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Liability for AI-Assisted Medical Decision-Making

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Abstract:

The integration of artificial intelligence (AI) into medical diagnostics and decision-making introduces significant legal challenges, particularly concerning the attribution of liability. While the European Union's new regulatory framework—comprising the Artificial Intelligence Act (AI Act) and the Revised Product Liability Directive (RPLD)—imposes strict safety and liability rules on AI providers, it leaves the civil liability of healthcare professionals to national tort law. This thesis examines how the mandatory obligations established by EU digital regulations interact with national fault-based liability, specifically focusing on the evolution of the healthcare professional's duty of care (*lex artis*) within the care relationship.

Methodologically, the study employs contextual legal dogmatics, guided by the teleological interpretation of the Court of Justice of the European Union (CJEU) and the principle of effectiveness (*effet utile*). This framework is utilized to analyse how national courts must adapt traditional medical liability concepts to new technological realities without compromising legal certainty.

The analysis demonstrates that the strict product liability of AI manufacturers and the fault-based professional liability of healthcare providers operate concurrently. The AI Act's requirements for transparency and human oversight mandate that high-risk medical AI systems be designed with a technical interface allowing for effective human control. Consequently, the national *lex artis* standard must evolve to encompass AI literacy and the active mitigation of automation bias. To operationalize this shift, the thesis proposes the "threshold of detectability" as the central legal-dogmatic mechanism for attributing liability in

clinical settings. By anchoring the assessment of fault-based liability to the boundaries of this interface, the study provides a coherent framework for distinguishing between inherent product defects and medical malpractice. Ultimately, this systemic interpretation reconciles European product safety mandates with national tort law, ensuring uninterrupted patient protection and formal predictability while respecting the division of competences.

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1 Introduction

The aim of this thesis is to examine how the obligations imposed by the Artificial Intelligence Act and the Revised Product Liability Directive shape the attribution of liability and the duty of care of healthcare professionals in the use of medical AI systems.

The analysis will show that the new European legal framework does not supersede national tort law, but rather necessitates a redefinition of its scope and content in relation to product safety.

The model of attributing liability established in this thesis represents a pan-European legal reality. The fault of the healthcare professional—assessed against a professional standard of care, whether termed *lex artis*, *ars medica*, or the "reasonable professional" standard—constitutes the fundamental, universally shared criterion for establishing medical responsibility across all European jurisdictions, regardless of the underlying civil or common law traditions.[1]

The solution proposed in this study—where the attribution of liability is determined by the *"threshold of detectability"* created by the AI Act's technical interface—serves as a legal-dogmatic framework for European courts. It suggests a coherent mechanism to integrate the new technological oversight requirements into the European *obligation de moyens*[2], ensuring that the healthcare professional's *lex artis* standard evolves uniformly across the Union without compromising legal certainty.

[1] Ferrara – Boscolo-Berto – Viel 2013, p. 8; Frati – Gulino 2013, pp. 72–77.
[2] Ferrara – Boscolo-Berto – Viel 2013, p. 8. In the context of medical liability, doctors are bound by an "obligation of means" (traditionally known as *obligation de moyens*) rather than an "obligation of result". Consequently, a healthcare professional's legal responsibility does not hinge on guaranteeing a successful cure or a flawless diagnostic outcome, but rather on ensuring that the medical intervention was executed in accordance with the prevailing professional standards. See also Sargos 1997, p. 2.

1.1 The Algorithmic Transformation of Healthcare: The Context in Which This Thesis Is Set

1.1.1 Predictive Medicine: How AI Is Changing Healthcare

Artificial intelligence[3] (AI) is not only fundamentally changing society, but also medicine and healthcare.[4] As of today, numerous machine learning-based solutions are already in clinical use as part of medical devices and software. Artificial neural networks have enabled the development of more complex image recognition algorithms, which are now widely used in radiology, pathological tissue sample examination and skin cancer detection, for example, as part of a clinician's daily work. Machine learning[5] can even be used to assess and predict the risk of disease even before actual treatment contact.[6]

Healthcare is shifting from treating symptoms (reactive care) to data-driven risk prediction (proactive care).[7] Various applications of artificial intelligence are accelerating this transition. AI can identify disease risks even before clinical symptoms appear by analysing diverse data sources. By combining genomic, clinical and lifestyle data risk assessments for cardiovascular disease and diabetes can be refined. Continuous glucose monitoring and AI-based analysis can in turn affect diabetes management. AI can also help in early detection of neurodegenerative diseases, such as Alzheimer's, for example, enabling targeted preventive measures.[8]

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[3] See Hietanen – Hirvonen 2026, pp. 33–34. AI fundamentally differs from traditional, deterministic software programming where a machine strictly follows human-written rules to produce predictable outcomes. Modern AI, particularly generative AI, operates on probabilistic models, meaning it infers outputs based on statistical probabilities rather than pre-determined rules, rendering its behaviour non-deterministic.

[4] Artificial intelligence can be seen as one of the most significant technologies driving change in professions. It is a common misconception to think that the only way to get machines to perform at the level of the best humans is to replicate the way that humans work. For this "AI Fallacy" see Susskind – Susskind 2015, p. 45.: "the mistaken supposition that the only way to develop systems that perform tasks at the level of experts or higher is to replicate the thinking processes of human specialists." When something is uncertain, people turn to the judgment of experts. However, modern AI systems are excellent at handling precisely this uncertainty with the help of massive amounts of data.

[5] European Commission, COM(2020) 65 final, p. 16.: "In case of machine learning techniques, which constitute a subset of AI, algorithms are trained to infer certain patterns based on a set of data in order to determine the actions needed to achieve a given goal."

[6] See for example Tikkanen - Sanmark - Holmström 2025.

[7] See WHO 2021, p. 50.: "Health care has always included and depended in part on predictions and prognoses and the use of predictive analytics. AI is one of the more recent tools for this purpose, and many possible benefits of prediction-based health care rely on use of AI…".

[8] Kallioniemi 2025.

Artificial intelligence models specialized in medicine are often trained using large and carefully selected data sets collected under controlled conditions. The benefits of AI applications in diagnostics include high accuracy and the ability to identify both subtle signs of disease and broad patterns in data that humans may not be able to detect or observe in a limited amount of time during a clinical visit.[9]

One concrete example of the potential for utilizing artificial intelligence in medical care is the diagnosis of cancer. Machine learning mechanisms are ideal for analysing vast amounts of data, such as imaging data (e.g., mammograms, CT and MRI images), pathological samples, and patient health information. Machine learning algorithms have learned to distinguish normal findings from cancerous changes when trained with a large number of images. In practice, promising research results on the application of artificial intelligence have been presented in all areas of cancer, such as non-invasive diagnosis of brain tumours, Gleason grading of prostate cancer, and even the identification of small nodules in lung cancer from low-dose CT images. Language models have also achieved over 95% accuracy in determining the spread of various tumours.[10]

1.1.2 EU's Digital Sovereignty: The EU's AI Strategy

The EU is strengthening its digital sovereignty by investing in new-generation technologies, infrastructure, and data skills.[11] It aims to develop artificial intelligence in line with European values.[12] The goal is to be a global leader in AI and to build alliances with partners who share the vision of ethical use of artificial intelligence.[13]

The EU's AI strategy is based on both investments in research and the creation of a regulatory framework that, with a human-centred approach, strengthens the atmosphere of trust by ensuring that fundamental rights are protected.[14] The

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[9] Sanmark - Honkanen 2025.
[10] See for example Tikkanen 2025.
[11] See European Commission, COM(2020) 65 final, p. 3.:"Harnessing the capacity of the EU to invest in next generation technologies and infrastructures, as well as in digital competences like data literacy, will increase Europe's technological sovereignty in key enabling technologies and infrastructures for the data economy."
[12] European Commission, COM(2020) 65 final, p. 1.
[13] European Commission, COM(2020) 65 final, p. 8.
[14] European Commission, COM(2020) 65 final. See also Regulation (EU) 2024/1689, Article 1.

Commission sees critical sectors such as healthcare as priority areas for the large-scale and safe deployment of AI.[15]

Risk-based legislation aims to avoid excessive bureaucracy.[16] The strictest requirements are imposed on AI applications classified as "high risk". Before they can be placed on the market, high-risk AI applications must undergo an impartial prior conformity assessment.[17] These AI applications are required to have, for example, high-quality training data, a clear system for storing data, and human oversight.[18]

1.1.3 Data Economy and the Symbiotic Transformation of Healthcare – Single Market for Health Data as the Foundation for EU's Digital Sovereignty

The use of artificial intelligence in medicine and healthcare in general is based on data. Medical AI systems based on machine learning require large, carefully selected, high-quality datasets of patient data in order to be developed and function properly. Clinical data can thus be seen as one of the most valuable resources of modern medicine and the technology industry, making healthcare part of broader data economy where patient data holds significant economic value.[19]

There are two lines of development whose simultaneous implementation is essential for the advancement of AI-assisted healthcare. The first of these is the algorithmic transition, in which machine learning models and AI in general are developed to support diagnosis and decision-making. The second is a data transition, in which large amounts of health data "transition" to cross-border utilization.[20] The algorithmic transition cannot occur without the data transition due to the technical nature of machine learning. Through its legislation, the EU aims to manage and promote both of these "transitions" as a unified whole.[21]

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[15] European Commission, COM(2020) 65 final, p. 8.
[16] European Commission, COM(2020) 65 final, p. 17.
[17] Regulation (EU) 2024/1689, Article 16.: "...high-risk AI system undergoes the relevant conformity assessment procedure as referred to in Article 43, prior to its being placed on the market or put into service".
[18] See Regulation (EU) 2024/1689, Articles 10, 12, 14, 43.
[19] See European Commission, COM(2020) 65 final and COM(2020) 66 final.
[20] European Commission, COM(2022) 197 final.
[21] European Commission, SWD(2022) 131 final, PART ¼, p. 4.: "EHDS is one of the priorities of the current College in the area of health and will be an integral part of building a European Health Union. It will ensure coherence with a number of other EU legislative frameworks, including the General Data Protection Regulation, the Data Governance Act, the AI Act, cybersecurity regulatory

Digital sovereignty is a key geopolitical goal for the EU. Since the development of medical AI requires large amounts of high-quality patient data, the European medical AI industry cannot compete globally without unified European data sets.[22] As the EU seeks to achieve digital sovereignty, it has created a single market for health data.[23] This has been implemented through the European Health Data Space Regulation[24] (EHDS).[25]

Healthcare was the first sector for which specific, in-depth internal market rules were created (EHDS).[26] With the entry into force of the EHDS Regulation, a unified European internal market for health data has been established. The EHDS turns health data into "*freely circulating goods*" in the internal market, combining European patients' data into a single large pool of data. Using this data pool, European companies can develop their own medical algorithms. This is achieved by enabling so-called "secondary use" of data.[27] This means that data originally collected for a patient's clinical care can now be legally utilized across national borders to train AI algorithms.[28] Together with the Artificial Intelligence Act[29] (AI Act), the EHDS forms a binding regulatory framework through which the EU accelerates and governs medical AI development.[30] The AI Act establishes a framework for AI-based technology. According to the European Commission's wording, these two pieces of legislation together form an "*ecosystem of excellence and trust*."[31]

1.1.4 Algorithmic Opacity, Human Oversight, and the Attribution of Liability

Although the EU's legislative framework and digital strategies aim to create, in the Commission's words, an "*ecosystem of excellence and trust*" for medical AI,

framework, the eIDAS regulation, the pharmaceutical regulatory framework and the medical device regulation."
[22] European Commission, COM(2020) 66 final, p. 28.
[23] Consolidated version of the Treaty on the Functioning of the European Union, Article 114.
[24] Regulation (EU) 2025/327.
[25] European Commission, COM(2022) 197 final, pp. 2 and 6.
[26] European Commission, COM(2022) 197 final, p. 1.: "The European Health Data Space ('EHDS') is the first proposal of such domain-specific common European data spaces."
[27] Regulation (EU) 2025/327, Article 53.
[28] Regulation (EU) 2025/327, Article 53(e).
[29] Regulation (EU) 2024/1689.
[30] European Commission, SWD(2022) 131 final.
[31] European Commission, COM(2020) 65 final.

integrating AI into healthcare is not merely a technological upgrade; it raises legal challenges that data market harmonization alone cannot resolve.

The core of the legal problem lies not only in the technical nature of algorithms, particularly the so-called "black box[32]" phenomenon, but in the clash between this technological opacity and the new regulatory requirements of EU law. Although the logic behind the recommendations provided by the most advanced neural networks is often impossible to fully trace and explain in an understandable way, the EU's AI Act requires deployers of high-risk systems, such as hospitals and the health care professionals working there, to maintain "human oversight".[33] Health care professionals are expected to be able to understand the system's limitations and, if necessary, disregard its recommendation, even if decision-making takes place under conditions of epistemic uncertainty. At the same time, the EU's Revised Product Liability Directive[34] (RPLD) imposes strict liability on the manufacturer of an AI system for software defects inherent in the device, creating a complex intersection between fault and product liability. As the Directive seeks complete harmonisation in the matters it regulates, Member States cannot impose stricter no-fault liability on manufacturers than what is provided in the Directive.[35]

This thesis argues that the systemic tension between strict product liability and fault-based professional liability is resolved through the threshold of detectability. If an algorithmic anomaly is clinically or formally detectable via the technical interface established by the AI provider, a health care professional who succumbs to automation bias and blindly follows the clearly erroneous output breaches their *lex artis* standard[36].

Consequently, this study addresses the question of how the new regulatory framework under EU law shapes the attribution of liability under tort law at the interface between the health care professional and the AI manufacturer, in a situation where duty of care

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[32] The term "*black box*" has a dual meaning. See Pasquale 2015, p. 3: "It can refer to a recording device, like the data-monitoring systems in planes, trains, and cars. Or it can mean a system whose workings are mysterious; we can observe its inputs and outputs, but we cannot tell how one becomes the other." In the context of AI we refer to the latter meaning.
[33] Regulation (EU) 2024/1689, Articles 14 and 26(2).
[34] Directive (EU) 2024/2853.
[35] C-52/00 *Commission v France*, ECLI:EU:C:2002:252, para 21.
[36] Professional standard of care, see chapter 2.5.

is tied to the ability to control a machine whose internal operating logic the human actor cannot fully comprehend.[37]

1.2 Research Question and Delimitations

The overarching objective of this thesis is to systematize the tort law regulatory framework governing AI-assisted medical decision-making and to examine how the introduction of AI software reshapes liability attribution. Accordingly, the primary research question is formulated as follows:

How does the European Union's digital regulatory framework—specifically the AI Act and the RPLD—shape the tort law liability regime and the professional standard of care, lex artis?

To systematically address this primary problem, the study is divided into two legal-dogmatic sub-questions:

1. *In what manner do the strict product liability of the AI manufacturer and the fault-based professional liability of the healthcare professional operate concurrently in the attribution of liability within a clinical setting?*
2. *How do the mandatory obligations established by the AI Act and the EU law principle of effectiveness, effet utile, redefine the healthcare professional's standard of care, lex artis, under national tort law?*

To ensure rigorousness of the thesis, the scope of this study is strictly delimited. Issues relating to procedural law, the practical presentation of evidence, and the allocation of the burden of proof are excluded from this study apart from a few instances where clarification is necessary. The RPLD already incorporates extensive legal presumptions regarding product defectiveness and the causal link in technically complex situations.[38] This thesis adopts a purely substantive law approach: it presumes that an AI safety defect and its factual causal link to the damage have already been established, focusing strictly on the attribution of liability.

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[37] On the high degree of epistemic opacity in AI systems, see for example Buijsman – Klenk – van den Hoven 2025, pp. 61–62.
[38] Directive (EU) 2024/2853, Articles 9 and 10.

Data protection and privacy matters under the General Data Protection Regulation (GDPR) and the EHDS, as well as intellectual property and copyright aspects of AI models, fall outside the scope of this study.

Public law administrative fines imposed by market surveillance authorities under the AI Act are excluded from this study. This study also does not specifically address liability arising under criminal law; in this regard, it can be noted that the same general rule as in fault-based liability applies to intentionally caused damage, that is, the principle of full compensation.

1.3 Methodology and Theoretical Framework

1.3.1 Contextual Legal Dogmatics

To address the research questions, this thesis relies methodologically on so called *contextual legal dogmatics*, as a purely analytical or linguistic interpretation of the law is insufficient in the context of EU law, because the system is strongly rooted in teleology and policies. In EU law, decision-making is based on a balance between linguistic, systemic, and teleological interpretation, and legal, economic, and political realism must be taken into account.[39]

Furthermore, since there is as of yet no established case law from the Court of Justice of the European Union (CJEU) or national supreme courts regarding civil law damages caused by medical artificial intelligence, traditional legal dogmatics[40], which focuses on the systematization and interpretation of existing law, proves inadequate in the face of new technology. Contextual legal dogmatics, on the other hand, enables the assessment of legal norms and regulatory shifts as part of their broader medical, technological, and European legal framework. This method allows for the examination of the attribution of liability for material damages not only *de lege lata*, but also for identifying how existing law adapts under the pressure of new legislation.[41] In this study, the method is used to examine how national private law tort norms horizontally absorb the regulatory mandates established by the AI Act.

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[39] See Raitio 2014, pp. 519-522 and 529–540.
[40] On legal dogmatics, see for example Aarnio 1989, p. 53. See also Peczenik 1969.
[41] See Aarnio 1997, p. 237.: "...legal system gives a framework for legal interpretation and, on the other hand, every interpretation must be realized within a certain systematic frame."

1.3.2 Teleology of the CJEU and the Principle of Effectiveness

The theoretical framework and central interpretive method of this study is the CJEU's teleological interpretation of law and the principle of effectiveness[42] (*effet utile*). The objectives of EU law, such as a high level of healthcare and patient safety, must be fulfilled in practice. This thesis analyses how the principle of effectiveness, *effet utile*, as established by the CJEU in its case law and the teleology of EU law oblige national courts, by virtue of the principle of indirect effect[43], to adapt the health care professionals traditional *lex artis* to the new public law regulatory requirements set by AI legislation, specifically the AI Act. The principle of consistent interpretation requires national courts to interpret national law, including the flexible *lex artis* standard, as far as possible in light of the wording and purpose of EU law.[44]

The general principles of EU law, which serve as the theoretical framework for this study, derive their precise content from the established case law of the CJEU.

In EU law, a purely linguistic interpretation is often insufficient, which is why the CJEU relies heavily on a teleological method of interpretation. In its established case law, the CJEU has held that a provision of EU law must be interpreted not only in the light of its wording, but also in the light of its context and the objectives pursued by it.[45] In this thesis, the teleological approach means that the overarching objectives of EU law – such as a high level of health protection and patient safety – must be effectively realised in practice when new technology is introduced into clinical decision-making.

At the heart of the principle of effectiveness lies the requirement that the rights conferred by EU law must be capable of being exercised in practice. The CJEU has, in its early case law, already established that national rules must not render the exercise of rights based on EU law practically impossible or disproportionately difficult.[46] The

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[42] See for example Raitio - Tuominen 2025, pp. 219–224. The principle of effectiveness, or *effet utile*, requires Member States to guarantee effective legal remedies to individuals and private legal entities. These remedies enable them to exercise their rights under Union law before national authorities and courts.

[43] See for example Raitio – Tuominen 2025, pp. 264–268. *Indirect effect* refers to the interpretative effect of EU law, that is, the principle of consistent interpretation. This means that the aim is to interpret provisions of national law in a way that is consistent with EU law and the objectives of integration. This effect is particularly evident in situations where EU law does not have *direct effect*.

[44] C-106/89 *Marleasing*, ECLI:EU:C:1990:395, para 8.

[45] C-283/81 *CILFIT*, ECLI:EU:C:1982:335, paras 18–20.

[46] 33/76 *Rewe*, ECLI:EU:C:1976:188, para 5; 45/76 *Comet*, ECLI:EU:C:1976:191, paras 13 and 16. See also C-276/01 *Steffensen*, ECLI:EU:C:2003:228, para 60.

CJEU has subsequently elaborated on this teleological objective, inter alia, in its judgments in Cases C-6/90 and C-9/90 (*Francovich*), in which it held that the full effectiveness of EU law would be called into question without effective national remedies for damages.[47] As will be demonstrated later in this thesis, the CJEU has also made extensive use of the principle of effectiveness in its interpretation of the PLD to ensure legal protection for patients in situations of medical uncertainty.[48]

The second key principle, legal certainty, has been a cornerstone of the CJEU's case law since its early years.[49] According to the CJEU's established definition, legal certainty requires that legal rules be clear, precise and predictable in their effects. Legal literature[50] has emphasised that this is closely linked to the principle of the rule of law: laws must be prospective, clear and relatively stable. Legislation must enable legal subjects to know their rights and obligations unambiguously and to act accordingly.[51] The predictability of rules is of particular importance where regulation entails financial or severe consequences.[52]

Legal certainty is inextricably linked to the principle of the protection of legitimate expectations, which, in the case law of the CJEU, safeguards an individual's legitimate expectations regarding the actions of the legislature or public authorities.[53] These principles have constitutional status in case law and may even serve as a criterion for assessing the validity of secondary legislation.[54] In judicial decision-making, in

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[47] C-6/90 and C-9/90 *Francovich*, ECLI:EU:C:1991:428, para 33.
[48] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 26–27 and 30–32.
[49] See 7/56 and 3/57 to 7/57 *Algera*, ECLI:EU:C:1957:7, pp. 54–55, where the Court established the limits on revoking administrative measures to safeguard confidence in the stability of the situation created. On the balancing of legal certainty and the protection of legitimate expectations in the *Algera* case, see also Raitio 2003, pp. 146–147. See also Tridimas 2020, p. 17. During the early development of EU law, the Treaties lacked specific dispositions, compelling the Court to fill these legal gaps by gaining inspiration from the solutions provided in national legal systems. The *Algera* judgment serves as an example of this methodology establishing general principles of law. This balancing was further developed in 42/59 and 49/59 *S.N.U.P.A.T. v High Authority*, ECLI:EU:C:1961:5, p. 87, where the Court recognized that the principle of respect for legal certainty cannot be applied in an absolute manner, but must be balanced against the principle of legality when withdrawing unlawful administrative acts.
[50] See, for example, Raitio 2003, pp. 138–140.
[51] C-201/08 *Plantanol*, ECLI:EU:C:2009:539, para 46. On the requirements of clarity, precision and foreseeability, see C-63/93 *Duff and Others*, ECLI:EU:C:1996:51, para 20; C-107/97 *Rombi and Arkopharma*, ECLI:EU:C:2000:253, para 66; and C-17/03 *VEMW and Others*, ECLI:EU:C:2005:362, para 80. Furthermore, on the requirement for legal persons to know the precise extent of their obligations, see C-17/01 *Sudholz*, ECLI:EU:C:2004:242, para 34.
[52] See, for example, 325/85 *Ireland v Commission*, ECLI:EU:C:1987:546, para 18. The Court emphasized that the requirement of legal certainty must be observed more strictly in the case of rules liable to entail financial consequences.
[53] See, for example, 120/86 *Mulder*, ECLI:EU:C:1988:213, paras 24–27.
[54] On the constitutional status of general principles of law, which take precedence over secondary legislation, see C-101/08 *Audiolux*, ECLI:EU:C:2009:626, para 63. Consequently, these principles serve

addition to procedural considerations, the substantive acceptability of the decision must also be taken into account.[55] In this thesis, the principle of legal certainty is considered to require that the new obligations imposed by the AI Act be integrated into national strict liability in a manner which safeguards, on the one hand, the formal predictability of a doctor's actions and, on the other, the patient's substantive legal protection and the acceptability of the decision.

Furthermore, to evaluate the systemic adaptation of national tort law, this thesis utilizes the analytical legal theory of legal certainty and interpretive coherence. The principle of legal certainty requires that legal adjudication must be both *formally predictable* (formal legal certainty, safeguarding the healthcare professional's right to rationally plan their professional conduct in accordance with coherent rules) and *substantively acceptable* (substantive legal certainty, fulfilling the teleological objective of consumer and patient protection). This theoretical dualism provides the essential benchmark to evaluate whether the evolution of the *lex artis* standard maintains systemic coherence.[56]

Alongside teleological interpretation, this thesis utilises the concept of coherence when assessing the adaptation of national tort law to EU regulation. Legal argumentation and the rationality of the application of the law require internal consistency within the legal system, that is, *normative coherence*. It has been argued, however, that modern law no longer seeks deductive, *total coherence* encompassing the entire legal system; rather, *local coherenc*e based on principles specific to individual branches of law and general legal doctrines is sufficient. This thesis analyses how updating the content of the *lex artis* standard for healthcare professionals creates such local coherence at the interface between product liability and tort liability, whilst safeguarding formal justice and the predictability of the application of the law.[57]

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as criteria for assessing the validity of secondary legislation; see, e.g., C-236/09 *Test-Achats*, ECLI:EU:C:2011:100 (where the Court invalidated a directive provision for breaching the principle of equal treatment), and C-402/05 P and C-415/05 P *Kadi and Al Barakaat International Foundation*, ECLI:EU:C:2008:461, paras 281–285 and 326 (affirming the Court's jurisdiction to review the lawfulness of all Community acts, including those implementing UN Security Council resolutions, in light of fundamental rights).

[55] Raitio 2003, pp. 143–144.

[56] See Chapter 7.3. On legal certainty in the Nordics, see Raitio 2003, pp. 337–339.

[57] For further details on the requirement of *coherence* and *local coherence*, see Tuori 2000, pp. 123–126. According to Tuori, coherence is a fundamental prerequisite for the rationality of the administration of justice, which guarantees formal justice.

2 The Basic Legal Framework for Damages and the Traditional Distinction Between Product Liability and Professional Liability

In order to assess the impact of the new regulatory framework for digital health on liability for damages, the Artificial Intelligence Act and the Revised Product Liability Directive, it is first necessary to define the legal context affected by new AI-based technology. This chapter analyses the established framework of European and national law governing liability for damages arising from medical devices.

The analysis begins with the EU's product liability legislation and the relevant case law of the Court of Justice of the European Union, before moving on to an assessment of the duty of care of healthcare professionals as governed by national law.

2.1 Manufacturer's Strict Liability and Product Defect in the Case Law of the CJEU

Since 1985, product liability in the European Union has been defined by the Product Liability Directive (PLD).[58] The teleological basis of the PLD rests on two objectives, which are to some extent in tension with one another: on the one hand, the aim of harmonising the Union's internal market by removing distortions of competition and barriers to the free movement of goods, and on the other hand, the aim of ensuring adequate consumer protection against damage to health and property caused by products that are unsafe.[59]

The manufacturer's liability under the PLD is strict liability, irrespective of fault. Furthermore, under the PLD, it is not appropriate to set a monetary upper limit on this liability.[60] Under a system of strict liability (meaning liability without fault), the injured party does not need to prove the manufacturer's negligence. In accordance with Article 4 of the PLD, the injured party need only prove the defect in the product, the damage and the causal link between them.

In its case law, the CJEU has set strict limits on the extent to which Member States may modify this liability. In Cases C-52/00 (*Commission v France*), C-154/00 (*Commission v Greece*) and C-183/00 (*González Sánchez*), the CJEU confirmed that

[58] Council Directive 85/374/EEC.
[59] Council Directive 85/374/EEC, Recital 1. See also, for example, Fairgrieve – Goldberg 2020, p. 193 ff.
[60] Council Directive 85/374/EEC, Recitals 2 and 17.

the Directive seeks to achieve complete harmonisation of Member States' laws in the matters it regulates.[61] According to the CJEU, the PLD aims, in respect of the matters it regulates, at the complete harmonisation of the laws, regulations and administrative provisions[62] and, for this reason, Member States have no discretion to maintain or enact general product liability regimes that deviate from the Directive, even where the aim would be to provide a higher level of consumer protection.[63]

This principle of full harmonisation also extends to the definition of liable parties. The Community legislator has made a conscious choice to place strict liability on the manufacturer, as only the manufacturer has the ability to influence the quality of the product.[64] The CJEU clarified this limitation in Case C-402/03 (*Skov v Bilka*), which assessed the limits of liability for the retailer and the manufacturer. In its judgment in *Skov v Bilka*, the ECJ held that the scope of persons liable for damages is exhaustively defined in Articles 1 and 3 of the PLD.[65] A retailer, distributor or service provider may be held strictly liable under the Directive only in the exceptional cases listed in the Directive. It follows that national rules which automatically transfer the manufacturer's strict liability to the distributor or retailer may, in principle, be regarded as contrary to the Directive.[66] However, the PLD does not supersede national tort law, nor does the PLD preclude the application of other liability regimes based on different legal grounds, such as liability based on negligence.[67]

This dichotomy, confirmed in the CJEU's case law—the completely harmonised strict liability of the manufacturer and the fault-based liability of the service provider, which is left to national discretion—forms the systemic foundation upon which the attribution of liability for medical AI systems is built later in this thesis. Only after understanding this distinction is it possible to evaluate the safety expectations set by the CJEU for medical devices.

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[61] C-52/00 *Commission v France*, ECLI:EU:C:2002:252, para 16; C-154/00 *Commission v Greece*, ECLI:EU:C:2002:254, para 12; C-183/00 *González Sánchez*, ECLI:EU:C:2002:255, para 25.
[62] C-52/00 *Commission v France*, ECLI:EU:C:2002:252, para 24; C-154/00 *Commission v Greece*, ECLI:EU:C:2002:254, para 12.
[63] C-402/03 *Skov v Bilka*, ECLI:EU:C:2006:6, paras 41–44.
[64] C-402/03 *Skov v Bilka*, ECLI:EU:C:2006:6, paras 28–29.
[65] C-402/03 *Skov v Bilka*, para 33.
[66] C-402/03 *Skov v Bilka*, paras 34, 37, 45. Article 3 of the PLD also includes importers and "own-branders" as manufacturers, but regular retailers fall outside this strict liability unless the manufacturer is unidentified.
[67] C-402/03 *Skov v Bilka*, para 47.

Under Article 6 of the PLD, a product is deemed to be unsafe if it does not offer the level of safety that a person is entitled to expect (legitimate expectation of safety), taking into account the information provided about the product, its reasonably foreseeable use and the time of its placing on the market. Under Finnish law, this assessment of product safety under the PLD is not linked to the concept of a defect under the Sale of Goods Act, and damage caused by products falls within the scope of tort law rather than contract law. Whereas in the sale of movable property, a matter considered to be a defect is primarily resolved on the basis of the parties' contract, the safety of a product under the PLD is assessed regardless of what has been agreed.[68] Consequently, by proving that a product is unsafe, one proves that the product is defective. According to the official Finnish translation of the PLD, the injured party must prove that the product is unsafe, whereas according to the English version, the injured party must prove that the product is defective.[69] However, Article 6 of the English version defines what is meant by "*defect*" in the context of the Directive: a product is defective if it does not offer the level of safety that a person is entitled to expect, i.e. it is unsafe.

In the context of medical devices and health technology, the PLD has been interpreted in the case law of the CJEU, and the safety expectation set out in the PLD has been held to a high standard in this context.[70]

2.1.1 *Boston Scientific* and the Teleological Extension of Safety Expectations

The judgment of the European Court of Justice (ECJ) in Joined Cases C-503/13 and C-504/13 (*Boston Scientific*) concerned cardiac pacemakers in which a higher than usual risk of failure had been identified. The *Bundesgerichtshof* referred two questions for a preliminary ruling to the ECJ in the case.

The first question referred for a preliminary ruling concerned whether a medical device implanted in the human body could be regarded as defective in terms of safety within

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[68] See Government Proposal HE 119/1989 vp, p. 27; Ståhlberg – Karhu 2020, pp. 181–184.
[69] See Council Directive 85/374/EEC, Article 4. In the English version, Article 4 is worded as follows: "*The injured person shall be required to prove the damage, the defect, and the causal relationship between the defect and the damage.*" Similarly, the French (défaut) and German (Fehler) versions, for example, use terminology referring to a defect. In the official Finnish translation, however, the term "defect" has been translated as "*lack of safety*". As is evident from Article 6(1) of the English version ('A product is defective when it does not provide the safety which a person is entitled to expect'), the defect referred to in the directive is explicitly the lack of safety.
[70] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148.

the meaning of the PLD on the grounds that the risk of malfunction in products of the same product group is significantly high, or where a large proportion of products in the same series have exhibited malfunctions, but in the specific case in question, no safety defect had been established in the implanted device.[71]

Answering the second question referred for a preliminary ruling required the ECJ to give an affirmative answer to the first question referred for a preliminary ruling. The second question concerned whether the costs incurred in fitting a replacement medical device to the human body or in removing the old device constituted damage resulting from personal injury within the meaning of the PLD.[72]

According to the ECJ, the issue of a lack of safety had to be assessed from the perspective of the public. According to paragraph 37 of the judgment, the assessment must be carried out in accordance with the level of safety that the public using the product could reasonably expect; in other words, the safety of the product must be assessed taking into account the specific characteristics of its user group.[73]

In the case of medical devices, the safety requirements are set at a very high level, given the particularly vulnerable position of patients.[74] ECJ endorsed the opinion put forward by the Advocate General in his Opinion on how the term "*defective safety of a product*", as set out in Article 1 of the Directive, should be defined. According to the Advocate General, the interpretation of the concept of "*safety that can reasonably be expected*", although the concept itself is imprecise, is limited by the requirement to comply with the objectives of the PLD.[75] When the concept is interpreted teleologically in the light of the Directive's objectives, and when the matter is examined from the perspective of the fair allocation of risks associated with technical production, the concept may be regarded as applying to products involving an unusual and unreasonable risk to the user's safety that differs from the risk associated with normal use. When considering the concept of "*safety that can reasonably be expected*", the focus should therefore be on assessing the magnitude of the risk of harm. A product is deemed to be unsafe, as set out in Article 1 of the Directive, where the risk of harm

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[71] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, para 28(1).
[72] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, para 28(2).
[73] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, paras 37–38.
[74] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, para 39.
[75] Opinion of AG Bot in Joined Cases C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2014:2277, point 30. (The ECJ adopted the Advocate General's reasoning in paragraph 40 of its judgment).

associated with the product is so great that it deviates from the public's expectations of safety.[76]

The Court of Justice of the European Union concluded that if "*products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective*."[77] The ECJ applied a teleological interpretation and based its decision on the Directive's objectives regarding the fair allocation of risks between the injured party and the manufacturer.[78]

It is important to note that the basis for product liability is the safety of the product; where this is lacking, it gives rise to a defect in the product, and such a safety deficiency is addressed exclusively from a safety perspective. Article 6 of the PLD explicitly defines this defect in terms of a lack of safety.[79] As is apparent from the Advocate General's Opinion, where other technical devices manufactured in the same way and possessing the same characteristics present a high risk of malfunction or problems with functionality, the product is equated with those products in terms of the risk of malfunction on the basis of the safety that can reasonably be expected.[80]

In justifying its decision on the first question in the request for a preliminary ruling, the ECJ therefore held, in line with the Advocate General, that the requirement of reasonably expected safety is breached in the context of a medical device when the public is exposed to a risk of harm that differs from the risk associated with normal use, and in such cases, in accordance with Article 1, the manufacturer is liable for damage caused by the product's lack of safety.[81]

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[76] Opinion of AG Bot in Joined Cases C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, points 30 and 54. See similarly C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, para 40.
[77] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, para 41.
[78] Council Directive 85/374/EEC, Recital 2. See also, for example, Howells – Twigg-Flesner – Wilhelmsson 2018, pp. 39–40. Legal literature has criticised the fact that the original objective of the Product Liability Directive – the fair allocation of technological risks – has often been interpreted narrowly, and that the actual effectiveness of strict liability has been diluted. In this context, the ECJ's ruling in the Boston Scientific case concerning medical devices stands out as an exceptionally strong teleological decision.
[79] Council Directive 85/374/EEC, Article 6(1).
[80] Opinion of AG Bot in Joined Cases C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, points 30 and 55.
[81] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, paras 40, 43 and 45.

In answering the second question referred for a preliminary ruling, the Court addressed the issue of what constitutes damage. The ECJ endorsed the Advocate General's reasoning that the concept of damage resulting from death or other personal injury under the PLD must be interpreted broadly. Damage must cover all personal injury caused by a product's lack of safety. Personal injury includes medical expenses, all costs incurred by the injured party in connection with their treatment, and any impairment of their ability to work resulting from the personal injury. According to the Court, compensation for damage covers all measures taken to eliminate the harmful effects in order to restore the level of safety that may reasonably be expected under the PLD, as referred to in Article 6(1).[82]

In its ruling, the ECJ relied on a teleological approach emphasising patient safety and the principle of effectiveness, *effet utile*. The ECJ set very high standards regarding medical devices as to when a device may reasonably be expected to be safe.[83] Furthermore, the ECJ applied a broad interpretation of the concept of damage in order to protect consumers' health, meaning that compensation must cover all necessary costs to restore the level of safety that can reasonably be expected.[84]

2.1.2 *Sanofi Pasteur* and a Teleological Approach Emphasising Patient Protection in the Face of Medical Uncertainty

The ECJ's judgment in Case C-621/15 (*Sanofi Pasteur*) concerned the causal link between the hepatitis B vaccine and the patient's multiple sclerosis (MS). The *Cour de cassation* referred the following questions to the CJEU for a preliminary ruling.[85]

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[82] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, paras 11, 47 and 49. See also Opinion of AG Bot in Joined Cases C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, points 61–62.

[83] See, for example, Fairgrieve – Pilgerstorfer 2017, p. 888. It has been noted in legal literature that, in the Boston Scientific decision, the EUT took a significant step towards a more liberal approach by accepting the view that a mere possibility of failure constitutes a defect. The risk of a defect, however, had previously been established as a standard for determining defects. See *A v. National Blood Authority*. Boston Scientific is conceptually analogous to the "harmful characteristic" model in the *A v. National Blood* case; both refer to the mere possibility of an internal defect in a product.

[84] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, paras 39, 47 and 49–50. Denying compensation on the grounds of proactivity and requiring that the damage actually materialise would be contrary to the effectiveness of the Directive; see the Opinion of AG Bot in Joined Cases C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148, point 68.

[85] For more detailed background on the case, see C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 9–16.

The first question referred for a preliminary ruling concerned the possibility of a causal link between a lack of safety and the damage, as required by Article 4 of the PLD in situations where medical research has not established a link between vaccination and the onset of the disease. The court asked whether, within the limits of its discretion, it could assess the facts presented by the claimant constituted "*serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease*", or whether Article 4 of the PLD precludes such a presentation of evidence.[86]

The ECJ noted that the Product Liability Directive does not define the concept of "*causal link*", but the concept of "*lack of safety*" is defined in Article 6 of the Directive.[87] Here, the ECJ refers to the *Boston Scientific* judgment. With regard to the evidence, the Court notes that although, under Article 4 of the PLD, the burden of proof lies with the injured party – that is to say, the injured party must prove the damage – the Directive does not regulate the evidence in more detail.[88] The ECJ held that, within the limits set by the principles of equivalence and effectiveness, each Member State must define in its legal system both the required standard of proof and the procedures to be followed in the taking of evidence, the admissible means of evidence and the principles on the basis of which the national court assesses the probative value of the evidence submitted to it.[89] Under the principle of effectiveness, the exercise of rights established in the legal order of the Union must not, in practice, be rendered impossible or disproportionately difficult.[90]

According to the ECJ, it is apparent from the case-law of the CJEU that national procedural rules on the taking of evidence and the assessment of evidence must not be such as to undermine the effectiveness of the liability regime laid down in the PLD or the objectives pursued by the EU legislature through the PLD. A system of proof which does not require the injured party to adduce conclusive and irrefutable evidence of the product's lack of safety and of the causal link between that lack of safety and the damage suffered, but instead allows these matters to be established by means of presumptions of fact, or circumstantial evidence, alleviates the injured party's burden

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[86] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 17(1).
[87] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 22.
[88] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 24. See also the Opinion of AG Bobek in C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:181, points 16 and 20.
[89] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 25.
[90] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 26.

of proof in demonstrating the lack of safety and the causal link.[91] However, according to the ECJ, such a system of proof does not imply a reversal of the burden of proof incumbent on the injured party under Article 4 of the PLD, as the injured party must still establish the presumptions and indications relating to the facts, the combined effect of which allows the conclusion to be drawn that the product is defective in terms of safety and that there is a causal link between the defect and the damage suffered.[92]

Nor does national legislation which provides for the injured party's right to obtain information on the side effects of the product in question, and which, in this way, assists the injured party by making it easier for them to adduce the necessary evidence to hold the manufacturer liable, does not reverse the burden of proof or alter the conditions for exempting the manufacturer from liability laid down in Article 7 of the PLD.[93]

National courts must ensure that it is the injured party's responsibility to prove the lack of safety and the causal link to the damage, and that the injured party may rely on means of proof recognised under national law. These include, for example, the evidence presented, which must be sufficiently credible, precise and consistent to demonstrate that the product's lack of safety is the most plausible explanation for the damage, notwithstanding the defence put forward by the manufacturer. This requires the court to retain its discretion in assessing the evidence until it has been made aware of all the facts presented by both parties. The court must therefore assess the sufficiency of the evidence on a case-by-case basis and only after it has taken note of and weighed up all the facts and arguments put forward by both parties.[94]

In this system of evidence, which safeguards the effectiveness of the legal protection afforded by Union law, it is important that national courts do not apply the principles inherent in that system in such a way that this application would give rise, to the detriment of manufacturers, to unfounded presumptions contrary to Article 4 of the PLD, which could undermine the effectiveness of the substantive rules laid down in the

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[91] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 27 and 28.
[92] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 29.
[93] C-310/13 *Novo Nordisk*, ECLI:EU:C:2014:2385, paras 27 and 28; Opinion of AG Bobek in Case C-621/15 *Sanofi Pasteur*, points 22 and 23. Legal literature has also emphasised that such legislation is intended solely to address the significant information asymmetry between the pharmaceutical manufacturer and the consumer, without, however, affecting the essence of the liability regime established by the directive or the allocation of the burden of proof. See Brosset 2018, pp. 1908 and 1910.
[94] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 37 and 38.

Directive.[95] In accordance with the Advocate General's Opinion, this would include, for example, situations where national courts were to rely on irrelevant or insufficient evidence and fail to apply the system of proof with sufficient rigour. Furthermore, situations in which the national rules of evidence were applied in such a way that the circumstantial evidence presented would automatically give rise to a presumption of a link between a safety defect and the occurrence of damage would be contrary to the objectives of the Directive.[96]

Sanofi Pasteur demonstrates that national courts may rely on credible, precise and consistent circumstantial evidence to establish a causal link, even in the absence of absolute scientific proof.[97] In this judgment too, the ECJ relied on teleology emphasising patient safety and the principle of effectiveness. The judgment demonstrates how the ECJ uses the objective teleology of EU law and the *effet utile* to compensate for medical uncertainty.[98]

2.1.3 *Dutrueux*, *Veedfald* and the Scope of Product Liability

Case C-495/10 (*Dutrueux*) concerned a request for a preliminary ruling in a case involving compensation for burns caused by a heated mattress during a surgical procedure. During the surgical procedure, the patient had sustained burns from a heated mattress on which he had been placed and whose temperature control system was defective.[99] In France, the provisions of the PLD had been transposed into national law, but the liability of public healthcare institutions to compensate their patients was, in turn, governed by a special system concerning non-contractual liability. The

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[95] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 33 and 34.
[96] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 35 and 36.
[97] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, para 43. Legal literature has emphasised that the ruling explicitly confirms the independence of the assessment of legal causation in relation to medical and scientific causation (in the absence of scientific consensus). See, for example, Brosset 2018, pp. 1903–1904; Wnukiewicz – Kozłowska – Drozdowska 2021, pp. 268–270.
[98] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484, paras 30–32. The Court expressly held that requiring absolute medical proof would undermine the effective application, *effet utile*, of Article 1 of the Directive. CJEU derived this evidentiary rule by analogy from its earlier case law concerning the principle of effectiveness; see Case 199/82 *San Giorgio*, ECLI:EU:C:1983:318, para 14, where the Court held that national evidentiary rules making the recovery of claims practically impossible or excessively difficult are contrary to EU law. Legal literature has emphasised that, in its ruling, the CJEU disregarded the scientific consensus and elevated the private interest and safety of the vaccine recipient (the consumer of medical services) to the primary interpretative criterion of the Directive in the face of uncertainty. See Wnukiewicz – Kozłowska – Drozdowska 2021, pp. 264, 286. On the other hand, the CJEU's approach has also been criticised for distorting scientific evidence and disregarding medical methods in order to achieve legal and procedural objectives. See Smillie – Eccleston-Turner – Cooper 2018, pp. 141–144.
[99] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, paras 2 and 11.

principles governing that system include, in particular, the principle that a public hospital must compensate a patient for damage caused by a defect in equipment or a product used in treatment, even in the absence of any fault on the part of the institution.[100]

The *Conseil d'État* referred two questions for a preliminary ruling to the ECJ in this case. The first question concerned whether the PLD permits a compensation scheme for patients in public healthcare institutions based on their special status, in which patients are recognised, amongst other things, as having the right to claim compensation from the institutions for damage caused by the defectiveness of products and equipment used by the institution, even in the absence of any fault on the part of the institution, without this, however, limiting the institution's right of recourse against the manufacturer based on the warranty. The second question referred for a preliminary ruling concerned whether the PLD restricts the ability of Member States to regulate the liability for damages of persons who, whilst providing a service, use defective equipment or products and thereby cause harm to the recipient of the service, such as a patient.[101]

The ECJ responded to the second question referred for a preliminary ruling by reformulating the question so as to seek an answer to the question of whether the PLD applies to the liability for damages of a service provider who, in providing services similar to those given in a hospital setting, uses defective equipment or products and thereby causes harm to the recipient of the service, such that the Directive would preclude a national system which provides for the service provider's liability for damages caused, even in the absence of fault on its part.[102]

The ECJ held that, although the PLD is intended to approximate the laws of the Member States concerning the manufacturer's liability for damage caused by a product's lack of safety, and although the Directive aims, in respect of the matters regulated therein, at the full harmonisation of the laws, regulations and administrative provisions, its purpose is not to harmonise the field of liability arising from a product's lack of safety beyond the matters regulated therein.[103] Article 1 of the PLD provides

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[100] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, paras 8, 9 and 10.
[101] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, para 17.
[102] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, para 18.
[103] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, paras 19, 20 and 21; C-183/00 *González Sánchez*, ECLI:EU:C:2002:255, para 25. In legal literature, this established line of reasoning of the CJEU has

that the manufacturer is liable for damage resulting from a product's lack of safety, and Article 3 of the Directive specifies the conditions under which a person who presents themselves as the manufacturer of a product, a person who imports the product into the Union, or a person who has supplied the product is also to be regarded as a manufacturer within the meaning of the Directive. According to the ECJ, these articles must be interpreted in the light of the first and fourth recitals of the Directive in question, and they serve to identify, amongst the traders involved in the production and distribution process, the person on whom the liability established by the Directive falls.[104]

The first recital of the Directive states that the legislation in question concerns the manufacturer's liability for damage caused by a product's lack of safety, and the fourth recital specifies that liability should apply to every manufacturer involved in production whose finished product, component or raw material supplied is defective in terms of safety. Thus, liability would also extend to importers and, amongst others, to entities acting as manufacturers of the product.[105]

The ECJ held that liability for damages arising in respect of a user of a product who, in the course of treatment provided to a patient, uses a product or device such as a heating mattress which they have previously acquired does not fall within the scope of the Directive, as such a user cannot be regarded as forming part of the product's production and distribution chain.[106] The fact that, alongside the manufacturer's liability scheme under the PLD, there exists a national scheme providing for the service provider's strict liability, does not undermine the effectiveness of the system of manufacturers' liability nor prevent the achievement of the objectives pursued by the EU legislature through that system, provided that the possibility of holding the manufacturer liable is also maintained where the conditions for liability under the PLD are met. Such a possibility of holding the service provider liable must therefore be granted not only to the injured party but also to the service provider.[107]

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been described using a conceptual distinction: the harmonisation sought by the directive is "complete" in the matters it regulates, but it is not "exhaustive" in matters outside its scope. See Baeyens – Goffin 2012, pp. 322–323; Gsell–Mayrhofer 2025, p. 210.

[104] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, para 26.

[105] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, paras 1 and 4.

[106] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, paras 27 and 28.

[107] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, para 30; C-203/99 *Veedfald*, ECLI:EU:C:2001:258, para 27. The service provider's concurrent strict liability does not undermine the effectiveness of the directive.

According to the ECJ, a service provider who, in the context of providing services such as medical treatment in a hospital setting, uses equipment or products that are unsafe and of which it is not the manufacturer cannot be regarded as a manufacturer of a product within the meaning of the PLD, nor does the liability for damages of such a service provider fall within the scope of the PLD.[108]

The situation is different when the user of a product is also its manufacturer, as the manufacturer is, in principle, liable for any safety defects in the product. Exemption from liability under Article 7(a) of the PLD is possible in situations where the manufacturer has not "*put the product into circulation*". In Case C-203/99 (*Veedfald*), the Court ruled on how "*putting into circulation*" should be interpreted in a medical context where the service provider – that is, the user of the product – is also the manufacturer of the product. The case concerned a failed organ transplant resulting from a perfusion solution prepared in a hospital laboratory that did not meet safety standards. The ECJ stated that a product with inadequate safety is deemed to have been placed on the market when it is used in the context of the provision of a specific medical service – in this case, the preparation of a human organ for transplantation – and when the damage to the organ results from that preparation.[109]

2.2 Development Risk as a Substantive Limitation on Liability

The manufacturer's strict liability is limited by the so-called *"development risk defence"* provided for in the PLD Article 7(e).[110] Under the Directive, a manufacturer is not liable if it can demonstrate that *"the state of scientific and technical knowledge"* at the time the product was placed on the market was not such that the safety defect could have been detected.

The CJEU has confirmed in its case law[111] that this knowledge is assessed objectively on the basis of the highest level of international knowledge available, not on the basis of the manufacturer's subjective ability. According to the Advocate General's Opinion[112] , since Article 7(e) refers exclusively to the state of scientific and technical

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[108] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869, para 39.
[109] C-203/99 *Veedfald*, ECLI:EU:C:2001:258. The Court's ruling on the first question referred for a preliminary ruling.
[110] See, for example, Report of the Working Group on Product Liability OM 2026:8.
[111] C-300/95 *United Kingdom*, ECLI:EU:C:1997:255.
[112] Opinion of AG Tesauro in Case C-300/95 *United Kingdom*, ECLI:EU:C:1997:35.

knowledge at the time the product is placed on the market, the provision does not apply to the standard safety practices or safety rules in force in the industrial sector in which the manufacturer operates. According to the ECJ, the state of scientific and technical knowledge referred to in the article includes the most advanced state of the art as it stood at the time the product in question was placed on the market, without any restrictions whatsoever.[113]

The PLD does not take into account the level of knowledge that the manufacturer in question actually or subjectively possessed or might have possessed, but rather the objective level of knowledge of which the manufacturer is presumed to be aware.[114] Since the provision of the Directive does not concern the standard safety practices or safety rules in force in the industrial sector in which the manufacturer operates, this provision is therefore irrelevant to the question of exemption from liability in a situation, for example, in which none of the manufacturers in question takes the necessary measures to eliminate a safety defect or to prevent its occurrence, if such measures could have been taken in the light of the state of scientific and technical knowledge, including the state of the art.[115]

The adoption of the PLD at the time was based on Article 100 of the then EEC Treaty, which required unanimous agreement from the Council of Ministers.[116] The Federal Republic of Germany was among the delegations that strongly opposed extending strict liability of the manufacturer to development risks.[117] The Member States' views on liability for development risks differed, and Article 15 was added to the Directive, giving Member States the explicit option to choose whether or not to extend liability to development risks. The majority of countries (such as Germany, the UK, Denmark and Italy) decided to allow the use of development risk as a ground for exemption from

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[113] C-300/95 *United Kingdom*, ECLI:EU:C:1997:255, para 26; Opinion of AG Tesauro in Case C-300/95 *United Kingdom*, ECLI:EU:C:1997:35, point 20.
[114] C-300/95 *United Kingdom*, ECLI:EU:C:1997:255, para 27.
[115] Opinion of AG Tesauro in Case C-300/95 *United Kingdom*, ECLI:EU:C:1997:35, point 20.
[116] Treaty establishing the European Economic Community (Treaty of Rome, 1957), Article 100.: *"Der Rat erläßt einstimmig auf Vorschlag der Kommission Richtlinien…"*. Following the Treaty of Amsterdam in 1997, Article 100 of the Treaty establishing the European Economic Community became Article 94 of the Treaty establishing the European Community (EC). Today, the corresponding legislation is found in Article 115 TFEU.
[117] See, for example, Schwenzer 1991, p. 64. *"Il fallait s'attendre à cette décision du législateur allemand, étant donné que la R.F.A. faisait partie des délégations qui s'étaient vivement prononcées en faveur d'une exclusion des risques de développement du champ d'application de la directive."*

liability, whilst Luxembourg, for example, decided to omit this exemption from its legislation.[118]

In Finland, the PLD was implemented by the Product Liability Act[119], which came into force on 1 September 1991; in this Act, Finland did not permit this ground for exemption from liability, meaning that in Finland, development risk cannot be invoked to avoid liability.

The Government's proposal for the Product Liability Act sets out the rationale behind Finland's approach to development risk. According to the proposal, excluding development-related damage from the scope of product liability can be justified, amongst other things, on the grounds that it is unfair to hold a manufacturer liable for matters beyond its control. Furthermore, there have been concerns that such liability would hamper product development, increase insurance premiums – particularly in the fields of chemistry and genetic engineering – and undermine the competitiveness of Finnish industry. As regards the argument of fairness, according to the Government's proposal, this criticism of unfairness could be levelled at any form of liability independent of negligence, but this has not, however, prevented the drafting of provisions concerning liability for damages independent of negligence. On the other hand, the inclusion of development risk within product liability is supported by the position of the injured party, as it is unreasonable to leave the consequences of development-related damage to be borne by a private party. With liability in place, the financial impact is spread more widely, for example through prices and insurance premiums. Furthermore, claims that this would hinder product development and lead to higher insurance premiums were considered exaggerated, as, for example, in Norway, the inclusion of development risk in the law has not significantly increased costs. On the basis of these factors and the protection of the injured party, the proposal concludes that a manufacturer in Finland cannot be exempted from liability by invoking development risk defence.[120]

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[118] See Lewis 1994, pp. 186–187 (tables).
[119] Product Liability Act (694/1990).
[120] Government Proposal HE 119/1989 vp, p. 30.

2.3 Legislation Concerning Medical Devices

A distinction must be made between product liability and product safety. The purpose of the PLD is to provide compensation to consumers, after the event, for damage caused by a defective product that fails to meet safety standards. However, there are other European Union legislation designed to prevent damage in advance by ensuring that products placed on the EU market are safe, such as the Medical Devices Directive[121] (MDD) and the subsequent Medical Devices Regulation[122] (MDR).

It is worth noting that the MDD and MDR are ex-ante market access regulations and, as such, do not contain provisions on liability for damages. However, from the perspective of the research questions, these regulations are relevant in the following way.

Article 1 of the MDD sets out the definition of a medical device. A medical device is any instrument, apparatus, material or software necessary for its operation, which the manufacturer intends to be used on humans for medical purposes. The intended purpose of the device is either the diagnosis, prevention, monitoring or treatment of diseases or injuries; the investigation or modification of human anatomy or physiology; or the regulation of conception. The device must achieve its principal effect on the human body by means other than pharmacological, immunological or metabolic means, although these means may be used to assist the device's function.[123]

The safety requirement set out in Article 2 of the MDD, which stipulates that devices that, amongst other things, endanger the safety and health of patients and users may not be placed on the market or put into service, aims to ensure that no dangerous devices are present on the market. However, the article imposes this restriction on a product only if it is properly installed, maintained and used in accordance with its intended purpose.[124] The manufacturer must guarantee safety only for the intended use as defined in the MDD. The intended use is defined in Article 1(2)(g). It refers to the use for which the equipment is intended, as indicated in the manufacturer's markings, instructions for use and/or promotional material.[125] The manufacturer

[121] Council Directive 93/42/EEC.
[122] Regulation (EU) 2017/745.
[123] Council Directive 93/42/EEC, Article 1(2)(a).
[124] Council Directive 93/42/EEC, Article 2.
[125] Council Directive 93/42/EEC, Article 1(2)(g).

therefore defines the limits of its liability through the documents it produces. Furthermore, Section 13 of Annex 1 to the MDD sets out the information to be provided by the manufacturer. According to Section 13.1, the device must be accompanied by the information necessary for its safe use and for identifying the manufacturer, taking into account the training and knowledge of potential users.[126]

The MDR, which came into force on 26 May 2021, did not alter the aforementioned principle of the intended purpose as the limit of liability, but it introduced product liability and financial liability for damages into the regulation of medical devices. Under Article 10(16), compensation may be claimed for damage caused by a defective device. Furthermore, manufacturers must have measures in place that are proportionate to the risk class, type and size of the company to cover the liability and financial compensation arising from the PLD or, where applicable, national legislation imposing stricter liability.[127] In other words, the manufacturer must be prepared for situations in which financial liability is directly attributed to the manufacturer under the PLD.

The MDR broadens and clarifies the concept of a medical device in Article 2. In addition to instruments, software and materials, the definition explicitly covers implants and reagents as well. In addition to the diagnosis, treatment and monitoring of diseases and injuries, the intended purposes of a device now clearly include the prediction of diseases and the formulation of prognoses, the investigation of pathological conditions, and the collection of data using *in vitro* methods from samples taken from humans. The requirement concerning the principle of operation remains unchanged. The device's principal effect must not be achieved by pharmacological, immunological or metabolic means, but such means may be used to support the device's function.[128]

Furthermore, Section 23.4 of Chapter III of Annex 1 to the MDR defines the information to be provided in the instructions for use in a manner that is considerably broader than that set out in the MDD. The instructions for use must specify, amongst other things, the device's contraindications, undesirable side effects and the information to be provided to the patient regarding these, as well as the specifications

[126] Council Directive 93/42/EEC, Annex I, Section 13.1.
[127] Regulation (EU) 2017/745, Article 10(16).
[128] Regulation (EU) 2017/745, Article 2(1).

required by the user to operate the device correctly, such as the accuracy of the device's measurement function. Furthermore, with regard to software, which is itself considered a device, the minimum requirements must be specified, covering, amongst other things, hardware, IT network capabilities and IT security measures.[129] Where the manufacturer complies with the requirements of the Regulation, strict instructions for use serve as a limitation of liability clause for the manufacturer.

Article 10(16) of the MDR links the safety regulation of medical devices to product liability regulation. In the event of a malfunction, the requirements of the MDR must be taken into account when determining liability.

2.4 Limits to the Scope of Product Liability and the Service Provider's Liability for Damages

The PLD and the relevant case law of the CJEU define the liability of a medical device manufacturer in situations where the product is unsafe. As is evident from the *Dutrueux* judgment, the liability regime under the PLD applies to entities within the production and distribution chain. However, the scope of the Directive does not cover the liability of a service provider who uses a device they have acquired in the course of providing treatment to a patient, unless that service provider also acts as the manufacturer of the product. Nor does the PLD preclude national systems which provide for a service provider's liability for damages, provided that it is possible to attribute liability to the manufacturer under the PLD.

EU law on product liability is therefore not, on its own, a sufficient legal basis for addressing liability for damages arising from the clinical use of a device. It is necessary to define the service provider's liability so that liability can be attributed between the device manufacturer and the party using the device.

[129] Regulation (EU) 2017/745, Annex I, Chapter III, Section 23.4(g), (h) and (ab).

2.5 Healthcare Professional's Duty of Care and Professional Liability

Regulation of quality requirements for medical devices falls within the exclusive competence of the European Union, but health policy in other respects falls within the competence of the Member States.[130]

In accordance with Article 5(1) and (2) of the Treaty on European Union (TEU), the Union's competence is determined by the principle of conferral, meaning that it acts only within the limits of the powers conferred upon it by the Member States in the Treaties.[131] In accordance with Article 6(a) of the Treaty on the Functioning of the European Union (TFEU), the protection and improvement of human health is one of the areas in which the EU is competent to take measures to support, coordinate or supplement the actions of the Member States.[132] However, it cannot replace the competence of the Member States in such areas.[133] Under Article 168(7) TFEU, the definition of health policy and the organisation and delivery of health services and medical care are the responsibility of the Member States.[134] The Union primarily promotes cooperation between Member States and supports their actions.[135] Even with regard to the prevention of diseases and the combating of health threats, the EU cannot take measures that would result in the harmonisation of Member States' laws and regulations.[136] EU health policy therefore, at most, complements and supports the national health policies of the Member States.[137]

Under Article 168(4)(c) TFEU, the Union may adopt measures to set high standards of quality and safety for medicinal products and medical devices. The EU therefore regulates medicinal products and medical devices on the basis of the functioning of the internal market[138] and, through this, the safety requirements for devices[139]. However,

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[130] Lehtonen, "Rajat ylittävä terveydenhuolto Euroopan unionissa", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[131] Consolidated version of the Treaty on European Union, Article 5(1) and (2).
[132] Consolidated version of the Treaty on the Functioning of the European Union, Article 6.
[133] Consolidated version of the Treaty on the Functioning of the European Union, Article 2(5).
[134] Consolidated version of the Treaty on the Functioning of the European Union, Article 168(7).
[135] Consolidated version of the Treaty on the Functioning of the European Union, Article 168(2).
[136] Consolidated version of the Treaty on the Functioning of the European Union, Article 168(5).
[137] Lehtonen, "Rajat ylittävä terveydenhuolto Euroopan unionissa", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[138] Consolidated version of the Treaty on the Functioning of the European Union, Article 114. Article 114 TFEU confers on the European Parliament and the Council the power to adopt measures 'to approximate the laws, regulations and administrative provisions of the Member States'.
[139] Consolidated version of the Treaty on the Functioning of the European Union, Article 168.

product liability rules alone do not cover the field of liability for damages relating to the clinical use of devices; it is also necessary to define the service provider's liability for damages. Since the formulation of health policy and the organisation and provision of health services and medical care are the responsibility of the Member States, and the TFEU does not permit the harmonisation of health policy legislation, in order to attribute liability for damages between the manufacturer of the device and the entity using it, a professional standard applicable to the user of the device must be defined under national law, alongside the assessment of safety deficiencies in medical devices.

Section 15 of the Finnish Act on Healthcare Professionals 559/1994 stipulates that healthcare professionals must, in the course of their professional activities, apply generally accepted and empirically justified methods in accordance with their training.[140] In this study, this obligation is referred to as the *duty of care*. The content of this duty of care is derived from the professional standard in force at any given time. The individual tasks performed by a healthcare professional must comply with the professional standard generally required in healthcare in terms of the qualifications and training requirements necessary for the task.[141] In this work, the professional standard that fulfils this duty of care is referred to as *lex artis*.[142]

Current Care Guidelines are medical, independent, research-evidence-based national treatment guidelines.[143] They are drawn up in accordance with international methods of evidence-based medicine (EBM).[144] They can be regarded as a description of the level of medical knowledge at that particular point in time, i.e. a description of what constitutes the correct course of treatment in accordance with the prevailing *lex artis*.[145]

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[140] Act on Health Care Professionals (559/1994), Section 15(1).
[141] Lehtonen, "Ammattihenkilön oikeudet", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[142] The Latin term *lex artis* refers to the rules of skill or profession, professional conduct, i.e. generally accepted professional practice.
[143] Finnish Medical Society Duodecim: Current Care Guidelines.
[144] Finnish Medical Society Duodecim: Current Care Guidelines, Methods.
[145] Suomen Lääkäriliitto 2021, p. 82. See also Ferrara – Boscolo-Berto – Viel 2013, p. 8. The interpretation of the *duty of care* has not been harmonised across Europe; rather, its application is divided into two basic models: in some jurisdictions, the *lex artis* concept—which is tied to the highest level of scientific knowledge—is used as a reference, whilst in others, potential liability is assessed by comparing the professional's actions to the knowledge and technical-operational level of an 'average professional' in the relevant speciality.

2.5.1 The Care Relationship as the Basis for the Duty of Care

The care relationship refers to the legal relationship between the person receiving treatment, i.e. the patient, and the healthcare professional. Its existence requires that the person receiving treatment has an objectively demonstrable need for healthcare or medical care, and where the clear purpose of the actions of the healthcare professional—who has a de facto influence over treatment decisions—is to assess, maintain or improve the patient's state of health.[146] A care relationship has not only formal criteria for its existence but also a physical starting and ending point, beginning from the moment the characteristics of a care relationship are met and continuing until the moment they cease.[147] A care relationship may arise, for example, at the patient's initiative, in which case the patient's expressed need for care gives rise to legal consequences, or on the basis of a duty of care in situations requiring urgent treatment[148] or in situations where the patient is unable or unwilling to express their wishes and has not otherwise made their wishes known in advance.[149]

The care relationship is therefore formed between two parties: the person receiving care, i.e. the patient, and the healthcare professional providing that care.[150] Section 2 of the Act on the Status and Rights of Patients 785/1992 defines a patient as a person who uses health and medical care services or is otherwise the subject of such services.[151] The distinction between using services and being the subject of services lies in whether the patient uses health and medical care services of their own volition or is the subject of such services regardless of their will. The scope of the concept of a "*patient*" is broad. The threshold for being a "*user of service*" would be crossed, for example, by being admitted to hospital or registering at an outpatient clinic.[152] However, it should be noted that the legal relationship between a healthcare organisation and a patient cannot be regarded as a care relationship, as legislation governing healthcare organisations does not allow them to intervene in individual treatment decisions;

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[146] Lehtonen 2001, p. 87.
[147] Lehtonen 2001, p. 30.
[148] Act on Health Care Professionals (559/1994), Section 15(3). See also Lehtonen 2001, p. 97. A patient in need of urgent care refers to a person whose life or health would be seriously endangered without immediate medical intervention.
[149] Lehtonen 2001, p. 97.
[150] Lehtonen 2001, p. 31
[151] Act on the Status and Rights of Patients (785/1992), Section 2.
[152] Government Proposal 185/1991, p. 13.

consequently, the defining characteristics of a care relationship are not met without the organisation having actual influence over treatment decisions.[153]

Patients' rights and the professional duties of healthcare professionals are defined within the care relationship through pairs of rights and duties. When certain rights are granted to a patient, this inherently entails corresponding duties for healthcare professionals.[154] A patient's right to adequate social and health services is enshrined in the Finnish Constitution[155]; in other words, a patient's right to receive care appropriate to their state of health is, in principle, a social right[156], the safeguarding of which is ultimately the responsibility of the public authorities.[157] The public sector therefore has a duty to organise healthcare services, but the treatment relationship is not established between the public sector and the patient, but rather between healthcare professionals and the patient, and the responsibility for making decisions regarding treatment lies with the healthcare professional. Consequently, the healthcare professional is ultimately responsible for ensuring that their actions meet the standard of *lex artis*. The obligations relating to the care relationship are, in fact, obligations arising from the healthcare professional's "*status*".[158] These obligations relating to the care relationship include, for example, the duty to provide good care[159], the duty to respect the patient's right to self-determination[160] and the duty of confidentiality[161].[162] A large proportion of these obligations must be observed by all healthcare professionals.[163]

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[153] Lehtonen 2001, p. 87. As such, the Government Proposal HE 185/1991 does not regard the treatment relationship as a concept with the same meaning as in Lehtonen's theory of the treatment relationship. According to the government Proposal, admission to hospital would be sufficient evidence of the commencement of the care relationship, which in turn would be a prerequisite for the patient's status to arise. However, this study follows Lehtonen's theory of the care relationship, in which the care relationship arises only between natural persons.
[154] Lohiniva-Kerkelä, "Sääntelyn lähtökohdat", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[155] Constitution of Finland (731/1999), Section 19.
[156] Tuori – Kotkas 2023, pp. 1–9. Social law comprises the legal norms governing social security, which in turn is divided into income security and social- and healthcare, a classification followed in the provision on fundamental social rights in Section 19 of the Constitution of Finland (731/1999).
[157] Lohiniva-Kerkelä, "Sääntelyn lähtökohdat", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[158] Lehtonen 2001, pp. 82–83.
[159] Act on the Status and Rights of Patients (785/1992), Section 3.
[160] Act on the Status and Rights of Patients (785/1992), Section 6.
[161] Act on Health Care Professionals (559/1994), Section 17.
[162] Lehtonen 2001, p. 82.
[163] Lehtonen 2001, p. 32.

The establishment of a care relationship is therefore a prerequisite for the duty of care set out in Section 15 of the Act on Health Care Professionals 559/1994.[164] In individual care encounters, the requirements placed on the actions of healthcare professionals are emphasised from the perspective of the quality of care. This quality is linked to the competence and professional skills required of healthcare professionals. For healthcare professionals to provide high-quality care, they are also required to act in accordance with their statutory and ethical obligations, adhering to the standards expected of an experienced professional.[165]

In practice, the assessment of the need for care carried out by a nurse or public health nurse is based on guidance provided by the lead or supervising doctor. The lead or supervising doctor is therefore responsible for this activity.[166] Furthermore, it is ultimately the doctor's responsibility to assess what kind of care the patient's medical condition requires.[167] Under the Act on Health Care Professionals, a registered doctor decides on the patient's medical examination, diagnosis and related treatment.[168]

It could indeed be argued that the doctor's duty of care arising from the care relationship and the professional standard required to fulfil it are no different from the requirements set for other healthcare professionals. The standard of practice for healthcare professionals is described by the term "*good care provided by an experienced practitioner*".[169] In their professional practice, healthcare professionals must apply generally accepted and empirically justified procedures in accordance with their training.[170] In their work, doctors are required to make decisions on more complex treatment-related matters than many other healthcare professionals. This may give the impression that a doctor's duty of care differs from that of other healthcare professionals, but there is no legal basis for such a view.

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[164] A prerequisite for the obligation to follow generally accepted and empirically justified methods in accordance with one's training.
[165] Lohiniva-Kerkelä, "Laadultaan hyvä hoito", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[166] Lehtonen, "Hoitoon pääsy", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[167] Lohiniva-Kerkelä, "Potilaan oikeus hoitoon", in Lehtonen – Lohiniva-Kerkelä – Pahlman, Terveysjuridiikka (Alma Insights).
[168] Act on Health Care Professionals (559/1994), Section 22.
[169] Lehtonen 2001, p. 39. Here, Lehtonen refers to the now-repealed Patient Injuries Act (585/1986). Currently, a corresponding description of the standard can be found in Section 23 of the Patient Insurance Act, which replaced the Patient Injuries Act.
[170] Act on Health Care Professionals (559/1994), Section 15(1).

3 Artificial Intelligence Systems and Product Liability

3.1 Software and Learning Systems as Tangible Products

The RPLD defines "*software*" as a product. The term "*product*" refers to all movable objects, even if the object is integrated into or attached to another movable object or to immovable property. The object described above includes electricity, digital manufacturing files, raw materials and software.[171] In the PLD, the term "*product*" referred to movable objects, even if the object was attached to another movable object or to immovable property, as well as electricity.[172] With regard to software, the legal situation was previously considered unclear.[173] However, the RPLD does not define the term "*software*"; but rather outlines the scope of the concept by listing certain types of software, such as operating systems, firmware, computer programmes, applications and artificial intelligence systems.[174]

In the AI Act, the term "*AI system*" refers to a machine-based system designed to operate at varying levels of autonomy after deployment, which may exhibit adaptability after deployment and which reasons from the input it receives for explicit or implicit objectives, how to generate outputs, such as predictions, content, recommendations or decisions, which may affect physical or virtual environments.[175]

The RPLD confirms that, in the context of artificial intelligence, AI systems and goods incorporating AI are products. They therefore fall within the scope of the RPLD, meaning that compensation may be claimed if defective AI causes damage, without the injured party having to prove a manufacturing defect, in accordance with the principle of strict liability.[176] Under this strict liability regime, software is considered a product regardless of how it is supplied or used, and thus regardless of whether the software is

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[171] Directive (EU) 2024/2853, Article 4(1).
[172] Council Directive 85/374/EEC, Article 2.
[173] See Steininger 2026, p. 2; Fairgrieve et al. 2020, pp. 18–19; European Commission, SWD(2018) 157 final, p. 51. See also C-128/11 *UsedSoft*, paras 58 and 61. In *UsedSoft* software downloaded from the Internet was treated as equivalent, both economically and functionally, to a physical copy, supporting the notion that software is a product. In contrast, see C-65/20 *KRONE-Verlag*, paras 29 and 36. According to *KRONE-Verlag* passive advice incorporated into a physical medium constitutes a service that falls outside the scope of the Directive. It has been stated in legal literature that the relevant question concerns the information inherent in the software, the question being whether errors in the information inherent in the software qualify it as a defective product. See Ulfbeck 2020, pp. 146–147.
[174] See Li – Schütte 2023, p. 6. The authors refer to Directive (EU) 2024/2853, Recital 12.
[175] Regulation (EU) 2024/1689, Article 3(1).
[176] European Commission, COM(2022) 495 final, pp. 5 and 11.

stored on a device, used via a communications network or cloud technologies, or delivered via a web application service model.[177]

The provider of an artificial intelligence system is treated in the same way as the manufacturer of a product, meaning that strict liability, irrespective of fault, is attributed to the provider. Software developers, producers and providers as defined in the AI Act are treated as manufacturers for the purposes of product liability.[178] According to Article 3(3) of the AI Act, the term "*provider*" refers to a natural or legal person, a public authority, agency or other body that develops or commissions the development of an AI system or a general-purpose AI model and places it on the market or puts the AI system into service under its own name or trade mark, either for a fee or free of charge.[179]

Under Article 11(1)(c) of the RPLD, a manufacturer is not liable for damage caused by a product with a safety defect if they can prove that it is probable that the defect causing the damage did not exist at the time the product was placed on the market or that the defect arose after that time.[180] However, under Article 11(2), the manufacturer is not exempt from liability if the defect is attributable to a service related to the product, software, including software updates or version updates, the absence of software updates or version updates necessary to maintain security, or a significant modification to the product, provided that the matter in question is within the manufacturer's control.[181] As digital technologies enable manufacturers to monitor a product after it has been placed on the market or put into service, manufacturers must also be held liable for defects arising after that point in time which are attributable to software or related services under their control, whether these take the form of improvements, updates or machine learning algorithms.[182] The RPLD therefore changes the assessment of product defects. A product's defectiveness is no longer determined on the basis of when it was placed on the market; instead, the decisive moment is considered to be the point at which the product ceases to be under the manufacturer's

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[177] Directive (EU) 2024/2853, Recital 13.
[178] Directive (EU) 2024/2853, Recital 13 and Article 4(10).
[179] Regulation (EU) 2024/1689, Article 3(3).
[180] Directive (EU) 2024/2853, Article 11(1)(c). See also Mayrhofer 2026, p. 97.
[181] Directive (EU) 2024/2853, Article 11(2). See also Mayrhofer 2026, p. 97. Mayrhofer interprets Article 11(2) of the Directive (EU) 2024/2853.
[182] Directive (EU) 2024/2853, Recital 50.

control.[183] It has indeed been suggested that the moment at which a product ceases to be under the manufacturer's control may be of decisive importance in terms of determining safety requirements[184], in terms of a subsequent defence based on defect[185] and in terms of a defence based on development risk[186].[187]

When assessing a product's inadequate safety, all factors must be taken into account, including the impact on the product of its potential ability to continue learning or acquire new features after it has been placed on the market or put into service.[188] This is necessary in order to take into account the reasonable expectation that the product's software and its underlying algorithms have been designed to prevent dangerous behaviour on the part of the product. A manufacturer who designs a product capable of behaving in an unexpected manner must be held liable for any behaviour of the product that causes harm.[189]

In Finland, in order to bring the scope of the Product Liability Act up to date, it has been proposed that the Act's definitions and provisions be amended so that they better reflect the requirements of the digital environment. In line with the RPLD, for example, it is proposed that the definition of a "*product*" be extended to also cover intangible products, such as software and digital manufacturing files.[190] Furthermore, it is proposed that more detailed provisions be added to the Product Liability Act concerning the parties liable for damages, the conditions for exemption from liability, criteria for assessing safety deficiencies and limitation periods, as well as new provisions including, amongst other things, presumptions regarding safety deficiencies and the causal link between a safety deficiency and the damage incurred, and provisions concerning the duty to disclose and the publication of judgements.[191]

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[183] Li – Schütte 2023, p. 15.
[184] Directive (EU) 2024/2853, Article 7(2)(e) and Article 7(3).
[185] Directive (EU) 2024/2853, Article 11(1)(c) and Article 11(2).
[186] Directive (EU) 2024/2853, Article 11(1)(e).
[187] Mayrhofer 2026, p. 89.
[188] Directive (EU) 2024/2853, Article 7(2)(c).
[189] Directive (EU) 2024/2853, Recital 32.
[190] Report of the Working Group on Product Liability OM 2026:8, p. 12.
[191] Report of the Working Group on Product Liability OM 2026:8, p. 12. The same report sets out a proposal to amend the Product Liability Act concerning Section 1a, in which "*product*" means a movable object, including an object that is integrated into or attached to another movable object or immovable property, as well as electricity, digital manufacturing files, raw materials and software, but not a building situated on another person's land. For further details, see the Report of the Working Group on Product Liability OM 2026:8, p. 94.

3.2 Strict Liability of the Manufacturer and Development Risk

The RPLD allows a manufacturer to be exempted from liability if the objective state of scientific and technical knowledge did not permit the safety defect to be detected at the time the product was placed on the market, put into service or whilst under the manufacturer's control.[192] Under the PLD, the requirement regarding the level of scientific and technical knowledge for this so-called "*development risk*" defence was linked to the date on which the product was placed on the market.[193]

The RPLD allows Member States to derogate from this ground for exemption from liability and to maintain a national system in which economic operators are also liable for defects that are beyond the current state of scientific knowledge. Notwithstanding the provisions of Article 11(1)(e), Member States may maintain in their legal systems existing measures, introduced by PLD, under which economic operators are liable even when they can prove that the objective level of scientific and technical knowledge at the time the product was placed on the market or put into service, or during the period in which the product was under the manufacturer's control, was not such that the lack of safety could have been detected.[194] Member States may, furthermore, derogate from this possibility by introducing new measures or amending existing measures so as to extend liability in such situations to cover certain types of products, if this is deemed necessary, proportionate and justified by objectives in the public interest.[195]

In Finland, no amendments are proposed to the national Product Liability Act with regard to the development risk defence; in other words, the development risk defence would continue not to be applied in Finland as a ground for exemption from liability.[196] The fact that Finland is maintaining the *status quo* regarding development-related damage means, in practice, that manufacturers retain strict liability for all product damage, including unforeseeable safety defects.[197] In other words, in a case where a product equipped with artificial intelligence begins to exhibit unexpected behaviour that causes a safety defect, the manufacturer is liable for the resulting damage, even if

[192] Directive (EU) 2024/2853, Article 11(1)(e).
[193] Council Directive 85/374/EEC, Article 7(e).
[194] Directive (EU) 2024/2853, Article 18(1).
[195] Directive (EU) 2024/2853, Recital 59, Article 18(2) and Article 18(3).
[196] Report of the Working Group on Product Liability OM 2026:8, p. 32.
[197] Report of the Working Group on Product Liability OM 2026:8, p. 39.

the behaviour only manifests itself after the product has been placed on the market.[198] This strict liability therefore also covers unforeseeable errors generated independently by the AI "black box", and the legislator's intention is to hold the manufacturer strictly liable for as long as the manufacturer retains control over the product. The retention of control would be assessed, for example, on the basis of software updates. With regard to software, it would not be required that updates actually be carried out; the mere possibility of them would suffice to maintain control.[199]

[198] Report of the Working Group on Product Liability OM 2026:8, p. 59.
[199] Report of the Product Liability Working Group OM 2026:8, p. 60.

4 AI Act and the Healthcare Sector

Although the risks associated with AI systems may stem from the way in which they are designed, these risks are also influenced by how the systems are used. Those deploying high-risk AI systems play a key role in this regard.[200] Whilst the RPLD tighten the liability of the manufacturer – and, by extension, the provider – the AI Act also imposes obligations on the deployer of a high-risk system. Given the nature of AI systems and the risks to safety and fundamental rights associated with their use, it is justified to impose certain obligations on deployers; for example, deployers should implement technical and organisational measures to ensure that they use high-risk AI systems in accordance with the instructions for use.[201]

In the AI Act, "*deployer*" means a natural or legal person, public authority, agency or other body that uses an AI system under its control, unless the AI system is used in a personal capacity other than in the course of a professional activity.[202] As stated above[203], the scope of the RPLD does not cover the liability of a service provider who uses equipment they have acquired in the context of treatment provided to a patient, unless the service provider also acts as the manufacturer of the product. On the other hand, the RPLD does not affect Member States' national legislation concerning contractual or non-contractual liability on grounds other than a product safety defect.[204]

There are still few specific liability provisions in EU legislation; the AI Act does not contain clear or detailed liability provisions, and civil liability issues are addressed through national legal remedies.[205] With the exception of the RPLD, tort law is in fact a matter for national law, and national law remains the primary source of law in matters of liability for damages relating to artificial intelligence.[206]

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[200] Regulation (EU) 2024/1689, Recital 93.
[201] Regulation (EU) 2024/1689, Recital 91.
[202] Regulation (EU) 2024/1689, Article 3(4).
[203] See Chapter 2.1.3.
[204] Directive (EU) 2024/2853, Article 2(4)(c). See also Report of the Working Group on Product Liability OM 2026:8, p. 27.
[205] Havu et al. 2024, p. 17 (4.7).
[206] Bruyne – Ooms 2025, p. 162. See also European Commission, COM(2022) 496 final. The authors describe the AI Liability Directive as an attempt to harmonise European AI liability provisions, which they regard as "heterogeneous". However, the AI Liability Directive was withdrawn in 2025.

High-risk AI systems play a significant role in the attribution of liability for damages due to the obligations imposed on their deployers and providers by AI Act. Software, such as AI systems, constitutes a product, and the liability of the provider of the product is equivalent to that of the manufacturer. The manufacturer's liability is governed by product liability legislation, whilst the deployer's liability is determined in accordance with national tort law. Consequently, the service provider's liability for damages is governed by national law.

However, before assessing the legal significance of these obligations, it is necessary to define what a high-risk AI system means in a medical context.

4.1 High-Risk Medical AI Systems

AI systems defined as high-risk should be limited to those that may have a significant adverse impact on people's health, safety and fundamental rights within the Union, and such a limitation should minimise any restrictions on international trade.[207] AI systems that are safety components of products falling within the scope of specific Union harmonisation legislation listed in Annex 1 to the AI Act, or that are products in their own right, should be classified as high-risk, if the product undergoes a conformity assessment procedure at a third-party conformity assessment body in accordance with the relevant Union harmonisation legislation.[208] Standalone AI systems — that is, high-risk AI systems other than those that are safety components of products or that are products in their own right — should, in turn, be classified as high-risk, if, based on their intended use, they pose a high risk to human health and safety or fundamental rights, taking into account both the severity of the potential harm and the likelihood of its occurrence, and are used in sectors specifically defined in the AI Act.[209]

Article 6 of the AI Act sets out the rules for classifying high-risk AI systems. According to the article, an AI system is to be considered high-risk, inter alia, if both of the following conditions are met: (a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product falling within the scope of Union harmonisation legislation listed in Annex I; (b) product of which the AI system is a safety component pursuant to point (a), or the AI system, which is a product in its

[207] Regulation (EU) 2024/1689, Recital 46.
[208] Regulation (EU) 2024/1689, Recital 50.
[209] Regulation (EU) 2024/1689, Recital 52.

own right, must undergo a third-party conformity assessment in order to be placed on the market or put into service in accordance with the Union harmonisation legislation listed in Annex I. This applies regardless of whether the AI system is placed on the market or put into service separately from the products referred to in subparagraphs (a) and (b).[210]

Annex I to the AI Act includes, amongst others, the MDR[211] and the In Vitro Diagnostic Regulation[212].[213] The MDR defines software intended by the manufacturer to be used on humans for medical purposes as medical devices.[214] Consequently, as medical devices fall within the scope of the harmonisation legislation listed in Annex I, they fulfil the requirement set out in Article 6(1)(a) of the AI Act.

In order to meet the requirement set out in Article 6(1)(b), a medical device must undergo a conformity assessment carried out by a third-party conformity assessment body prior to being placed on the market. In the MDR, the term "*notified body*" refers to a body that carries out conformity assessment activities, such as calibration, testing, certification and inspections, as a third party.[215] Manufacturers must carry out a conformity assessment of the device before placing it on the market or putting it into service.[216] The involvement of a notified body[217], i.e. a conformity assessment body, is required for all Class III devices[218], all Class IIb devices not intended for individual use or for research purposes[219] and all Class IIa devices not intended for individual use or for research purposes[220].[221] As a general rule, manufacturers of Class I devices self-declare the device's conformity. However, the involvement of a notified body is mandatory under certain conditions for sterile devices[222], devices with measuring

[210] Regulation (EU) 2024/1689, Article 6(1).
[211] Regulation (EU) 2017/745.
[212] Regulation (EU) 2017/746.
[213] Regulation (EU) 2024/1689, Annex I, Section 11; Regulation (EU) 2024/1689, Annex I, Section 12.
[214] Regulation (EU) 2017/745, Article 2(1).
[215] Regulation (EU) 2017/745, Article 2(41).
[216] Regulation (EU) 2017/745, Article 52(1) and Article 52(2).
[217] Regulation (EU) 2017/745, Article 2(42). The term "*notified body*" refers to a conformity assessment body.
[218] This also includes implantable devices manufactured for individual use.
[219] With a few exceptions, Class IIb implantable devices are also subject to an assessment of the technical documentation for all devices.
[220] The assessment of technical documentation must be carried out on at least one device representing each Class IIa device category.
[221] Regulation (EU) 2017/745, Article 52(3), Article 52(4) and Article 52(6).
[222] The organisation's involvement is limited to the establishment, verification and maintenance of sterility.

functions[223] and reusable surgical instruments[224].[225] In addition, further procedures carried out by a notified body are always required, as appropriate, in the case of devices containing medicinal substances or blood derivatives[226], devices utilising animal or human tissues or cells, or their derivatives[227], and devices consisting of substances intended to be introduced into the human body and which are absorbed by or degrade locally within the human body.[228]

A large proportion of active devices[229] meet the requirement set out in Article 6(1)(b) regarding a third-party conformity assessment of a medical device prior to placing it on the market, as they fall within Classes IIa, IIb and III. Software constitutes an active device.[230] Active devices are divided into two sub-categories: active therapeutic devices[231] and active devices intended for diagnosis and monitoring[232].[233] Software intended to provide information used in making diagnostic or therapeutic decisions is classified as Class IIa, unless such decisions could result in the death of a person or a permanent deterioration in their state of health, in which case it is classified as Class III, or a serious deterioration in a person's state of health or a surgical procedure, in which case they are classified as Class IIb. Furthermore, software intended for the monitoring of physiological functions is classified as Class IIa, unless they are intended to monitor vital physiological parameters in a situation where variations in these parameters may pose an immediate risk to the patient, in which case they are classified as Class IIb.[234] Software that controls a device or influences its use falls into the same class as the device.[235] Consequently, in the context of artificial intelligence, active

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[223] The assessment of the facility is limited solely to those aspects relating to the metrological conformity of the devices.
[224] The assessment of the facility is limited to aspects relating to the reuse of devices, in particular cleaning, disinfection, sterilisation, maintenance, performance testing and instructions for use.
[225] Regulation (EU) 2017/745, Article 52(7).
[226] Regulation (EU) 2017/745, Article 1(8), first subparagraph.
[227] Regulation (EU) 2017/745, Article 1(6)(f), Article 1(6)(g) and Article 1(10), first subparagraph.
[228] Regulation (EU) 2017/745, Article 52(9), Article 52(10) and Article 52(11).
[229] Regulation (EU) 2017/745, Article 2(4), first subparagraph. An active device is a device whose operation is based on a source of energy other than energy derived directly from the human body or from gravity, and which functions by altering the density of that energy or by converting it. Devices that transfer energy, substances or other factors between an active device and the patient without significant changes are not considered to be active devices.
[230] Regulation (EU) 2017/745, Article 2(4), second subparagraph.
[231] Regulation (EU) 2017/745, Annex VIII, Chapter I, Section 2.4.
[232] Regulation (EU) 2017/745, Annex VIII, Chapter I, Section 2.5.
[233] Regulation (EU) 2017/745, Annex VIII, Chapter I.
[234] Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 6.3 (Rule 11), first and second paragraphs.
[235] Regulation (EU) 2017/745, Annex VIII, Chapter II, Section 3.3, first paragraph.

therapeutic devices with an integrated or incorporated diagnostic function that significantly influences the treatment provided by that device must also be taken into account, such as closed-loop systems or automated external defibrillators, which are classified as Class III.[236]

As set out above, Article 52 of the MDR contains exemptions from the obligation to have conformity assessed by a third party. However, these exemptions do not apply to software. Consequently, all AI software falling within Classes IIa, IIb and III requires a third-party conformity assessment and is therefore classified as high-risk AI systems as defined by the AI Act. Software intended by the manufacturer for use on humans for medical purposes constitutes a medical device, and where it meets the requirements of Article 6(1) of the AI Act, it constitutes a high-risk AI system. In this thesis, software meeting these criteria is referred to as a high-risk medical AI system or, more simply, a medical AI system, as all medical AI systems are high-risk.[237]

4.2 The Deployer in Healthcare Context

Deployers have a number of obligations, as certain risks may arise not only during the design and development phase of a product, but also during its use, and these must be mitigated appropriately.[238] The AI Act sets out a number of requirements and obligations for deployers of high-risk medical AI systems and, consequently, also for hospitals and their management and committees.[239] Hospitals must be regarded as deployers within the meaning of the AI Act, as they are legal entities that use medical AI systems under their own responsibility. This also applies to doctors and other healthcare professionals who use a medical AI system as natural persons in the course of their professional activities. Deployers have various obligations under the AI Act, depending on the risk classification of the AI system used.[240]

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[236] Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 7.9 (Rule 22).
[237] The Class IIb exemption regarding the exemption from the assessment of the technical documentation for devices applies to implantable devices such as sutures, hooks and screws. As software, artificial intelligence software does not fall within the scope of these exemptions. Nor is artificial intelligence software a sterile or surgical instrument. It follows from the definition of a medical device that there are, in fact, no Class I artificial intelligence systems that can be classified as medical devices. See Medical Device Coordination Group, MDCG 2019-11, pp. 17–18. A Class I device is not intended to provide information used to make decisions relating to diagnosis or treatment, nor is it intended to monitor physiological processes or parameters.
[238] Braun – Harasimiuk 2026, p. 18.
[239] Bruckmüller – Altrichter 2025, p. 298.
[240] Bruckmüller – Altrichter, p. 297.

4.3 The Obligations Established by the AI Act and Their Significance in a Care Situation

As a general rule regarding AI systems, providers and deployers must, to the best of their ability, implement measures to ensure that those responsible for the operation and use of the systems possess sufficient AI literacy. In this context, consideration is given to the technical knowledge, experience and training of these individuals, the context in which the AI systems are used, and the individuals or groups of individuals for whom the AI systems are intended.[241] In this thesis, the examination of the obligations of providers and deployers is limited to those obligations that can be considered relevant in the event of patient injury[242] in terms of the attribution of liability for damages.

The problem of attributing liability arises in situations where a product defect enables harm to occur during treatment. Consequently, this study is limited to examining only such cases of harm where there is a defect in the product – in this instance, in a high-risk medical AI system. As this study focuses on determining the attribution of liability in cases of harm where the product is defective, it is not meaningful to examine the proof of the defect; for this reason, the study does not address issues relating to the burden of proof, apart from a few references necessary to clarify the situation.[243]

For the same reason, this study excludes those obligations of providers whose breach has no direct causal link, in a patient injury situation, to the healthcare professional's breach of the duty of care. When attributing liability for damages between the provider and the deployer, only those breaches of the provider's obligations that result in the device being unsafe which the deployer could have detected by fulfilling their own obligations are relevant.

By contrast, no such limitation can be imposed on the obligations of the deployer, i.e. the service provider. This is because the purpose of the deployer's obligations is to act as a final safety net and to reveal any shortcomings in the AI system before damage

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[241] Regulation (EU) 2024/1689, Article 4.
[242] Patient Insurance Act (948/2019), Section 2(8). "*Patient injury*" refers to personal injury sustained by a patient in the course of the provision of health and medical care.
[243] See Directive (EU) 2024/2853, Article 9 and Article 10. The rules regarding presentation of evidence and burden of proof are laid down in Articles 9 and 10 of the RPLD.

occurs.[244] Therefore any breach of the deployer's obligations may be used as grounds for liability for damages under the *conditio sine qua non* principle.[245] However, in order to give rise to liability for damages, this breach – that is, the necessary cause – must be sufficiently effective to bring about the damage that has occurred.

In a case of patient injury the sufficiency of the causal link is assessed in a situation where two different bases of liability co-exist: the strict liability under product liability legislation and the fault-based liability of a healthcare professional.[246]

Product liability is strict liability, which does not require fault. The causal link between a product defect and harm in relation to medical devices has been assessed in the case law of the CJEU. Where the evidence is incomplete, circumstantial evidence that are sufficiently credible, precise and consistent to demonstrate that the product's lack of safety is the most plausible explanation for the damage, despite the manufacturer's defence, have been deemed sufficient to establish a causal link between the damage and the lack of safety.[247] In the case of AI with limited 'explainability[248]', such sufficiently credible, precise and consistent circumstantial evidence could be regarded as sufficient to establish a causal link between the patient injury and the lack of safety.[249]

The liability of healthcare professionals, which is governed by national law, is based on fault. Fault concerns the assessment of whether behaviour is reprehensible. Fault constitutes a failure to exercise the due care required in each case. By failing to exercise due care, a person simultaneously creates or increases the risk of harm.[250] A breach of

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[244] Regulation (EU) 2024/1689, Recital 93.
[245] See, for example, Hemmo, "Syyn välttämättömyys ja riittävyys", in Saarnilehto et al., Varallisuusoikeus (Alma Insights). The cause of the damage relevant under tort law is sought to be established by asking whether the damage would have occurred if the event suspected of causing the damage had not taken place.
[246] Strict liability can be understood in a broad sense, i.e. as encompassing damage caused by both intentional acts and negligence, or resulting from carelessness, or in a narrow sense, excluding intent. In this study, liability in tort is understood, as a starting point, in the narrow sense in accordance with the wording of the Damages Act. See Ståhlberg – Karhu 2020, p. 87.
[247] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484. See Chapter 2.1.2 for further details.
[248] See Amann et al. 2020, p. 2. Explainability can be understood as a property of an AI-based system that allows a person to determine why a particular AI has arrived at the presented predictions. It is important to note that explainability has many dimensions, and the terminology surrounding explainability has not been precisely defined. Other terms, such as interpretability or transparency, are often used as synonyms for explainability.
[249] Directive (EU) 2024/2853, Article 10(4)(b). The claimant must demonstrate that it is probable that the product is defective in terms of safety, or that there is a causal link between the product's safety defect and the damage, or that both of these conditions are met.
[250] Ståhlberg – Karhu 2020, pp. 91–93.

due care by a healthcare professional constitutes a breach of the duty of care, i.e. conduct contrary to *lex artis*. In the context of this study, assessing the significance of fault is straightforward in a sense that, if the conduct is fault-based, it is always causally linked to the harm, as the harm has occurred. When a healthcare professional, as the user of a medical AI system, breaches their obligations, there is always a causal link between the healthcare professional's negligent conduct and the damage. However, the question of whether negligent conduct gives rise to a liability for damages is always a matter of case-by-case assessment.

Damage caused by a product's lack of safety covers all personal injuries resulting from that lack of safety. Personal injuries include medical expenses, all costs incurred by the injured party as a result of treatment, and any impairment to the ability to work resulting from the personal injury. Compensation for damages covers all measures taken to eliminate the harmful effects in order to restore the level of safety that could reasonably be expected from the product.[251]

Liability for damages based on fault is, in principle, governed by the principle of full compensation. Anyone who causes harm to another person, whether intentionally or through fault, is obliged to compensate for it. In certain circumstances, compensation may be adjusted if the obligation to pay is deemed unreasonably onerous, taking into account the financial circumstances of the person who caused the damage and the person who suffered it, as well as other relevant circumstances. However, if the damage was caused intentionally, full compensation must be awarded, unless there are special reasons to reduce the damages.[252]

The following chapter systematises, from the obligations of the provider and the deployer, the relevant tort law framework, on the basis of which liability for damages is assessed in cases of patient injury and on the basis of which changes to the professional standard of the duty of care of healthcare professionals are determined within the new regulatory framework.

To improve clarity, the framework is presented by starting with the provider's obligations, which serve as a prerequisite for the deployer's obligations.

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[251] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148. See chapter 2.1.1.
[252] Damages Act (412/1974), Chapter 2, Section 1.

5 The Regulatory Framework for Healthcare Tort Law Under the AI Act

5.1 Provider Obligations and Product Safety Requirements

Article 16 of the AI Act sets out the obligations of providers of high-risk AI systems. These obligations include, amongst other things, ensuring that AI systems comply with the requirements of Articles 8–15.[253] These articles set out the requirements for high-risk AI systems. Providers are therefore responsible, under product liability, for ensuring that medical AI systems comply with these requirements.[254]

According to Article 13 of the AI Act, high-risk AI systems must be designed and developed in such a way as to ensure that their operation is sufficiently transparent[255] so that users can interpret the system's outputs and use them appropriately. High-risk AI systems must be accompanied by user instructions, which must provide concise, complete, accurate and clear information that is relevant and understandable to deployers. The user instructions must include, at a minimum, the intended use of the system and the levels of accuracy, stability and cybersecurity referred to in Article 15, against which the high-risk AI system has been tested and validated and which can be expected, as well as all known and foreseeable circumstances that may affect the expected level. The instructions must include all known or foreseeable circumstances, relating to the use of the high-risk AI system in accordance with its intended purpose or under reasonably foreseeable conditions of misuse, and which may give rise to risks to health and safety. In addition, where applicable, the instructions must include the technical capabilities and characteristics of the high-risk AI system to explain its outputs and, where necessary, information enabling deployers to interpret the outputs of the high-risk AI system and use them appropriately. The instructions for use must

[253] Regulation (EU) 2024/1689, Article 16(a).
[254] See, for example, Lindroos-Hovinheimo – Koivisto – Koulu – Sankari 2025, pp. 96–99. Primary responsibility for conformity assessment and compliance rests with the provider before the product is placed on the market.
[255] Regulation (EU) 2024/1689, Recital 72. The transparency requirement for high-risk AI systems means that they should be designed in such a way that users can understand how the AI system works, assess its performance and understand its strengths and limitations. Transparency, including the accompanying user instructions, should assist users in operating the system and support them in making informed decisions. User guides must contain relevant and comprehensible information that takes into account users' needs and foreseeable level of knowledge, and should cover the characteristics, capabilities and performance limitations of the AI system, information on circumstances and changes that may give rise to risks, and relevant human-performed oversight measures.

also include the human oversight measures referred to in Article 14, including technical measures put in place to make it easier for deployers to interpret the outputs of high-risk AI systems.[256] With regard to medical devices, the MDR specifies in detail the information to be provided both with the device and in the instructions for use.[257]

Furthermore, providers must establish, implement and document a risk management system for high-risk AI systems[258] and maintain it; providers must develop high-risk AI systems on the basis of training, validation and testing datasets that meet the quality requirements[259] and they must be designed and developed in such a way that they achieve an appropriate level of accuracy, stability and cybersecurity[260] and perform consistently in this regard throughout their entire lifecycle.[261] The system must also be designed to automatically record event logs throughout its entire lifecycle.[262]

Breaches of provider's obligations regarding the technical requirements of the AI systems from a product safety perspective shall be assessed in accordance with product liability rules. Under the revised product liability rules, a product is considered defective when it fails to provide the safety a person is entitled to expect, and the statutory provisions presented in the RPLD on safety required under Union or national law are part of the legitimate safety expectations as a minimum standard.[263] When assessing a product's lack of safety, relevant product safety requirements – including

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[256] Regulation (EU) 2024/1689, Article 13.
[257] For further details, see Chapter 2.3.
[258] Regulation (EU) 2024/1689, Article 9.
[259] Regulation (EU) 2024/1689, Article 10.
[260] Regulation (EU) 2024/1689, Article 15.
[261] See, for example, Bolek-Fügl 2025, pp. 71–75.
[262] Regulation (EU) 2024/1689, Article 12.
[263] See Directive (EU) 2024/2853, Article 7(1); European Parliament, Legislative resolution P9_TA(2024)0132. See also Huber 2026, pp. 117–123. The PLD based the assessment of defects on the so-called *Consumer Expectation Test* (CET): a product was defective if it did not provide the level of safety that a person was entitled to expect. Article 7(1) RPLD introduced a second, alternative criterion alongside this: *a statutory defect*. A mere violation of safety requirements may in itself constitute a defect. The relevance of this addition is, however, unclear, as Article 7(1) is considered to be in conflict with the presumption rule (Article 10(2)(b)). If a violation of a safety provision means, under Article 7(1), that a product is automatically defective, why does Article 10(2)(b) provide that, in the same situation, we are in the presence of a rebuttable presumption. These statutory provisions are therefore considered to constitute part of the legitimate safety expectations as a minimum standard, in other words a violation of statutory provisions would not constitute defectiveness if there is no violation of legitimate safety expectations. See also Wagner 2025, p. 144. The presumption of defect (lack of safety) in Article 10(2)(b) RPLD is worded more narrowly than the definition of defect itself in Article 7(1) RPLD.

cybersecurity requirements relevant to safety – and the product's characteristics, including its design, shall be taken into account.[264]

Furthermore, it is established in case law that, in the case of medical devices, the safety requirements for such devices are set at a very high standard, given the particularly vulnerable position of patients, and a safety deficiency is deemed to exist even where the risk of harm associated with the product is so great that it deviates from the public's expectations of safety.[265] If harm results from a breach of the obligations described above, the rules on product liability attribute liability to the provider for the product's lack of safety under the principle of strict liability. It should be noted, however, that when assessing a product's lack of safety, account is taken of the information provided about the product, as well as its assembly, installation, operating and maintenance instructions.[266] The provider of the product therefore, for its part, defines the limits of its liability through the documents it draws up; in other words, the information provided about the product acts as a 'limitation of liability' clause.

Other obligations of the provider, which may be argued to fall within the scope of obligations that deployers are required to monitor, but which do not directly describe the requirements for an AI system, include the obligation to take corrective measures after placing the product on the market[267], as well as the formal requirements concerning CE marking[268], the declaration of conformity[269] and registration[270]. From the perspective of the provider it is worth noting, however, that unlike substantive safety requirements, purely formal compliance obligations do not generally dictate the assessment of a product's safety defect under product liability rules.[271]

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[264] Directive (EU) 2024/2853, Article 7(2)(a) and Article 7(2)(f).
[265] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148.
[266] Directive (EU) 2024/2853, Article 7(2)(a).
[267] Regulation (EU) 2024/1689, Article 20. If a supplier has reason to suspect that a system does not comply with the requirements, it must immediately take corrective measures to ensure compliance, withdraw the system from the market or organise a recall.
[268] Regulation (EU) 2024/1689, Article 16(h) and Article 48, and more specifically, Regulation (EU) 2017/745, Article 20(3) require that the CE marking be affixed to the device in a visible, legible and durable manner.
[269] Regulation (EU) 2024/1689, Article 47.
[270] Regulation (EU) 2024/1689, Article 49.
[271] Huber 2026, pp. 130–131.

5.2 Deployer Obligations: Clinical Monitoring and Human Oversight

The obligations of deployers of high-risk AI systems are set out in Article 26 of the AI Act. The obligations of providers set out above are such that a deployer is able to (and also must) monitor their fulfilment by complying with its own obligations. In the use of a high-risk medical AI system, the following obligations of the deployer constitute the obligations under the AI Act for which liability is provided for under national tort law.

The AI Act obliges the deployer to use the AI system in accordance with its instructions for use. The deployer must ensure, through technical and organisational measures, that the device is used in accordance with the instructions for use supplied with it.[272] It is impossible to fulfil this obligation if the actual user does not read the instructions and assess their adequacy in relation to the clinical situation. Furthermore, the MDR requires that the deployer use the device within the limits of its intended purpose. If the instructions are incomplete or fail to warn of an obvious risk, it is the deployer's responsibility to identify the shortcomings in the documentation.[273] The AI Act imposes an obligation on the deployer to retain logs generated automatically for an appropriate period, but for at least six months.[274] The deployer cannot fulfil this retention obligation unless they ensure that the device generates the relevant logs.

The AI Act imposes an obligation on the deployer to monitor the system's operation and, where necessary, suspend its use.[275] Furthermore, it obliges the deployer to ensure that its own input data is relevant.[276] If a healthcare professional inputs high-quality data into an AI system, but the system nevertheless produces inaccurate or incorrect results, the user of the medical AI system must, in accordance with its monitoring obligation[277], determine that the system does not meet the requirements. If deployers have reason to believe that the use of a high-risk AI system in accordance with its

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[272] Regulation (EU) 2024/1689, Article 26(1).
[273] Regulation (EU) 2017/745, Article 2(12) and Article 5(1).
[274] Regulation (EU) 2024/1689, Article 26(6).
[275] Regulation (EU) 2024/1689, Article 26(5).
[276] Regulation (EU) 2024/1689, Article 26(4).
[277] The term "*monitoring obligation*" is used to describe the obligation to monitor the operation of the system (Regulation (EU) 2024/1689, Article 26(5)). Deployer's must monitor the operation of a high-risk AI system in accordance with the user instructions supplied with the system. If, during monitoring, it is found that the use of the system may pose a risk to health, safety or fundamental rights, the deployer (that is to say the user in question) must suspend use of the device and notify the provider or distributor, as well as the market surveillance authority.

instructions for use may result in that AI system posing a risk to human health or safety or to fundamental rights[278], they must, without undue delay, notify the provider or distributor and the relevant market surveillance authority of the matter and suspend the use of the system in question.[279] Once the deployer has made the notification, their responsibility for patient safety requires them to monitor whether the provider rectifies the fault[280] before they put the suspended device back into service. The provider's inaction is then apparent to the deployer.

Article 5(1) of the MDR stipulates that a device may only be placed on the market if it complies with the Regulation. The CE marking is evidence of this conformity. By affixing or having the CE marking affixed, the manufacturer demonstrates that it accepts responsibility for the product's compliance with all applicable requirements laid down in the relevant harmonisation legislation governing the affixing of the CE marking. Furthermore, the CE marking is the only marking that certifies that the product complies with the applicable requirements of the relevant harmonisation legislation governing the affixing of the marking.[281] On this basis, the deployer may be required to verify the presence of the CE marking on the medical AI system, its packaging or the accompanying documentation.[282]

If a deployer, which is a public authority or a Union institution, body, office or agency, finds that a high-risk AI system it intends to use has not been registered, it must not use that system. In such a situation, the deployer must notify the system provider or distributor of the matter.[283] A public hospital acting as the deployer of a medical AI system is an example of such an operator.

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[278] See Regulation (EU) 2019/1020, Article 3(19). A product presenting a risk means a product that endangers, in an unreasonable and unacceptable manner, essential interests protected by EU legislation, such as human health, occupational safety, consumer protection, the environment or public safety. The risk posed by a product is always assessed in relation to its intended use and to normal or reasonably foreseeable conditions of use. The assessment is not limited to the actual moment of use, but covers the product's entire life cycle, including requirements relating to its commissioning, installation and maintenance.
[279] Regulation (EU) 2024/1689, Article 26(5), first subparagraph, and Article 79(1).
[280] A "*defect*" refers to the situation described in Regulation (EU) 2024/1689, Article 20, where an AI system does not comply with the Regulation.
[281] Regulation (EC) No 765/2008, Article 30(3) and Article 30(4).
[282] Regulation (EU) 2024/1689, Article 16(h).
[283] Regulation (EU) 2024/1689, Article 26(8).

When a public hospital carries out procurements that meet certain criteria[284], it is obliged to verify the conformity of tenders, i.e. that the tender complies with the requirements, conditions and criteria set out in the contract notice and the procurement documents. As high-risk AI systems are required to have a declaration of conformity, verifying this during the procurement process is justified from the perspective of patient safety.

As regards the clinical use of a medical AI system, the most significant obligation on the provider is most likely to be the obligation under Article 14 of the AI Act to ensure that human oversight is possible. This Article imposes an obligation on the provider to design and develop a high-risk AI system in such a way that natural persons can effectively supervise it. The article specifies the control measures – such as detecting anomalies, halting the system and overriding its outputs – which the staff of the deployer designated under Article 26(2) must be able to carry out. Article 26(2) requires deployers to assign the task of human oversight of the AI system to natural persons who possess the necessary qualifications, training and authorisation for the task. Furthermore, the deployer must provide these individuals with the necessary support.[285]

Under Article 14 of the AI Act, the provider must design and develop high-risk AI systems in such a way that natural persons can effectively supervise them whilst they are in use and the system must be provided in such a way that supervisors of the system can understand its capabilities and limitations, remain aware of automation bias[286], interpret the outputs correctly, decide in any specific situation to disregard, correct or revoke the outputs, and intervene in the system's operation or bring it to a safe state.[287]

A natural person, such as a doctor, must be able to supervise the medical AI system. The provider must incorporate tools into the user interface that enable the doctor to intervene in the system's operation, disregard its output or, if necessary, shut down the entire system. Deployers must assign the task of human supervision to natural persons

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[284] Public procurement. See the Act on Public Procurement and Concession Contracts (1397/2016). Public procurement legislation applies if the contract exceeds the threshold values (Section 25 and Section 26), meets the definition of a procurement contract under Section 4(1) etc. On public procurement see for example Raitio 2013, pp. 713 ff.
[285] Regulation (EU) 2024/1689, Article 14 and Article 26.
[286] Regulation (EU) 2024/1689, Article 14(4)(b). Supervisors must remain aware of any tendency to rely automatically or excessively on the outputs generated by a high-risk AI system.
[287] Regulation (EU) 2024/1689, Article 14.

who possess the necessary qualifications, training and authorisation, and must provide the necessary support.[288] Deployers, when they are legal entities such as a hospital, therefore delegate the necessary powers, rights and training to natural persons and also provide them with the necessary support.[289] As it is primarily the responsibility of doctors to implement regulatory measures in this field, they must also receive appropriate training. Ultimately, it is doctors who make the diagnosis based on the results generated by the medical AI system, in other words with the support of AI.[290]

5.3 Independent Administrative and Procedural Obligations of Deployers

Deployers also have the following obligations, which are not based on the monitoring of the provider's obligations, and which are of an administrative, procedural and legal protection nature. These obligations also differ from those described earlier in that the causal link, under tort law, between a breach of these obligations and the occurrence of damage, is less obvious. However, since any breach of any deployer's obligation may be used as a basis for liability for damages, it would be judicially untenable to disregard, in the assessment, some of the possible grounds for liability for damages, however difficult it may be to establish the causal link.

The AI Act requires that, prior to the deployment of a high-risk AI system in the workplace, the deployer – who is the employer – must inform employee representatives and those employees affected by the use of the system.[291] For example, doctors and nurses working in a hospital would need to be informed of the introduction of such a system. Furthermore, the AI Act requires that public-law bodies or private organisations providing public services must carry out an assessment of the potential impact of the system's use on fundamental rights before introducing certain high-risk AI systems.[292] This obligation can be considered to apply at least to public hospitals and wellbeing services counties.[293]

The AI Act requires that deployers of high-risk AI systems which make, or assist in making, decisions relating to natural persons must inform those natural persons that

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[288] Regulation (EU) 2024/1689, Article 26(2).
[289] Eisner 2025, p. 289.
[290] Bruckmüller – Altrichter 2025, p. 300.
[291] Regulation (EU) 2024/1689, Article 26(7).
[292] Regulation (EU) 2024/1689, Article 27(1).
[293] See Keller 2025, pp. 170–173. The fundamental rights impact assessment is specifically mandated for deployers that are public bodies or private entities providing essential public services.

a high-risk AI system is being applied to them. This obligation, which relates to the legal protection of individuals and patients' rights, is supported by Article 86 of the AI Act, which states that, if an AI system is used in decision-making that has significant legal or similarly significant effects, the individual has the right to receive an explanation of the role of AI in the decision.[294] Furthermore, it is important to note that where AI is used in direct interaction with a person (AI chatbot for patients, for example), this must be clearly disclosed.[295]

Under the AI Act, deployers must, where necessary, use the information provided pursuant to Article 13 of the AI Act – such as user manuals or other documentation – in order to comply with, for example, their obligation under Article 35 of the GDPR to carry out a data protection impact assessment.[296] The deployment of high-risk AI systems in healthcare almost invariably requires a data protection impact assessment to be carried out, and the AI Act obliges deployers to make use of the technical documentation provided by the AI system in this context.[297]

As a final obligation, the AI Act imposes a duty on deployers to cooperate with the relevant competent authorities in all actions they undertake in relation to the AI system for the purposes of implementing the Regulation.[298] This obligation applies to both hospitals and individual healthcare professionals as deployers.

The following chapter interprets the regulatory framework described above in the context of tort law. The chapter sets out the legal frame on the basis of which the liability of a healthcare professional is assessed in the event of patient injury. Furthermore, the chapter identifies the changes brought about by the new legislation to the professional standard of the duty of care, *lex artis*. The aim of the chapter is to clarify how the national *lex artis* standard should be interpreted in the light of the new legislation.

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[294] Regulation (EU) 2024/1689, Article 26(11) and Article 86(1).
[295] Regulation (EU) 2024/1689, Article 50(1) and Article 50(5).
[296] Regulation (EU) 2024/1689, Article 26(9).
[297] See Regulation (EU) 2024/1689, Article 27(4). This is evident from Article 27(4). If a deployer is required to carry out an impact assessment concerning fundamental rights in accordance with the Regulation, this assessment supplements the data protection impact assessment already carried out under the GDPR. This demonstrates that the legislator has expressly intended these documents and assessments to form a mutually supportive, indispensable whole in the case of a high-risk medical AI system.
[298] Regulation (EU) 2024/1689, Article 26(12).

6 Liability in Healthcare and the Evolution of the *Lex Artis* Standard under the AI Act

6.1 The Coexistence of Product Liability and Fault-Based Liability in Healthcare

When medical AI systems are used in healthcare to support clinical decision-making, liability under tort law is divided between two parallel, separate yet interlinked systems: the strict product liability of the device manufacturer, and the national fault-based liability of the service provider and healthcare professional using the device.

Although the manufacturer's strict liability is broad, it is limited to parties within the production and distribution chain. The scope of the RPLD does not cover the liability of a service provider who uses a device they have acquired in the context of treatment provided to a patient. An exception to this is where the user of the product also acts as the manufacturer of the product. Alongside the manufacturer's liability scheme under the RPLD, there may be a national liability scheme for service providers.[299] These systems are separate, but they intersect in a healthcare context, as the national liability system must not jeopardise the objectives of the RPLD; rather, the possibility of holding the manufacturer liable where the conditions of the Directive are met must always be preserved.[300]

A hospital or an individual doctor, as a deployer of a medical AI system, therefore does not, as a general rule, fall within the scope of the RPLD. Product liability legislation does not, therefore, as such, cover the field of tort law relating to the clinical use of the device, which is why the service provider's liability must be determined separately.

6.1.1 Strict Liability of the Manufacturer for Medical Artificial Intelligence

Following the reform of the PLD, software and AI systems have been defined as products, and in matters of product liability, the provider of an artificial intelligence system is treated as equivalent to the manufacturer of the product. The system is based on strict liability, irrespective of fault. Under this system, the injured party does not

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[299] C-285/08 *Moteurs Leroy Somer*, ECLI:EU:C:2009:351, para 31; C-52/00 *Commission v France*, ECLI:EU:C:2002:252, para 22. The CJEU has established that the harmonised product liability regime does not preclude the application of national rules of non-contractual liability that rest on a different basis, such as fault.

[300] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869.

need to prove the manufacturer's negligence, but only the defect in the product, the damage suffered and the causal link between them.

In the case of medical devices, the CJEU has set safety expectations extremely high due to the vulnerable position of patients. A product is deemed to be unsafe when the associated risk of harm is so great that it deviates from the public's reasonable safety expectations. The manufacturer is therefore liable for algorithmic, technical and, for example, training data-related errors in the AI system that cause harm to a patient. In Finland, this liability is based not only on the nature of product liability legislation but also on Finland's national legislative choice. The RPLD allows Member States to maintain a system in which economic operators are also liable for errors that are beyond the current state of science and technology, i.e. so-called "*development-related damage*". In Finland, no amendments to the Product Liability Act are proposed with regard to the defence against development risks, which in practice means that manufacturers retain strict liability for all product damage, including unforeseeable safety defects.

This strict liability therefore also covers unforeseeable errors generated independently by the "black box" of artificial intelligence. The legislator's intention is to hold the manufacturer liable for as long as they retain control over the product, which is assessed, for example, through the possibility of software updates. Consequently, patient injury resulting from a device's inaccuracy or distorted data is, in principle, a safety defect for which the manufacturer is liable under product liability rules.

6.1.2 Division of Competences Within the EU and National Liability for Damages

The liability for damages of the service provider and the clinical user is determined on the basis of national law. This stems from the division of competences between the Union and the Member States as laid down in the Treaties. Although the European Union imposes high quality and safety requirements on medical devices and artificial intelligence in the name of the functioning of the internal market[301] and the protection of public health[302], the Union's competence in this area is limited.

[301] Consolidated version of the Treaty on the Functioning of the European Union, Article 114.
[302] Consolidated version of the Treaty on the Functioning of the European Union, Article 168(4)(c).

Pursuant to Article 168(7) TFEU, the definition of health policy and the organisation and delivery of health services and medical care are the responsibility of the Member States. The TFEU does not permit the harmonisation of health policy legislation by the Union. For this reason, product liability legislation alone cannot cover the field of liability for damages relating to the clinical use of medical devices. The AI Act does not contain clear or detailed liability provisions, and in matters of civil liability, recourse is made to national legal remedies.

Liability for damages relating to clinical use is therefore determined on the basis of national law. In Finland, this liability is based on the care relationship between the patient and the healthcare professional. This relationship gives rise to a duty on the part of the healthcare professional to provide good care and to comply with their statutory duty of care. The duty of care derives its substantive content from *lex artis*, that is, the requirement to follow generally accepted and empirically justified methods in accordance with their training.

6.1.3 Attribution of Liability in a Care Situation and the Integrity of the Division of Competences

When patient harm occurs in an AI-assisted care situation, the attribution of liability between the manufacturer's product liability and the healthcare professional's fault-based liability becomes the focus of the assessment. Under national law, the liability for damages of a healthcare professional and a service provider requires fault, which in the context of this thesis means a breach of the duty of care.

When assessing fault in the use of medical AI systems, the ultimate question is whether the new rules impose clinical or administrative obligations on the deployer, the breach of which would result in the healthcare professional or hospital being held liable for damages due to fault based on a safety deficiency in the medical AI system. The AI Act requires, amongst other things, that the device's operation be monitored, that its outputs be interpreted correctly and, where necessary, disregarded.

It is, in itself, legitimate to ask whether the impact of such regulatory obligations imposed on the deployer on the assessment of national fault-based liability undermines the division of competences between the Union and the Member States. However, the division of competences is not infringed in this context. Although the

European Union imposes obligations on deployers of high-risk AI systems that are necessary to minimise risks to safety and fundamental rights, the EU does not regulate the civil liability consequences of breaches of these obligations in the healthcare sector. Instead, the Member State's national system of compensation for damages, and in particular the *lex artis* standard, incorporates these new technological and safety requirements into the standard of care expected of an experienced professional in each case.[303] The allocation of liability is thus determined through the national threshold of negligence, as required by the Treaties.

6.2 Two Categories of Obligations for Deployers

The AI Act imposes a number of obligations on deployers of high-risk AI systems, such as hospitals and the healthcare professionals working within them. These obligations are significant, as certain risks may arise not only during the design and development phase of a product but also during its use, and these risks must be mitigated appropriately. The purpose of the deployer's obligations is, in effect, to act as a final safety net and to identify any shortcomings in the AI system before a patient injury occurs.

From the perspective of attributing liability, these obligations on the deployer set out in the AI Act can be divided into two categories. The first category consists of monitoring obligations linked to the clinical use of the device and its technical interface, the fulfilment of which requires the device provider to fulfil their obligations. In this context, the technical interface refers to the overall framework – including transparency, comprehensible user instructions and human oversight mechanisms – that the device provider establishes between the medical AI system and the healthcare professional using it. The user cannot technically fulfil their own clinical oversight obligations unless the provider has first established this interface.

The second category, on the other hand, consists of independent regulatory obligations of an administrative and procedural nature, the fulfilment of which can be assessed regardless of the system's characteristics or the functionality of the technical interface.

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[303] C-219/15 *Schmitt*, ECLI:EU:C:2017:128, paras 59 and 60. The CJEU has acknowledged this exact mechanism in its case law, establishing that the breach of EU regulatory and monitoring obligations can constitute a culpable failure that triggers fault-based liability under national tort law.

6.2.1 Obligations Derived from the Technical Interface and the Threshold for Clinical Detectability

The AI Act imposes a number of technical requirements relating to product safety on providers of medical AI systems, and breaches of these requirements are assessed under product liability rules. Among other things, the provider must establish a risk management system, develop the system on the basis of high-quality data, and ensure an appropriate level of accuracy, stability and cybersecurity. However, as the user, a healthcare professional cannot directly verify compliance with these requirements. When attributing liability for damages between the provider and the deployer, only those breaches of the provider's obligations that result in the lack of device safety – and which the deployer can detect by fulfilling their own obligations – are relevant.

This clinical detectability is made possible by the provider's obligations under Articles 13 and 14 of the AI Act. Under Article 13, the system must be designed to be sufficiently transparent and must be accompanied by concise, complete and clear instructions for use, setting out, inter alia, the device's characteristics, risks and performance limitations. Article 14, in turn, requires that the system be designed and developed in such a way that natural persons can effectively exercise control over it.

The deployer's responsibility is based on the use of this technical interface. The AI Act obliges the deployer to use the AI system in accordance with its user instructions. The deployer must ensure the relevance of their own input data and monitor the system's operation. Human supervision must be entrusted to natural persons who possess the necessary qualifications and training. A healthcare professional must be able to understand the system's capabilities, remain aware of automation bias, interpret the outputs correctly and, where necessary, disregard or overrule the system's output and halt the device.

If a healthcare professional inputs high-quality data into the AI system but the system nevertheless produces inaccurate or incorrect results, they must, in accordance with their duty of supervision, recognise that the system does not meet the requirements. Consequently, clinical detectability sets the threshold for when a product defect may give rise to fault on the part of the user. A healthcare professional cannot be held liable for algorithmic errors that are not detectable via the technical interface. On the other hand, it should be noted that if the user instructions are manifestly incomplete, are

entirely absent, or fail to warn of an obvious risk, the deployer may be deemed to have a duty to identify the inadequacy of the documentation even before actual use.

If the deployer detects that the use of a high-risk medical AI system may pose a risk to health or safety, they must, without undue delay, suspend use of the system and notify the provider or distributor and the relevant market surveillance authority of the matter. However, simply suspending use is not sufficient to fulfil the duty of care regarding patient safety; the deployer must also monitor whether the provider rectifies the fault in the device before it is put back into service. Any inaction on the part of the provider is then clearly discernible to the deployer.

6.2.2 Independent Administrative and Legal Protection Obligations

The second category comprises the deployer's obligations, which are of an administrative, procedural and legal protection nature. Although the tort law related causal link between a breach of these obligations and the actual patient injury may be more difficult to establish than in the case of technical interface obligations, any breach of any of the deployer's obligations may be used as a basis for liability for damages under the *conditio sine qua non* principle.

This category includes the verification of the device's formal requirements. The AI Act requires, inter alia, CE marking, a declaration of conformity and registration. In the interests of patient safety, a deployer, such as a public hospital, may be required to verify these during the procurement process. If an end-user, which is a public authority or a body governed by public law, finds that a high-risk AI system it intends to put into service has not been registered, it must not use the system at all. Similarly, the deployer is obliged to retain the event logs automatically generated by the system for at least six months; this obligation cannot be fulfilled without ensuring that the device actually generates those logs.

The legislation also imposes notification and assessment obligations on the organisation and its employees. Prior to implementation, the implementing organisation, acting as the employer, must notify employee representatives and those employees affected by the use of the high-risk AI system. Public-sector bodies must carry out an assessment of the potential impact of the system's use on fundamental

rights, and technical documentation obtained from the system must be utilised in conducting a data protection impact assessment.

To guarantee the individual legal protection of patients, the AI Act requires that deployers of high-risk AI systems which make or assist in making decisions relating to natural persons must inform those individuals of the use of the AI system. Patients also have the right to receive an explanation of the role of AI in the decision. It is also important to note that if a patient is interacting directly with an AI system, this must be clearly communicated to the patient. Finally, the deployer has a general obligation to cooperate with the competent authorities in matters relating to the AI system.

6.3 Attribution of Liabilities and Obligations: Organisational Liability and the Duty of Care of Healthcare Professionals

Under the AI Act, a deployer may be either a natural person or a legal person. As the concept of the "*deployer*" is broad in the Regulation, the obligations it imposes apply, in the healthcare context, to both individual healthcare professionals and the hospitals or other healthcare units that employ them.

A hospital is a legal person responsible for organising healthcare services and procuring equipment, whereas a healthcare professional, as a natural person, is always responsible for treatment and the related clinical decision-making. The division of the deployer's obligations, as outlined in the previous sub-section, can be further broken down in such a way that clinical obligations arising from the technical interface fall under the healthcare professional's duty of care and its standard, *lex artis*, whilst independent administrative obligations fall within the scope of the hospital's organisational liability. Understanding this allocation of liability is essential for the correct assessment of fault in the event of patient injury.

6.3.1 The Hospital's Organisational Liability as the Bearer of Administrative Obligations

As an organisational service provider, the hospital can be regarded as bearing primary responsibility for the independent, administrative and procedural regulatory obligations laid down by the AI Act. As the hospital, as an organisation, is not a party to the care relationship, its liability is not determined by *lex artis*, but by assessing its

actions in relation to the legal and administrative standards governing the safe implementation of the device.

The hospital's organisational responsibility includes ensuring the system's compliance with the law and that the conditions for its safety are met before it is put into clinical use. At the procurement stage, it is the organisation's responsibility to ensure the system's CE marking, declaration of conformity and registration. If a public-law institution fails to verify the registration and permits the device to be put into use, the organisation is in breach of its statutory duty. Similarly, the assessment of the impact on fundamental rights, the data protection impact assessment and the provision of informing the staff are obligations at organisational level.

Furthermore, the hospital must create the structural conditions to enable healthcare professionals to fulfil their own clinical supervision obligations. The requirement in the AI Act that human supervision must be entrusted to persons with the necessary qualifications and training places an obligation on the employer to provide adequate training to ensure an understanding of the device's technical interface and limitations. The hospital must also be responsible for its IT infrastructure in such a way as to fulfil the obligation to retain the event logs generated by the device, and act as a point of contact for market surveillance authorities and the provider in the event of any hazardous situations.

Should the hospital neglect these administrative obligations, this constitutes fault falling within the scope of organisational liability. A failure to fulfil the hospital's safety-related obligations regarding the deployment of the device contributes to the materialisation of the risk of harm.[304]

6.3.2 The Duty of Care of Healthcare Professionals and the New *Lex Artis* Standard

Once a medical AI system has been introduced by a hospital, responsibility for the system's immediate patient safety in a care situation passes to the healthcare

[304] It is also possible for a hospital to act as an AI developer. Since the software developer is treated as a manufacturer from the perspective of product liability, a hospital utilising the AI it has developed is no longer merely a service provider, but is equated with the manufacturer of the product. See C-203/99 *Veedfald*, ECLI:EU:C:2001:258. As the *Veedfald* ruling demonstrates, a product is deemed to have been placed on the market when it is used in the context of providing a specific medical service. In such a situation, the hospital's liability for any harm caused to a patient is not limited to fault-based liability; rather, the hospital bears the strict liability of a manufacturer under product liability legislation for safety defects in the AI system it has developed.

professional using the device. From a legal perspective, the duty of care arising from the care relationship and the professional standard required to fulfil it do not, in principle, differ between different healthcare professionals. The performance of all healthcare professionals is assessed against the benchmark of "*good care provided by an experienced practitioner*", and each must apply generally accepted and empirically justified methods in accordance with their training.

However, the regulatory obligations linked to the technical interface and clinical use of artificial intelligence impose requirements that are specifically geared towards the most demanding aspects of clinical decision-making. In their work, doctors are required to make decisions on more complex treatment-related matters, such as diagnoses and medical procedures, than many other healthcare professionals. Although a doctor's duty of care does not differ legally from that of other healthcare professionals, the interpretation of information generated by high-risk medical AI systems and the making of decisions based on it fall primarily to doctors, due to the scope of their clinical responsibility and the level of training required. For this reason, the changes to the *lex artis* standard brought about by the new legislation are particularly evident in the doctor's duty of care.

The new AI regulations reshape this professional standard by imposing new requirements on healthcare professionals relating to technological literacy and proficiency. In future, professional diligence will require the ability to interact with the technical interface created by the device provider. Before making a clinical decision, it falls within the healthcare professional's *lex artis* to assess whether the device is suitable for the treatment in question and whether the data entered by the patient is relevant in relation to the device's instructions for use.

The key change in the substantive content of the duty of care concerns the relationship between human decision-making and machine-generated information. The requirement for human oversight under the AI Act makes the prevention of automation bias a legal obligation. The professional standard for an experienced doctor now includes the ability to critically assess the outputs of AI that provide a diagnosis or treatment recommendation, interpret them correctly and, in accordance with their training, make an independent medical decision as to when the output should be disregarded or the use of the device suspended due to a safety risk. If the device's interface allows a doctor to detect a malfunction in the device, but the doctor blindly

relies on the device's incorrect response, they are breaching their duty of care, which is based on generally accepted methods.[305]

Obligations relating to patients' rights also fall on the healthcare professional using the device in a practical clinical setting. As the care relationship exists between the patient and the natural person treating them, the duty to disclose the use of artificial intelligence in decision-making, as well as the right to receive a comprehensible explanation of the role of artificial intelligence in the treatment decision, fall to the healthcare professional responsible for the care situation, typically a doctor. The ability to provide this explanation demonstrates that the healthcare professional has internalised the device's operational logic in accordance with their professional standards.

6.3.3 Parallel Liabilities and the Determination of Fault in a Care Situation

In general, it can be stated that the requirements imposed on deployers of AI systems can be consistently integrated into the liability frameworks of national law.

From the perspective of tort law, it is essential to understand that product liability and national liability for negligence are not mutually exclusive, but may apply concurrently.

As is evident from the case law of the CJEU, the manufacturer's liability under the RPLD and the national service provider's liability are separate systems, the coexistence of which is legally permissible and appropriate.[306] If a medical artificial intelligence system is not reasonably safe, for example as a result of an algorithmic error, the manufacturer of the device bears strict liability for this error, regardless of the conduct of healthcare professionals. In the case of medical devices, these safety expectations are set high due to the vulnerable position of patients.[307] Patient protection is further emphasised by the fact that, in the face of medical uncertainty, the causal link between

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[305] See C-634/21 *SCHUFA*, ECLI:EU:C:2023:957, paras 48, 50 and 61; Opinion of AG Pikamäe in Case C-634/21 *SCHUFA*, ECLI:EU:C:2023:220, points 42 and 47. It is important to distinguish between AI outputs that constitute actual decisions and those that function primarily as recommendations. The difference lies in the fact that if an AI output actually determines the outcome, the formal decision-maker no longer influences that outcome. In the current medical scenario, where the doctor has the ability to oversee the medical AI system and is also obligated to do so, the doctor is the actual decision-maker. See also Hietanen - Hirvonen 2026, pp. 182–187.

[306] C-495/10 *Dutrueux*, ECLI:EU:C:2011:869. See also C-285/08 *Moteurs Leroy Somer*, ECLI:EU:C:2009:351, para 31; C-52/00 *Commission v France*, ECLI:EU:C:2002:252, para 22. The harmonised product liability regime does not preclude the application of national rules of non-contractual liability that rest on a different basis.

[307] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148.

a product's safety defect and the harm caused can be established on the basis of sufficiently credible, precise and consistent circumstantial evidence.[308]

Alongside this strict product liability incumbent on the manufacturer, the fault-based liability of the healthcare organisation and the healthcare professional is also assessed. Fault refers to a failure to exercise the due care required in each case, whereby the person or organisation simultaneously causes or increases the risk of harm. Although a healthcare professional's fault may, in the traditional sense, arise from any breach of *lex artis*–such as, for example, disregarding a patient's previous medical history–the distinction, specifically in the case of fault arising from technical errors in a medical AI system, is drawn on the basis of clinical and formal detectability.

If the harm results solely from an unforeseeable internal error within the AI's "black box"–which cannot be detected through the deployer's obligations, the technical interface or administrative measures–there has been no breach of the duty of care in this respect. In such cases, the hospital or healthcare professional bears no liability for the technical fault in the medical AI system.

If the harm caused by the device materialises because the hospital has failed to verify the device's safety at an organisational level, or because a healthcare professional, contrary to the *lex artis* standard, has failed in their duty to monitor, suspend operations or disregard a clearly erroneous result, this constitutes a breach of the duty of care. However, the assessment of negligence is fundamentally a matter of evaluating the culpability of the conduct. Once negligence has been established, the nature and degree of the lack of care demonstrated by the conduct have a significant impact on the overall legal assessment. Whether a negligent act ultimately gives rise to an actual liability for damages is always a matter of case-by-case assessment, in which the culpability of the person who caused the damage and the causal link between the damage and the fault are weighed up.[309]

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[308] C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484.

[309] See Damages Act (412/1974), Chapter 2, Section 1. Pursuant to Section 1, compensation for personal injury sustained by a patient in the course of health and medical care is governed by the Patient Insurance Act (948/2019). See Patient Insurance Act (948/2019), Section 45. The Patient Insurance Centre has a right of recourse against the party responsible for the injury if the patient injury was caused intentionally or through gross negligence. If the conduct of a healthcare professional were deemed to be grossly negligent or deliberate, the Patient Insurance Centre would pay compensation to the injured party, but the Patient Insurance Centre could, by virtue of its right of recourse, claim back the amount of compensation it has paid from the healthcare professional.

7 Conclusions

7.1 Separation and Parallelism of Liabilities in Healthcare

The first key conclusion of this study concerns the structure of liability systems. When it comes to compensating for patient harm caused by medical AI systems, two separate legal regulatory frameworks apply, which intersect and complement one another in a healthcare context: the strict product liability of the manufacturer under EU law and fault-based liability based on national law.

The RPLD imposes strict liability on providers of medical AI systems. Since a product's lack of safety is assessed, inter alia, on the basis of the AI's learning capacity and unpredictable behaviour, and since in Finland it is not possible to invoke "*development risk defence*" as a defence against liability, the manufacturer's liability extensively covers damage resulting from algorithmic and data errors in the system. The case law of the CJEU[310] further confirms that, in the healthcare context, the vulnerable position of patients and medical uncertainty justify a broad interpretation of product safety and the establishment of a causal link on the basis of circumstantial evidence. It should also be noted that the presumptions regarding a safety defect and the causal link between the safety defect and the damage incurred, as set out in the RPLD, serve this same purpose.

However, due to the division of competences established by the Treaties, Union regulation cannot extend to liability for damages arising from clinical use, which is determined on the basis of national law and the duty of care incumbent on healthcare professionals. The liability of service providers and healthcare professionals, which falls outside the scope of product liability, therefore always requires fault. In conclusion, it must be noted that the AI Act does not create a legal vacuum or infringe upon the division of competences within the Union. Instead, the AI Act lays down safety and supervision obligations which national tort law takes into account when assessing the culpability of the deployer's conduct and compliance with the duty of care.

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[310] C-503/13 and C-504/13 *Boston Scientific*, ECLI:EU:C:2015:148; C-621/15 *Sanofi Pasteur*, ECLI:EU:C:2017:484.

7.2 The Development of the *Lex Artis* Standard and the Threshold of Detectability

A second key conclusion concerns the substantive change to the professional standard – *lex artis* – for healthcare professionals, and, in the most demanding treatment decisions, for doctors. The technical and clinical obligations imposed by AI Act are altering the level of care expected of an experienced practitioner. In future, professional diligence will require not only traditional medical expertise but also AI literacy, the ability to counteract automation bias, and an understanding of the system's operational limitations.[311]

AI Act requires that high-risk AI systems be explainable. This imposes obligations on the provider regarding transparency, comprehensible user instructions and technical features that enable human oversight. The existence of this technical interface is a prerequisite for healthcare professionals to fulfil their own clinical oversight obligations. A healthcare professional's *lex artis* relies largely on the use of this interface; they must be able to interpret the outputs correctly, assess them critically against their medical expertise and, where necessary, disregard the output or discontinue use of the device.

Liability for fault is limited by the threshold of detectability. When a healthcare professional makes a final treatment decision supported by artificial intelligence, they cannot blindly rely on the information generated by the device. If a diagnosis or recommendation provided by AI is clinically illogical or contradicts the reliability assessments provided by the system, the healthcare professional must, by virtue of their professional expertise and regulatory obligations, identify this error. Succumbing to the "*automation bias*" and following a clearly erroneous result constitutes a breach of the duty of care. In addition to clinical assessment, the threshold for detection extends to the formal requirements for the safe use of the device. A healthcare professional's duty of care includes identifying obvious deficiencies in documentation even before the actual patient care begins.

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[311] Traditional medical expertise refers to medical training that does not include training in artificial intelligence. It is likely that medical training will be reformed so that it includes training in the AI skills required to such an extent that it can be regarded as part of "traditional medical expertise".

On the other hand, the threshold of detectability also protects healthcare professionals. Healthcare professionals are not liable for any latent algorithmic or training data-related errors in a medical AI system that produce results which are clinically entirely plausible but are in fact incorrect. If the system produces an incorrect output which even an experienced healthcare professional is unable to detect within the framework of the established interface and their medical expertise, the duty of care has not been breached. In such situations, a healthcare professional cannot be regarded as having acted negligently.

7.3 Legal Certainty and the Systemic Coherence of the Attribution of Liability

The division of the deployer's obligations into interface dependant clinical detectability and formal detectability, is not only significant from the perspective of systematisation, but is also a prerequisite for ensuring legal certainty in the age of artificial intelligence.

Within the field of analytical jurisprudence, the principle of legal certainty is understood to require that decisions having legal effect must be both formally predictable (formal legal certainty) and substantively acceptable (substantive legal certainty).[312] Formal legal certainty and the requirement of predictability entail the elimination of arbitrariness and randomness from the process of legal decision-making, so that legal practitioners can plan their actions rationally.[313]

In a doctor's clinical practice, this legal decision-making required by legal certainty is realised specifically through the court's retrospective assessment of negligence. Rational planning of actions by a legal professional – in this case, a healthcare professional – means the ability to align one's own clinical practice with a *lex artis* standard that the court is likely to accept in its assessment. When a court assesses a doctor's conduct in a case of patient injury, its decision must satisfy these criteria of formal and substantive legal certainty.

If a healthcare professional were to be held liable for fault arising from an internal algorithmic error within the "black box" of an artificial intelligence system – an error which, due to a lack of a technical interface, they could not have clinically detected, ignored or monitored – the attribution of liability would undermine formal legal

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[312] For further details, see for example Aarnio 1987, p. 3. See also Raitio 2012, p. 404.
[313] See Aarnio 1987, p. 4.

certainty and predictability. In such a case, the healthcare professional would be unable to rationally align their clinical practice with the required standard, as liability would arise from a factor beyond their control. On the other hand, in a situation where a hospital fails to check the CE marking and registration of an obviously high-risk device, or where a doctor disregards the absence of operating instructions and continues to use the device, relying solely on strict product liability would undermine substantive legal certainty. Failing to assess negligence in cases of medical malpractice would be neither morally nor socially acceptable.[314]

Reconciling artificial intelligence legislation with national tort law through the threshold of detectability ensures the systemic coherence of legal interpretation and avoids the so-called Casanova method. The "*Casanova method*" refers to a form of legal interpretation in which the adjudicator selects isolated arguments solely to maximise the case-specific acceptability of the decision, without being able to form a systematised and coherent whole from them (internal justification). If, in a case of patient injury, a doctor were to be held liable for damages solely to protect the patient—that is, the vulnerable party—without assessing the doctor's actual ability to detect the error, this would constitute a decision in line with the Casanova method, a solution that seeks merely substantive justice but runs counter to the internal logic of the legal system.[315]

The ability of the national *lex artis* standard to incorporate the clinical oversight obligations introduced by the AI Act resolves this problem. It creates a systematised model in which liability is attributed to the hospital, acting as a legal person, on the basis of its formal organisational obligations, and to the doctor, acting as a natural person, on the basis of his or her clinical supervision obligations, whilst setting a limit based on the detectability provided by the technical interface. This interpretative model fulfils the requirements for the internal justification of a legal solution and

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[314] See Raitio 2012, pp. 404–408. If a doctor or hospital acts with manifest negligence and the patient suffers harm as a result, the situation cannot be dealt with legally solely in the light of the rules on product liability. Such a legal interpretation, in which the clear negligence of a healthcare professional would be left entirely unassessed and liability would be automatically transferred to the device manufacturer, would undermine substantive legal certainty. Such a solution would not meet the minimum requirements of justice, nor would it be a morally or socially acceptable outcome.

[315] Raitio 2012, pp. 408–410. From the perspective of high-quality administration of justice, it is not sufficient for the argumentation to be coherent solely within the context of an individual decision. Raitio refers to this interpretative model, which promotes such casuistic coherence, as the *Casanova method*.

maintains the coherence of the division of competences between EU law and national law.

Although the division into *formal* and *substantive legal certainty* provides a clear evaluative framework, the concept of legal certainty in modern legal theory is recognized as considerably more multidimensional. It has been demonstrated that legal certainty in a modern legal order cannot mean absolute immutability or the illusion of perfect staticness.[316] Rather, it is a dynamic principle: a legal tool that assists legal subjects in acting and making rational decisions within an environment that is inevitably uncertain.

The *Cartesian logic* deeply rooted in legal thinking, which demands scientifically precise predictability from the law, has been criticized by legal scholars.[317] In a rapidly evolving environment characterized by epistemic uncertainty, such as medical artificial intelligence, this Cartesian requirement can indeed be seen as impossible to fulfil. Instead, grounding legal certainty in a "*fiduciary logic*"—an interactive trust, has been suggested as an alternative. The essential element is that the system protects the individual's legitimate expectations concerning the regulatory framework and the technology utilized.[318] In the context of AI-assisted healthcare, this means that while the doctor must be able to trust the system's technical interface (fiduciary logic), they are simultaneously expected to tolerate the dynamic nature of the technology.

To resolve these tensions surrounding legal certainty in an acceptable manner within adjudication, the legal system must exhibit coherence. Legal argumentation and formal justice—resolving similar cases in the same way—require internal consistency from the normative system.[319] However, in a modern, complex legal environment, the goal is no longer a deductive, total coherence that covers the entire legal order, but rather a

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[316] Popelier 2008, pp. 51–53. Popelier emphasises legal certainty as a relative and dynamic concept, which does not mean maintaining the status quo with absolute certainty, but rather safeguarding individual autonomy in the face of inevitable uncertainty.
[317] Van Meerbeeck, pp. 2–3, 8. According to Van Meerbeeck, *Cartesian logic* (the endeavour to master legal causes and predict consequences with scientific precision) is an untenable premise in the modern legal environment.
[318] Van Meerbeeck, pp. 3, 9–10. Fiduciary logic emphasises trust in the legal system and the duty of the authorities to take into account the legitimate expectations of legal persons.
[319] Tuori 2000, pp. 123–124. According to Tuori, *normative coherence* is a prerequisite for the rationality of an individual court decision. Formal justice and equality require that the norms underlying a decision can be traced back to broader principles which form a coherent normative whole.

sufficient local coherence.[320] The solution presented in this thesis—wherein the national *lex artis* standard absorbs the human oversight obligations of the EU's AI Act—is precisely an endeavour to establish such local coherence. It bridges two distinct regulatory frameworks (strict product liability and national fault-based liability) in a way that ensures legal adjudication maintains its internal consistency and secures the formal predictability of the healthcare professional's conduct.

7.4 Final Conclusions: A Systemic and Teleological Interpretation for the Protection of Patients

The legal framework for liability for damages arising from medical AI systems must be assessed from the perspective of methods of legal interpretation and the objectives of EU law.

Understanding EU law often requires a systemic interpretation, in which a single legal provision is placed within the broader legal context of which it forms part, emphasising the legal order as an internally consistent system. Systematising the concept of "*deployer*" in the AI Act within the framework of national fault-based liability and the strict liability of the RPLD is essential precisely to achieve this consistency.

Even more significant is the teleological interpretation of the law adopted by the CJEU, which is based on the realisation of the aim and purpose of the entire body of legislation. In its case law, the CJEU has often set aside the mere wording of a provision and explicitly assessed the consequences that the decisions are intended to achieve in the light of the Union's objectives.[321] In the case of medical devices, these objectives culminate in patient safety and the protection of health. As the case law of the CJEU demonstrates, the vulnerable position of patients and medical uncertainty justify setting safety expectations to a very high standard and lowering the threshold of proof for establishing a causal link.

The reformed product liability regulations and the AI Act embody this teleology, which emphasises patient protection. By maintaining strict liability for product defects in

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[320] Tuori 2000, pp. 125–126. Tuori emphasises that modern predictability and legal certainty do not require *total coherence* across the entire legal system, linked by deductive relationships. Instead, the aim is *local coherence* based on legal principles, which also allows for creative problem-solving and fairness.

[321] Raitio 2005, p. 278.

artificial intelligence – a position significantly influenced by Finland's national choice to reject the development risk defence – the legislator ensures that the risks posed by the technological "black box" are allocated to the manufacturer seeking economic gain.

In conclusion, it can be stated that the regulatory framework governing liability for damages arising from medical AI constitutes a legally sound system. The device provider is liable under the principle of strict liability for the intrinsic safety of the technology. The fault-based liability of healthcare providers, on the other hand, only arises where clinical or formal detectability is made possible by the technical interface and regulatory obligations set out in the AI Act. This separate yet seamless parallelism of responsibilities ensures, in accordance with the teleological objective, uninterrupted legal protection for the patient, whilst at the same time maintaining the doctor's legal position as formally predictable.

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Abbreviations

AG – Advocate General
AI – Artificial Intelligence
AI Act – Artificial Intelligence Act (Regulation (EU) 2024/1689)
CE – Conformité Européenne (CE marking)
CET - Consumer Expectation Test
CJEU – Court of Justice of the European Union
COM – European Commission document
CT – Computed Tomography
EBM – Evidence-Based Medicine
EC – European Community
ECJ – European Court of Justice
ECLI – European Case Law Identifier
EEC – European Economic Community
EHDS – European Health Data Space (Regulation (EU) 2025/327)
eIDAS – Electronic Identification, Authentication and Trust Services
EU – European Union
GDPR – General Data Protection Regulation (Regulation (EU) 2016/679)
HE – Hallituksen esitys (Government Proposal)
IT – Information Technology
IVDR – In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746)
MDD – Medical Devices Directive (Council Directive 93/42/EEC)
MDR – Medical Devices Regulation (Regulation (EU) 2017/745)
MRI - Magnetic Resonance Imaging
MS – Multiple Sclerosis
OJ – Official Journal of the European Union / Official Journal of the European Communities
OM – Oikeusministeriö (Ministry of Justice)
PLD – Product Liability Directive (Council Directive 85/374/EEC)
RPLD – Revised Product Liability Directive (Directive (EU) 2024/2853)
SWD – Commission Staff Working Document
TEU – Treaty on European Union
TFEU – Treaty on the Functioning of the European Union
UK – United Kingdom
vp – Valtiopäivät (parliamentary session)
WHO– World Health Organization