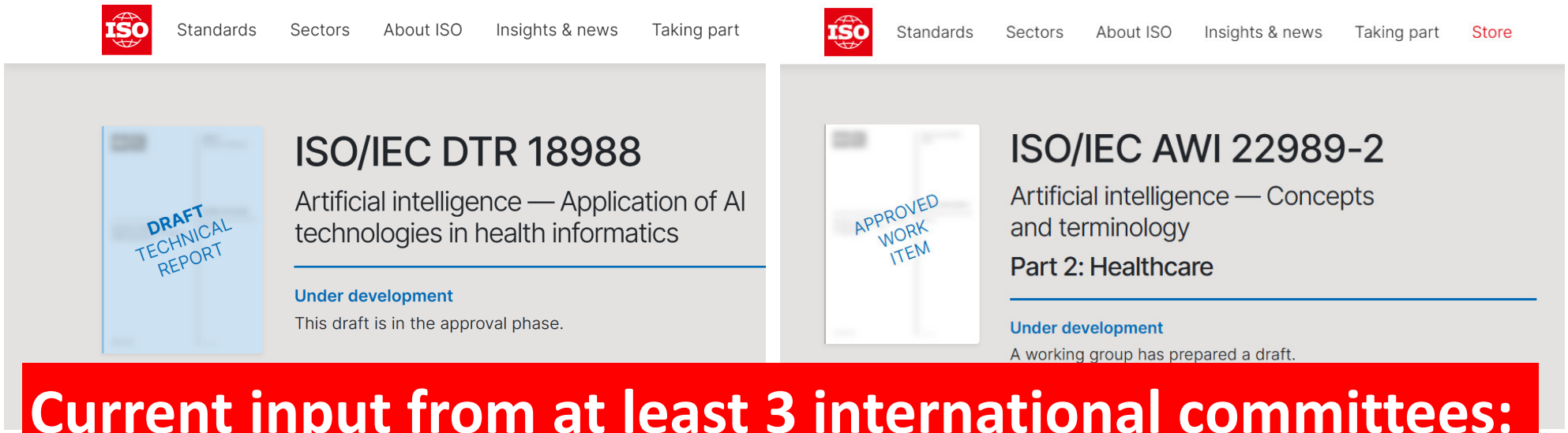

Current input from at least 3 international committees: ISO/IEC JTC 1/SC 42 – ISO TC 215 – IEC TC 62 - …

relating to the use of AI in health informatics to effectively realize the potential benefits for healthcare use cases. This document will identify use of AI in healthcare, for purposes of developing AIHI related standards, such as mapping and categorization, and point out the differences to generic AI …“

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Conclusions and options for standardization

TECHNISCHE HOCHSCHULE LÜBECK

Tagesordnung zur 28. Sitzung Berlin des NA 176-01-02 AA am 17. Juni 2026 WebEx

TOP		Schriftstücknr.
10.1	**Harmonisierung internationaler Normen**	
	- **Überführung/Harmonisierung internationaler KI-Normen in Europa?** - AI-Act: wie können sektorspezifische KI-Normen erstellt werden? Beispiel CENCLC TC 62?	
	- **Austausch mit KI-Ausschuss NA 176-02-05 AA**	
11	**Verschiedenes** — Überarbeitung der ISO 9001	
12	**Datum und Ort der nächsten Sitzung**	
13	**Genehmigung der Beschlüsse und Aktionen dieser Sitzung**	
14	**Schließung der Sitzung**	

Conclusions and options for standardization

TECHNISCHE HOCHSCHULE LÜBECK

Tagesordnung zur 28. Sitzung Berlin des NA 176-01-02 AA am 17. Juni 2026 WebEx

TOP	Schriftstücknr.
10.1 **Harmonisierung internationaler Normen**	

„AI-Landschaft: Auswirkungen auf zukünftige Normungsvorhaben

*Es wurde erörtert, dass die Branche … darlegen könnte, dass die **Bewertung von KI im Rahmen der MDR** erfolgt, **sofern hierfür geeignete Normen** vorliegen. Entsprechende europäische Normen stehen derzeit jedoch noch nicht zur Verfügung. Verwiesen wurde auf laufende bzw. bereits abgeschlossene **Aktivitäten von IEC im Bereich KI-Normung**. …*

*Im weiteren Verlauf wurde die Frage erörtert, wer sich in Europa **darum kümmern** sollte, **internationale KI-Normen in europäische Normen zu überführen**. In diesem Zusammenhang wurde auf … die mandatierten KI-Normen Bezug genommen sowie die Frage gestellt, **wie sektorspezifische Normen entwickelt werden können**. Als möglicher Anknüpfungspunkt wurde **CEN/CLC/TC 62** genannt, das über eine **Arbeitsgruppe zur Harmonisierung von Medizinproduktenormen** verfügt …*

*Abschließend wurde angemerkt, dass **Normung** in diesem Bereich voraussichtlich **nur eingeschränkt** als Business Case für Marktteilnehmer **attraktiv** ist, da sich **KI-Technologien sehr schnell weiterentwickeln** und **Normungsprozesse damit nur begrenzt Schritt halten** können. …“*

Source: 2026-03-24 Protocol excerpt NA 176-01-02 AA

Conclusions and options for standardization

TECHNISCHE HOCHSCHULE LÜBECK

- There are essentially two options for standardization in the field of AI in medical technology: 1. The application of overarching, horizontally applicable standards is combined with specific, sector-oriented standards for medical technology, or 2. Only specific standards focused on the AI sector in medical technology are used.
- In the EU, the choice of options is linked to the obligation to apply the relevant European legislation (see EU Proposal of 16 December 2025 and "Digital Omnibus on AI").
- Both options offer opportunities and risks regarding the transparency, consistency, and usability of the standards.
- The rapid pace of advancing AI technology contrasts sharply with the speed of complex standardization processes at the European and international levels.
- Interdisciplinary collaboration and communication between the standardization committees is essential.

TECHNISCHE HOCHSCHULE LÜBECK

Thank you.

The author of this presentation is chairman of the DIN committee NA 176-08-08 AA "Quality management in medical laboratories„ (mirror committee of ISO TC 212) and member of various working groups of the standardization committees ISO TC 210, ISO TC 212, IEC TC 62 ahG 9, IEC TC 62 JAG 5, CEN TC 140 and the corresponding national mirror committees at DIN.

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