A Systematic Review of the Current Legal Position of eHealth Standards in Norway

Marianne Lodvir Hemsing
Department of Business, Strategy and Political Science
University of South-Eastern Norway
Kongsberg, Norway
e-mail: mlhemsing@gmail.com

Abstract— **This systematic review investigates how Norwegian courts engage with technical standards and European Conformity (CE) marking in legal disputes involving eHealth and medical software. Although European regulation increasingly relies on harmonised standards, a systematic screening of 36 legal decisions from the national case-law database Lovdata Pro (2015–2025) found only five cases referencing either standards or CE-marking, and in none were these references determinative. Standards appeared as supportive background at best, and CE-marks were invoked as compliance signals rather than legal authority. These findings suggest that, unless legally "activated" via regulation or contract, technical standards play little role in litigation. The study offers a legal baseline ahead of European Health Data Space (EHDS) rollout and provides recommendations for improving the enforceability of standards in Norway.**

Keywords-Health Technology; Medical Software; Standards; Policy in Digital Health.

I. INTRODUCTION

Digital-health software ranges from Electronic Health-Record (EHR) systems, diagnostic software, and mobile apps to Software as a Medical Device (SaMD) governed by EU (European Union) Regulation. eHealth solutions and digital health tools increasingly rely on standards for quality, safety, security, and interoperability - and regulatory alignment to function effectively within and across national health systems [1][2].

Three major EU instruments define the regulatory landscape for digital health. The Medical Device Regulation (MDR) [3], and the In Vitro Diagnostic Medical Devices (IVDR) Regulation [4], requires SaMD and diagnostic software to be marked according to European Conformity (CE), and conform to essential safety and performance requirements. The European Health Data Space (EHDS) Regulation [5], effective since March 2025, establishes interoperability obligations for EHR systems and health-data access services.

European Technical standards are drafted by consensus by the formal European Standardization Development Organizations (SDOs) European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), and European Telecommunications Standards Institute (ETSI). Standards remain voluntary unless incorporated in law, regulation or contract [6]. Once cited in the Official Journal of the European Union (OJEU), they become harmonised standards [7] and confer a rebuttable presumption of conformity to EU regulation [8]. There are as of September 2025, 44 harmonised standards related to MDR and IVDR (not all related to eHealth).

The standardization landscape is complex, as of June 2025 ISO's Technical Committee for Health Informatics had published 242 standards [9], and CEN's had published 118 [10]. In addition, there are standards from the other SDOs and standardization bodies outside the formal European standardization system, such as Health Level Seven (HL7). EU's New Legislative Framework [11] are based on legislators drafting "essential requirements," while the European Standardization bodies supply detailed solutions. The European Standardization Strategy [6] reinforces this model.

Several studies and rulings have highlighted the complex relationship between technical standards and legal transparency in the EU, and the blurred line between hard and soft law. In the *Public.Resource.Org* case [12], the General Court of the European Union ruled that harmonised standards incorporated into EU law must be publicly accessible, as they form part of the legal order. This decision underscored growing concerns about the accessibility of legal norms developed through private standardisation bodies.

Building on this theme, researchers have argued that the paywalled nature of harmonised standards poses a structural barrier to their legal enforceability and public legitimacy [13]. This suggests that unless such standards are freely available and embedded into binding legal texts, they are unlikely to feature prominently in litigation or regulatory practice.

In Norwegian law, national standards are referenced in the Regulation on IT Standards in Health and Care Services [14], which mandates the use of specific standards for interoperability, messaging, and security in eHealth systems. In addition, the Norwegian Product Control Act [15], which establishes a general duty of care for safe products and technologies, identifies adherence to national or EU harmonised standards as an indicator of responsible practice.

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org

This creates a potential legal basis for invoking standards in negligence claims.

Menon Economics found in 2022 that references to standards are becoming more common in Norwegian regulations [16], yet there remains limited understanding of how courts treat such references in actual legal disputes.

Previous research suggests that standardization that relies on informal, consensus-driven public–private models, may hinder downstream legal enforceability in Norway [17]. Furthermore, research by Lindøe et al. [18] have identified three necessary legal hooks for standards to be influential in legal proceedings in Norway (the research did however not consider harmonized standard separately or eHealth specifically):

(1) explicit reference in contracts,

(2) incorporation into regulations or delegated law, and

(3) use in negligence assessments to define reasonable conduct.

No study has examined how Norwegian courts treat National and European standards in digital health disputes specifically. This paper provides a systematic legal review of Norwegian court practice on e-health standards, based on analysis of legal decisions from public legal records in Norway from the last decade. The aim is to determine whether, when, and how courts cite or rely on standards, and to offer a baseline for evaluating EHDS implementation in future litigation.

The remainder of this paper is structured as follows: Section 2 details the quantitative and qualitative method, Section 3 presents and discuss the findings, limitations and future research. Section 4 draws the conclusions.

II. METHODOLOGY

This study followed the PRISMA 2020 guidelines for systematic review [19]. The checklist, systematic review protocol, and strategy (including search terms, keyword logic, scripts, and classification scheme), is available at [20]. All legal data were sourced from Lovdata Pro, Norway's official case-law repository, which contains full-text judgments across all national court levels [21].

To capture the full scope of court decisions related to eHealth software, medical device software, and digital health technologies, two full-text Boolean searches were designed. These combined key words using logical AND/OR across two thematic fields (one term related to "software," one related to "health"). Searches were case-insensitive and used open-ended wildcards to capture inflectional forms. The time window was set from 1 January 2015 to 31 March 2025.

The search was structured as follows:

- Set 1 (software terms): technology*, informatics*, health record*, app, application*, software*
- Set 2 (health terms): health*, ehealth*, medicine*

The Boolean operator AND was applied between Set 1 and Set 2, requiring at least one keyword from each set to appear in the full text.

The dataset was in the initial analysis coded using a Python Script with a predefined coding scheme, as described in Table 1. Negatives were excluded from the dataset.

TABLE I. CASE CLASSIFICATION

Code	Description
eHealth	Case related to eHealth, Health Informatics, Medical app or technology
Standard	Cites an International, European or Norwegian Standard
MDR/IVDR/ CE	Cites the MDR, IVDR, references CE-Marking, references Harmonised Standards or OJEU

The following exclusion criteria was used:

- First Exclusion: Judgments unrelated to eHealth, medical technology, or software used in healthcare (including EHRs, apps, SaMD, CE-marked technology etc).
- Second Exclusion: Judgments unrelated to MDR, IVDR, CE-Marking, National or European Standards or OJEU
- Unit of analysis: Each full-text court decision.

After the initial quantitative screen, an interpretive, in-depth review of the full-text of each case was performed, to understand how each reference entered the legal reasoning and what weight the court gave it. For the identified qualitative sample, Case ID and date, Case summary, gateway (contract clause, regulation, negligence, or factual background), outcome role (determinative, supportive, descriptive), and cited standard(s) were recorded.

Figure 1 shows the PRISMA flow of records through the systematic review.

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org

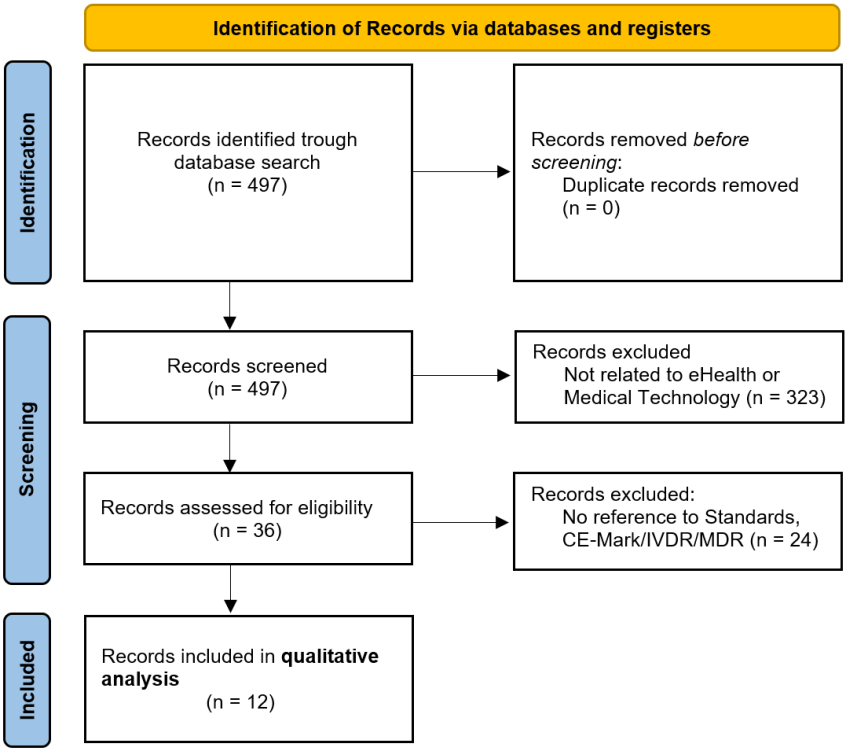

Figure 1. PRISMA Flow.

III. RESULTS

The database search yielded 497 judgments from the Norwegian legal database Lovdata Pro. After screening duplicates and irrelevant cases, a total of 36 legal decisions were identified as involving eHealth software, health information systems, or medical technologies. Among these, 12 cases were shortlisted as candidates for potentially involving references to technical standards or regulatory conformity frameworks.

A detailed qualitative analysis of these 12 cases revealed that only two decisions explicitly cited a formal technical standard. Notably, both of these cases also referenced CE-marking, suggesting that the standard citation was connected to product conformity documentation or procurement specifications. An additional three cases mentioned CE-marking without referencing any technical standard.

The remaining seven cases in the shortlist contained indirect references (such as mentions of regulatory requirements, compliance duties, or safety documentation) but did not directly cite or reference a standard or discuss CE-marking. The full list of the 12 cases is provided in Table 2, with cases referencing standards marked in Green and those citing CE-marking alone marked in Yellow.

These results suggest that while regulatory terminology may appear in health-tech litigation, direct engagement with standards remains rare.

TABLE II. CASE SUMMARY

Case no.	Subject	Standards in the reasoning
1	EPJ privacy dispute (2024)	Court reviews General Data Protection Regulation (GDPR) & Norwegian privacy rules, CE-Marking discussed
2	Proton Therapy System procurement (2023)	Addresses tender law; standards never cited. CE-Marking part of dispute
3	Online patient portal (2022)	Liability question decided on negligence; standards not referenced.
4	Wellness-app tax case (2022)	VAT classification only; standards not referenced.
5	Hospital IT-system outage (2023)	Focus on employer liability; standards not referenced.
6	Tele-medicine platform (2022)	Contract damages; standards not referenced.
7	Forensic phone-extraction tool used on medical professionals' communication (2022)	Proportionality & evidentiary law; standards not referenced.
8	Biofeedback fitness device (2021)	VAT issue; Standards and CE-Marking is cited
9	Bone-cement system (2021)	Product-liability; CE-Marking is cited
10	Anaesthesia equipment failure (2020)	Liability assessed via expert opinion; Standards and CE-Marking cited
11	Pacemaker follow-up system (2016)	Medical negligence claim; standards not referenced.
12	Medical equipment for local health care centre (2015)	Local contractual disputes; standards not referenced.

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org

A. Two cases citing standards

The two cases citing standards are summarized in Table 3. Both cases mention internationally recognised medical-device standards and CE-marking, used as background evidence. The standards cited are in both cases EU harmonised standards, i.e., demonstrating conformity to EU Regulation (in this case MDR).

In neither judgment does conformity (or non-conformity) with those standards decide the legal result; the norms serve only as expert background or to show baseline regulatory approval.

Standards are informative, not determinative. The rulings rely on tax and negligence principles rather than on compliance or breach of the cited norms.

TABLE III. STANDARD CASES

Point	Case 8	Case 10
Type of dispute	VAT & civil-liability case about a bio-feedback / electro-stimulation fitness device ("Bailine method").	Product-liability / negligence case about an anaesthesia workstation that allegedly malfunctioned.
Standards invoked	Expert for the device owner cites ISO 13485 as proof the manufacturer operates an approved quality-management system.	Experts cite IEC 60601-1 (electrical safety) and its EMC collateral IEC 60601-1-2 to describe the minimum design-safety level for the workstation.
CE-marking	Mentioned once: the Bailine apparatus is CE-marked as a class-I device.	Mentioned twice: the workstation carried a CE-mark and Declaration of Conformity.
Weight given to the standards	Court's outcome (VAT classification) does not turn on ISO 13485; standard is noted but not analysed.	Court's finding (negligence) does not hinge on IEC 60601; standard is illustrative of good practice, not determinative.

B. Three cases citing CE-mark

Across the three cases, summarized in Table 4, CE-marking is raised only as baseline regulatory compliance. In all three cases it is cited to show that the product had a formal Declaration of Conformity for EU Regulations (MDR).

The courts treat the CE-mark as necessary but not sufficient. Each judgment acknowledges that CE-mark is a minimum legal threshold, yet it does not settle the central question (privacy breach, procurement legality, or product defect).

No judgment turns on a finding of CE non-compliance. In short, the three cases use CE-marking as background evidence of market approval, but the mark itself never drives the outcome, and no other technical standards are cited.

TABLE IV. CE-CASES

Case no.	Why CE-marking is mentioned	How the court treats it
1	Defendant hospital notes that the module is *"CE-marked as a Class IIa medical device."*	Court accepts that CE shows formal EU conformity but rules on GDPR/consent issues; CE is not part of the legal test.
2	Tender documents required every offered device to be CE-marked. Losing bidder claimed the winner lacked final CE paperwork.	Court finds the winner could submit missing certificates after award; CE is a procedural tender condition, not a ground to annul the contract.
9	Manufacturer stresses that the cement kit was CE-marked under MDD 93/42/EEC.	Court notes the mark but decides liability on causation/expert evidence; CE carries no decisive weight.

C. Discussion

1) The Peripheral Role of Standards in Norwegian Case Law

This systematic review found that only two of the 36 eHealth-related legal cases referenced a technical standard, and both of these also cited CE-marking. In neither instance did the standard serve as a decisive factor in the court's reasoning. Instead, courts resolved disputes based on general legal doctrines, such as negligence, contract interpretation, or procurement law.

This confirms the pattern observed by Lindøe et al. [18]: technical standards tend to shape legal reasoning only when they are linked to one of three legal gateways:

1. Explicit contract clauses (e.g., references in procurement tenders or service agreements),
2. Regulatory incorporation (e.g., CE-mark),
3. Negligence benchmarks (e.g., evidentiary use to define "reasonable care").

Absent these anchors, standards play at best a descriptive or supportive role. They may appear as evidence of good practice or industry norm, but not as legal authority in themselves.

2) CE-Marking: Binding, Visible, but Legally Passive

CE-marking appeared in five of the 36 analysed cases, more often than references to technical standards. In all five, CE-marking was acknowledged as proof of regulatory conformity. However, in no case did the court treat the CE-mark as determinative for liability, dismissal, or award of damages.

Courts appear to treat CE-marking as a higher-order legal norm than any individual standard. It is:

- Conferred by law, as required by the MDR and IVDR
- Presumed to indicate compliance with essential requirements, and
- Frequently cited in litigation as evidence of market access or eligibility.

Nonetheless, CE-marking remains procedurally visible but legally passive. In procurement cases, it functions as a

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org

formal requirement. In product liability or privacy cases, it confirms baseline regulatory status, but courts still ground their decisions in traditional doctrines of causation, contractual breach, or data protection law.

As Volpato [8] notes, harmonised standards confer only a presumption of conformity unless incorporated into law. CE-marking may be invoked in litigation, but it rarely shifts outcomes without additional legal support.

3) *Why Courts Rarely Engage Directly with Standards*

While the Menon Economics report [16], documents an increase in regulatory references to standards across Norwegian legislation, the findings of this review suggest that such references rarely translate into legal reasoning or judicial outcomes unless standards are explicitly invoked through regulation, contract, or negligence frameworks.

The absence of standards in most decisions may reflect structural and procedural features of judicial reasoning:

- Deference to higher-order sources: Courts prioritize statutes, contracts, and regulatory instruments over third-party norms like standards.
- Lack of formal legal status: Most standards are non-binding unless cited in law or incorporated by contract. As Heyerdahl [17] shows, even nationally supported standardization efforts in Norway may operate outside formal legal channels, limiting their ability to shape judicial reasoning.
- Access barriers: Many technical standards are paywalled, hindering their citation and judicial consultation.
- Technical complexity: Standards often require domain-specific interpretation. Judges may prefer expert testimony or official guidance instead.

Together, these factors may explain some of the reasons why courts, even in technically regulated sectors, engage only superficially with formal standards unless they are "activated" through legal incorporation.

4) *Implications for Regulators, Litigators, and Industry*

The findings highlight a broader policy challenge; if courts do not engage with standards directly, even when invoked in digital health, the expected legal alignment under the EU Regulation may fail to materialize unless legal instruments and contracts explicitly operationalise them.

This limited judicial engagement with standards and CE-marking has important consequences:

- For regulators: Forthcoming EHDS common specifications must be embedded in binding instruments (e.g., delegated acts, procurement law) if they are to influence future litigation.
- For procurers and vendors: To give technical norms contractual force, actors should cite specific technical standards) in tenders and contracts.
- For litigators: CE-marking should not be assumed sufficient to establish compliance. Where relevant, standards should be referenced directly in pleadings and supported by expert interpretation.
- For standardisation bodies: The *Public.Resource.Org* ruling by the EU General Court calls for greater transparency in public access to harmonised standards, to enable legal analysis and citation.

Without these steps, courts will continue to default to general doctrines, and technical standards, however sophisticated, may remain silent in legal practice.

IV. CONCLUSION AND FUTURE WORK

A. *Limitations and Future Work*

The dataset from the Norwegian database Lovdata Pro excludes unpublished settlements and administrative market-surveillance measures; it therefore captures only disputes that reached the courtroom. Because all cases appeared in distinct factual settings, caution is needed before generalising.

Screening may have missed records that employed atypical terminology; Keyword-based scraping may miss cases that describe software obliquely. However, the highly specific keyword-set and automated full-text search mitigate this risk.

Further research should replicate this study in some years in the future, after the EHDS Regulation and its first harmonised standards are in force, to measure any uptake shift. A survey for litigants and judges on whether pay-walled standards deter citation in pleadings, could potentially test the transparency hypothesis.

B. *Conclusion*

This systematic review shows that Norwegian courts seldom cite technical standards or CE-marking when adjudicating disputes in digital health. In a decade's worth of cases, only five referenced either, and none treated these references as legally determinative. Instead, courts relied on established doctrines of contract, negligence, or procurement law, treating standards and CE-marks as background context rather than binding authority.

These findings underscore the limited traction of technical standards in Norwegian legal reasoning, despite their central role in the MDR, IVDR, and broader EU digital health strategy. Unless standards are explicitly incorporated into law, regulation, or contract, they are unlikely to play a decisive role in courtroom outcomes.

For policymakers and industry, this highlights the need to anchor technical norms, such as those soon to emerge under the EHDS, in binding instruments and contractual frameworks if they are to have legal bite. CE-marking, while more frequently cited than individual standards, is also treated as a procedural or evidentiary formality, rather than a substantive safeguard or evidence in litigation.

This reinforces two strategic insights:

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org

- To give technical norms legal bite, anchor them in delegated regulations or procurement frameworks.
- To ensure contract enforcement, cite specific standards directly in agreements.

Absent such hooks, standards may remain invisible in litigation.

The study provides an empirical baseline for the legal treatment of eHealth standards in Norway prior of the EHDS implementation. Future research should revisit this landscape as new EU requirements take effect, and explore how accessibility, transparency, and legal embedding of standards may shift the role of technical norms in judicial decision-making.

REFERENCES

[1] Z. Wong, Y. Gong, and S. Ushiro, "A pathway from fragmentation to interoperability through standards-based enterprise architecture to enhance patient safety," *npj Digital Medicine,* vol. 8, no. 1, p. 41, January 2025.

[2] J. Scheibner, M. Ienca, J. Sleigh, and E. Vayena, "Benefits, Challenges and Contributors to Success for National eHealth Systems Implementation: A Scoping Review," *Journal of the American Medical Informatics Association : JAMIA,* no. 28(9), p. 2039–2049, 2021.

[3] European Union, "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", January 2025.

[4] European Union, "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", January 2025.

[5] European Union, "Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847," March 2025.

[6] European Commission, "COM/2022/31 An EU Strategy on Standardisation - Setting global standards in support of a resilient, green and digital EU single market," February 2022.

[7] European. Commission, "Harmonized Standards," 2025. [Online]. Available: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en., retreived: September, 2025.

[8] A. Volpato, "The legal effects of harmonised standards in EU law: From hard to soft law, and back?" i *The Legal Effects of EU Soft Law*, Edward Elgar, 2023, pp. 193-212.

[9] ISO, "ISO/TC 215 International Technical Committee Health Informatics," 2025. [Online]. Available: https://www.iso.org/, retreived: September, 2025.

[10] CEN, "CEN/TC 251 European Technical Committee for Health Informatics," [Online]. Available: https://www.cencenelec.eu/, retreived: September, 2025.

[11] European Union, "Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93", July 2021.

[12] European Union, "Case T-185/19 Public.Resource.Org, Inc. & Right to Know CLG v European Commission, Judgment of the General Court (Fifth Chamber, Extended Composition)" July 2021.

[13] E. Tzoulia, "Harmonized Standards in the Public Domain? Better Not …," *IIC - International Review of Intellectual Property and Competition Law,* vol. 56, nr. 4, p. 692–712, 2025.

[14] Stiftelsen Lovdata, "FOR-2015-07-01-853 Norwegian Regulation on IT Standards in Health and Care Services (Forskrift om IT-standarder i helse- og omsorgstjenesten)", 2015.

[15] Stiftelsen Lovdata, "LOV-1976-06-11-79 Norwegian Product Control Act (Produktkontrolloven)", 2021.

[16] Ø. Vennerød et al., "Reference to Standards in Norwegian Regulations (Henvisning til Standarder i Norsk Regelverk)", *Menon Economics,* 2022.

[17] A. Heyerdahl, "Standardising policy in a nonstandard way: a public/private standardisation process in Norway" *Journal of Public Policy,* nr. 4, p. 761–790, 2023.

[18] P. Lindøe, J. Kringen, and G. S. Braut, «Regulation and standardization: perspectives and practice (Regulering og standardisering : perspektiver og praksis)», *Universitetsforlaget*, 2018.

[19] M. J. Page et al., "The PRISMA 2020 statement: an updated guideline for reporting systematic reviews,» *BMJ,* vol. 372, p. n71, 2021.

[20] "Figshare Dataset," [Online]. Available: 10.6084/m9.figshare.29610470.

[21] Stiftelsen Lovdata, "Lovdata Pro," [Online]. Available: https://lovdata.no/pro/.

Courtesy of IARIA Board and IARIA Press. Original source: ThinkMind Digital Library https://www.thinkmind.org