Specialeafhandling:
Balancing Innovation & Patient Safety: Product Liability for AI-driven Medical Devices

Fagområde: Life Science Law
Problemformulering: To what extent does the new Product Liability Directive (Directive (EU) 2024/2853) adequately address legal challenges posed by medical devices that are influenced by, driven by, or constitute AI-software, what challenges remain, and how can they be resolved?

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Abstract

Dette speciale har til formål at fastlægge produktansvarsreglerne for medicinsk udstyr drevet af kunstig intelligens ("**KI**") i EU, og udlede udfordringer, der består, samt løsninger herpå. Specialet tager særligt udgangspunkt i systemer, der yder beslutningsstøtte til læger i en klinisk kontekst. Specialets undersøgelse er således tredelt, hvor den første del fastlægger gældende ret for KI-produktansvar ved hjælp af den retsdogmatiske metode. Den anden og tredje del benytter den retspolitiske metode til at identificere udfordringer med gældende ret i relation til KI-drevet medicinsk udstyr og foreslå løsninger herpå.

Specialets første del finder, at EU's nylige revision af produktansvarsdirektivet ("**PAD**") adresserer KI-produkter ved at definere software som produkter, og tage eksplicit stilling til selvlærende systemer, og den uforudsigelighed, der hermed følger for brugeren. Direktivet fastslår, at producenten er ansvarlig for selvlærende KI-systemer, selv efter at brugeren har taget produktet i brug. Derudover lemper PAD kausalitet- og bevisbyrderegler i forbindelse med sager af høj kompleksitet, såsom sager vedrørende KI-produkter.

Specialet vurderer, at PAD på den ene side placerer en væsentlig byrde på producenter til at forudsige og kontrollere deres udstyr, selv når de ikke længere har systemerne i hænde. På den anden side tager PAD ikke højde for skadelidte patienters udfordringer med at bevise kausalitet, når KI alene indgår som støtte i en læges beslutning. Specialet finder overordnet set, at PAD er gennemsyret af generaliseret tilgang til KI-systemer, der ikke er forenelig med systemernes kompleksitet og forskelligheder i både teknikalitet, anvendelse og indflydelse på samfundet. Direktivet har desuden en binær tilgang til ansvar, der som oftest kun tildeler én aktør ansvar, mens KI-systemernes kompleksitet fordrer, at ansvar bør fordeles mere balanceret mellem producenter af systemer og komponenter, samt professionelle brugere.

Derfor foreslår dette speciale en række forslag, der skal nuancere erstatningsansvaret og tilpasse det specifikt til sundhedssektoren. Forslag inkluderer i) konkrete auditeringsforpligtelser og en hertil knyttet ansvarsundtagelse for uforudsigelige defekter, ii) en ny kausalitetsvurdering for klinisk beslutningsstøttende KI-systemer, iii) fordelt ansvar for skade forvoldt af KI-systemer produceret af flere bidragsydere, iv) forsikringsforpligteler og v) erstatningsforpligtelser for de professionelle brugere, der drager fordel af og er nærmest til at bære risikoen for KI-systemer. Forslagene har dét til fælles, at de tør gå konkret til værks med de udfordringer KI i medicinsk udstyr medfører i sundhedssektoren.

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Chapter I

1. Introduction

The introduction of artificial intelligence ("**AI**") is currently taking the world by storm. AI is the new black, and the emerging technology affects society at large, and the health care sector is no exception.[1] Alongside America, having already deployed AI-driven surgical robots in their operation rooms, the EU has had a significant increase in approvals of CE-marked medical devices based on AI and machine learning ("**ML**") algorithms in recent years.[2]

The manufacturers of AI-driven medical devices promise an improved detection of potential pathology and thereby contribute to increased precision in healthcare as well as easing the burden on stressed healthcare professionals.[3] Studies even find that AI-driven medical devices can outperform physicians.[4] The rapid increase and use of AI tells us that it is merely a matter of time before AI will be a perfectly natural part of our visit at the hospital.

However, as new technology emerges, new legal landscapes begin to form. The implications of AI-driven medical devices on patient safety are yet unknown, and the legal consequences remain largely unsolved. Although manufacturers of AI promise improvements, AI-driven devices have come under public scrutiny for inconsistent performance, particularly in its assessment of minority groups.[5] The implications of these inconsistencies can be crucial for the patients whose doctors rely on the AI-

[1] Healthtech, 'AI in healthcare: 2024 stats explained', <https://ventionteams.com/healthtech/ai/statistics?utm_> Visited on 28 February 2025.
[2] For example the da Vinci AI tool: Intuitive Surgical as mentioned in: American Hospital Association, '3 Ways Robotic Surgery Is Changing Health Care This Year' <https://www.aha.org/aha-center-health-innovation-market-scan/2025-03-04-3-ways-robotic-surgery-changing-health-care-year> Visited on 30 April 2025. And Muehlematter J, Daniore P and Vokinger K, 'Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015-20): a comparative analysis', [2021] The Lancet Digital Health. 3.10.1016/ S2589-7500(20)30292-2.l.
[3] Alowais S and other, 'Revolutionizing healthcare: the role of artificial intelligence in clinical practice', [2023] BMC Med Educ 23, 689.
[4] Armitage H, ' Study suggests physician's medical decisions benefit from chatbot', <https://med.stanford.edu/news/all-news/2025/02/physician-decision-chatbot.html> Visited on 30 April 2025 and Hswen Y and Rubin R, 'An AI Chatbot Outperformed Physicians and Physicians Plus AI in a Trial—What Does That Mean?', [2024] JAMA 2025;33(4): 273-276.
[5] E.g. reflected in James T, 'Confronting the Mirror: Reflecting on Our Biases Through AI in Health Care' <https://postgraduateeducation.hms.harvard.edu/trends-medicine/confronting-mirror-reflecting-our-biases-through-ai-health-care> Visited on 30 April 2025 and Horowitz, B, 'How AI Bias Is Impacting Healthcare', <https://www.informationweek.com/machine-learning-ai/how-ai-bias-is-impacting-healthcare> Visited 30 April 2025.

devices and could likewise be an enormous risk of liability to the hospitals and physicians applying the systems.[6]
This raises several questions: What happens when AI malfunctions and causes harm? Who is liable when an ML-algorithm develops a biased personality of its own outside the manufacturer's control? How should liability be allocated between hospitals and the manufacturer of the AI-systems that they rely on?

Questions of product liability for AI have gained legal attention with the recent adoption of the new EU Product Liability Directive ("**PLD**") that seeks to modernise regulation for products in light of emerging technologies such as AI software.[7][8] The PLD seeks to balance innovation and consumer protection. However, questions remain as to whether PLD can adequately address specific legal challenges posed by AI-driven medical devices.

Furthermore, some EU Member States have established national insurance schemes that seemingly "covers the bill" for manufacturer's defective devices by making claims more feasible under these frameworks.

In light of these recent developments and the legal challenges posed, this thesis investigates whether the new PLD sufficiently addresses the legal complexities of AI-driven medical devices. Thus, challenges of liability for AI-driven medical devices will be identified. Finally, solutions to the identified challenges will be presented.

The thesis is structured in five chapters. Chapter 1 introduces the topic, methodology, and delimitations. Chapter 2 outlines key definitions and the regulatory framework for AI and medical devices. Chapter 3 analyses relevant liability regimes, including the Danish national insurance schemes and the revised PLD with particular focus on its regulation of AI. Chapter 4 goes over the PLD's challenges of liability for AI-driven medical devices. Chapter 5 proposes solutions to the identified issues, and Chapter 6 concludes the thesis.

[6] See as an example article on racial bias risk detected in healthcare algorithm: https://www.informationweek.com/machine-learning-ai/how-ai-bias-is-impacting-healthcare Visited 30 April.
[7] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC [2024] OJ L 2024/2853 ("PLD").
[8] Although the AI Liability Directive was dropped, the new PLD also addresses some of the more fundamental challenges of intangible products, such as software.

1.1 Problem Statement

To what extent does the new Product Liability Directive (Directive (EU) 2024/2853) adequately address legal challenges posed by medical devices that are influenced by, driven by, or constitute AI-software, what challenges remain, and how can they be resolved?

1.2 Scope and Delimitation

To answer the thesis question, the analysis starts by providing an overview of the core definitions and regulatory framework applicable to medical devices and AI software. The purpose of this is to ensure clarity regarding which types of products are included in this thesis, and how such products enter the market. Although, going through classification and statutory requirements briefly, the thesis does not explore this in depth, nor is it concerned with in vitro diagnostics. Moreover, the distinction between different types of AI software and the way in which they are integrated into medical devices is only applied in relation to the general classification overview under the MDR, where classification depends on both integration and type, but not in the liability assessment.

The thesis further examines national rules that may supplement or influence product liability within the healthcare system. This part primarily focuses on Danish law, while other legal systems are included to a limited extent to provide cross-country comparison within the EU. Since these supplementary rules serve only to highlight additional influences on product liability and potential challenges arising therefrom, the thesis does not examine the procedural aspects of national complaint systems or the quantification of damage. Likewise, it does not address healthcare law more broadly, or related patient protection regimes such as data protection, rights to information, intellectual property, or cybersecurity.

In the main part of the thesis concerning the PLD, the concept of product liability as regulated in the EU is examined with reference to relevant case law from both the CJEU and Member States. The types of harm considered are limited to personal injury caused in the context of hospital treatment. In other words, the thesis concerns bodily harm resulting from the use of AI systems by physicians for diagnostic or therapeutic purposes, either in hospital settings or private practice. This excludes property damage and patient-operated AI systems.

Of particular relevance to the thesis is the use of clinical decision support systems ("**CDSS**") designed to assist physicians in their clinical tasks. In this thesis, CDSS refers to analytical tools that support clinicians in various ways, for example, by analysing data from other devices such as radiology systems, organising information received from the clinician, or functioning as interactive chatbots

during patient consultations. The thesis does not cover CDSS operated directly by patients, unless explicitly stated. Nor does it concern fully autonomous systems capable of independently determining and executing treatment, as such systems are not yet used in the EU healthcare sector.

Moreover, the thesis does not examine the quantification of damages under product liability rules, nor does it include insurance law, specific rules for the right to recourse, or procedural rules on bringing product liability claims.

The thesis is naturally limited by the fact that AI products have not yet been subject to judicial interpretation by EU courts. These products are relatively new, and the thesis seeks to offer a perspective on how they are and should be regulated from a liability perspective. The determination of applicable law is therefore limited to what may be inferred from the wording and purpose of the relevant rules, while acknowledging that final interpretation rests with the courts. The thesis further draws inspiration primarily from Danish law, as well as other national systems, when interpreting the PLD. In particular, the discussion on causality relies heavily on national rules, as causality remains largely a matter of national law. The thesis thus operates on the assumption that national causality rules remain unchanged in the context of AI, except for those aspects directly modified by the PLD. However, it is conceivable that both the principle of causality and evidentiary standards may in the future be relaxed for AI-related harm, although this cannot currently be determined.

1.3 Methodology Section

One of the primary objectives of this thesis is to present the current state of the law in relation to AI-driven medical devices. The problem statement necessitates an analysis of the applicable legal framework as it currently stands, with particular attention to the involved parties, including patients, manufacturers and users, in order to identify the legal challenges that persist in this context. This analysis is primarily conducted in Chapters 2 and 3.

To that end, the thesis adopts a doctrinal legal method, which seeks to identify, interpret and systematise the applicable law (*de lege lata*).[9] This entails a comprehensive examination of relevant legal sources, including legislation, case law, preparatory works and official guidance. Where legal instruments are already in force, relevant case law is analysed to clarify how legal provisions have been interpreted by national courts and the ECJ, particularly through preliminary rulings.[10]

[9] Blume P, Retssystemet og juridisk metode, (4th Edition, 2020), p. 32 f.
[10] Ibid., p. 303.

In addition to established legal frameworks, the thesis also considers regulatory instruments that have either only recently been adopted at EU level or are still in draft form and awaiting national implementation. This is especially relevant in the context of the AI Act and the PLD. As these rules have not yet been fully implemented or interpreted by courts, their legal effects remain judicially untested. Consequently, the analysis of remaining legal challenges may be somewhat weakened by the absence of judicial authority. The thesis highlights areas where judicial clarification will be essential.

To interpret these provisions, a range of interpretative methods is employed. These include literal interpretation, focusing on the wording of the legal texts,[11] and teleological interpretation, which considers the objectives and context of the legislation, drawing on recitals, preparatory works and other legislative materials.[12] In some instances, the analysis is extended by analogy or through purposive reasoning, in order to assess how the proposed legal framework for AI in medical devices may operate in practice.[13]

The legal sources primarily examined are EU legal instruments. As the revised PLD is a fully harmonising directive, Member States may not adopt national provisions that diverge from or conflict with its rules, and that national courts interpret domestic provisions in conformity with the PLD's objectives.[14] The primacy of EU law over conflicting national rules reduces the aforementioned limitations posed by the lack of national implementation.

A comparative legal method is also employed throughout the thesis to compare the rules of the former PLD to the revised PLD.[15] Moreover, it is used to examine how selected Member States have structured their healthcare systems and liability regimes in response to AI-induced harm. This method helps highlight legal fragmentation across the EU and identifies alternative legal approaches that could inspire future efforts and the suggestion section in Chapter 5. The comparison also serves to illustrate the challenges posed by software-based medical products and demonstrates the extent of regulatory divergence.[16]

To address the final part of the research question, about how challenges can be solved, the thesis applies a legal policy method.[17] This forward-looking approach (*de lege ferenda*) is used to formulate

[11] Ibid., p. 175 f.
[12] Ibid., p. 177 f.
[13] Ibid., p. 185.
[14] Ibid., p. 293.
[15] See the distinction in Section 3.3.
[16] Hamer C R and Schaumburg-Müller S, Juraens verden, (Chapter 17: Comparative law method), (1st Edition, DJØF, 2020), p. 368.
[17] Blume P, Retssystemet og juridisk metode, (4th Edition, 2020), p. 52.

normative recommendations for how the law ought to develop.[18] Based on the challenges identified, the thesis proposes a set of legal solutions aimed at improving the regulation of AI in the medical sector.

The thesis draws on a broad range of normative legal sources, including binding legislation, preparatory works and official commentaries relevant to *de lege lata* interpretation.[19] Scholarly literature is also used to substantiate interpretations of current law. Scholarly literature can serve as a normative source of information when it relies on authoritative sources, which is the case for this thesis.[20] However, when appropriate, and especially in the proposals for solutions, the thesis incorporates academic articles and other political sources, which Blume refers to as "un-formalised law". He describes un-formalised law sources as sources aiming at influencing the development of law as a dynamic institution, and thus not normative sources.[21] These academic interpretations, legal opinions and proposed reforms provide a foundation for the discussion in Chapters 4 and 5, while the scholarly sources are used for the analysis of the current state of the law in Chapter 2 and 3.

[18] Ibid., p. 346.
[19] Ibid., p. 183.
[20] Ibid., p. 192 f.
[21] Ibid., p. 193.

Chapter II

2. Medical Devices Incorporating AI

As this thesis focuses on medical devices, it is essential to establish a clear definition. The following section will address the legal definition and the current regulatory framework governing medical devices.

2.1 What is a Medical Device?

Medical devices are products which are used in the medical sector for purposes related to the diagnosis, prevention, or treatment of illness etc. Currently there are more than half a million available medical devices spanning from wheelchairs, glasses, bandaids and hearing aids to pacemakers, implants and apps.[22]

The World Health Organization broadly defines medical devices as apparatus that are used for preventing, diagnosing or threatening illness or diseases.[23] A medical device generally is thus a product of a mechanical structure, which has some form of health purpose.

From a legal perspective, the definition of medical devices is established in the primary regulatory framework: Medical Device Regulation (EU) 2017/745 ("**MDR**").[24] According to Article 2(1) of the MDR a medical device means:

> "*any instrument, apparatus, appliance, software, (...) or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> - *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,(...) injury or disability, (...) the anatomy or of a physiological or pathological process or state,(...)*"

[22] Danish Medicine Agency, 'Medical Devices', <https://laegemiddelstyrelsen.dk/en/devices/> Visited on 28 February 2025.
[23] World Health Organization, 'Health Products Policy and Standards'', <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices> Visited 25 February 2025.
[24] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (...), [2017] OJ L 117/1 ("MDR").

Additionally, Article 2(1) determines that medicine and other substances are not medical devices, although a device can be assisted in its function by substances.[25] Therefore medical devices can be products that incorporate pharma products, e.g. vaccines.[26] The vaccination fluid would though only be assisting the device, and not be part of the actual device being the syringe.

Notably, the definition explicitly includes software as a medical device ("**SaMD**"). The increasing digitization of healthcare has led to a surge in the use of software, ranging from administrative process optimization to direct support in the clinical decision-making.[27] Software plays a significant role in the implementation of AI in healthcare, constituting approximately 80% of AI-driven solutions in the sector.[28] As such, the classification of SaMD is a crucial aspect of assessing AI within the framework of MDR.

2.1.1 Software as a Medical Device

For a software to constitute a medical device on its own, the MDR establishes that it must be specifically intended by the manufacturer for one or more medical purposes.[29]

The Medical Device Coordination Group ("**MDCG**") published guidelines in 2019 providing definitions on the classification of medical device software.[30] According to these guidelines, software is defined as: "(...) *a set of instructions that processes input data and creates output data.*"[31] Put simply, a software is defined by its ability to convert an input of data into new data in the form of an output provided by the software.

Moreover, MDCG divides medical devices into three categories:

1) Standalone software performing a medical function (SaMD, cf. MDR Article 2(1)),
2) Software embedded within or influencing the function of a medical device.
3) Software serving as an accessory to a hardware medical device (MDR Article 2(2)).[32]

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[25] MDR, Article 2(1) in fine.
[26] MDR, recital 10.
[27] Beckers R & van Hoydonck P, 'Impact of the Regulatory Framework on Medical Device Software Manufacturers: Are the Guidance Documents Supporting the Practical Implementation?' [2023] JHPM 12/7470.
[28] Healthtech, 'AI in healthcare: 2024 stats explained', <https://ventionteams.com/healthtech/ai/statistics?utm_> Visited on 28 February 2025.
[29] MDR, recital 19.
[30] The MDCG is an EU body overseeing issues in the medical device sector.
[31] Medical Device Group Coordination Group Document, MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746 - IVDR, (MDCG 2019-11), p. 5
[32] Cf. also Tejaswi A and others, 'Software as a medical device', IJDRA, [2016] Vol. 4(2), pg. 10-18 ISSN: 2321 - 6794, p. 12 f.

The key characteristics of a SaMD thus is that it *in itself* performs a medical function. SaMD are subject to the same legal obligations as other medical devices. Legal requirements will be discussed below.

Besides SaMD, software can also qualify as *the driver* of a medical hardware, or as the accessory to medical devices. These two types of software are not subject to the same legal obligations, neither are they completely exempt from legal obligations.

According to Annex VIII, Rule 3.3 of the MDR, software that drives or influences a medical device is classified in the same risk class as the device it controls. This means that software integrated into a medical device does not escape regulatory scrutiny simply because it is not SaMD. Rather, it is subject to the same classification and compliance obligations as the overall hardware that it drives.

Software can also be an *accessory* without driving or influencing the function of a medical device, as seen in examples such as CDSSs. For these types of software a key indicator is that the software only works under the condition that the medical devices it is tied to works as well. For example a machine may capture retinal images being the primary medical device, and then the CDSS analyses them.[33]

These types of software do not undergo the same extensive statutory requirements as software that qualifies as a medical device in itself or that drives or influences hardware. However, they are still subject to certain MDR obligations, including classification and CE-marking, depending on their role in supporting the medical functionality of the device.[34] Thus, the accessory software is codependent on the hardware device, but is classified in its own right, not necessarily in the same risk class as the hardware it is assisting.[35]

2.1.1.2 Case Law on SaMD

Case law provides further clarity on the boundaries of what qualifies as a medical device under the MDR.

In C-219/11, *Brain Products*, the court ruled in accordance with the MDR that the sole usage of a software in a medical context was not sufficient to classify the software as a SaMD. The court ruled that the software must be manufactured for the purpose of being used in a more specific medical context.[36]

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[33] This is seen with the ReintaLyse system which helps physicians analyze retinal images: RetinaLyze, (Homepage), <https://www.retinalyze.com/> Visited 16 May 2025.
[34] MDR Article 2(2).
[35] MDR, Annex VIII, 3.2.
[36] C-219/11, Brain Products, para 16 and 17, and confirmed in C-329/16, Snitem, para 24.

Similarly, in the later case C-329/16, *Snitem*, the court ruled that software does qualify as a SaMD if it: "*while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data, (...)*"[37]. However, as the software in the case had the specific purpose of indicating to the physician the name of the generic drug associated with the one she plans to describe, it had the specific medical purpose as was required to classify as SaMD.[38] The Snitem-case thus confirms that the device needs a specific, not general, medical purpose.

Notably, the CJEU emphasized that software can qualify as a SaMD regardless of whether it directly interacts with the human body or not.[39] This means that AI-driven diagnostic or predictive tools can still fall under MDR even if they do not directly interact or intervene with the human body.

2.1.1.3 Sub-Conclusion

How software qualifies under the MDR is dependent on the way the software is intended to be used. Ultimately, software may qualify in one of three ways: i) as a SaMD, ii) as software driving hardware medical devices, or iii) as an accessory to the medical device. SaMD stipulates a software that single-handedly can be used in a specific medical context for a specific medical purpose, thereby necessitating its own qualification. Conversely, when software is driving or influencing hardware medical devices, the software and hardware becomes so intertwined that it requires a collective classification. Finally, software may merely assist hardware, but not drive it, giving rise to a separate classification that may differ from the hardware it assists.

2.1.2 Classes and Requirements

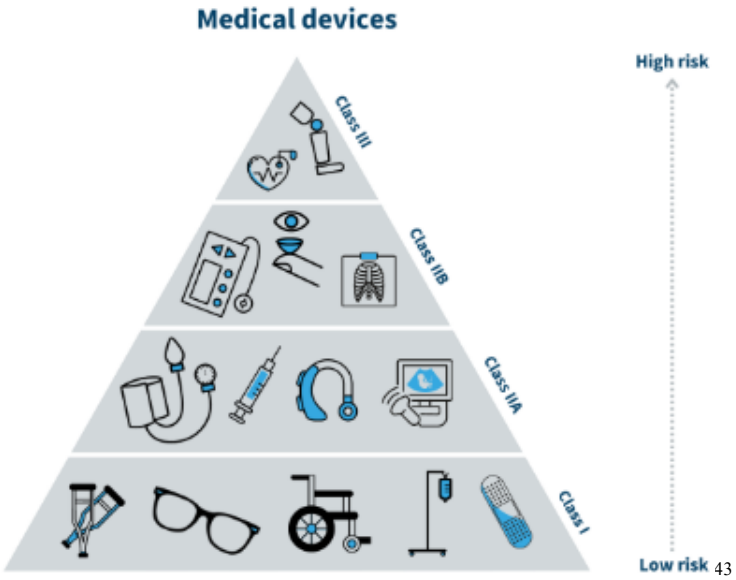
Medical devices that fall within the scope of the MDR are subject to statutory requirements. The rules and requirements in the MDR seek to ensure high standards of quality and safety for medical devices and to mitigate risks, especially for patients.[40] MDR does this by classifying medical devices and setting risk-proportional measures for each class.[41]

The next section will discuss the statutory requirements for deploying medical devices on the market, however, while the CE-marking requirements for software under the MDR will be outlined, a detailed analysis is beyond the scope of this thesis.

[37] C-329/16, Snitem, para. 26.
[38] Ibid., para. 34.
[39] C-329/16, Snitem, para 34.
[40] MDR, recital 2.
[41] MDR, recital 31-32.

2.1.2.1 Requirements for the CE-Marking

Medical devices are divided into four classes: I, IIa, IIb and III with Class III being the highest risk and Class I being the lowest.[42] The middle Class II is divided in two where A is lower than B in risk as illustrated below.



[43]

It is important to observe the rules of the MDR, as a medical device must obtain a CE-marking before being placed on the EU market.[44] A CE-marking signifies compliance with MDR requirements, and must be borne at all times.[45] The classification of a device determines the complexity of the conformity assessment process, which is laid out in Annex VIII of the MDR.

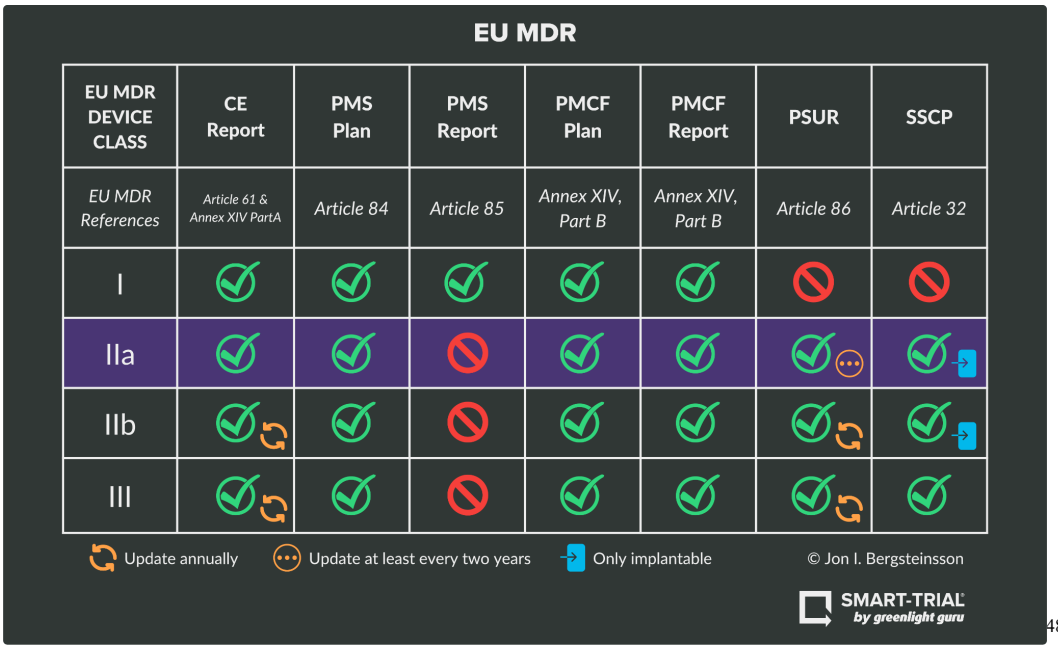
Annex VIII distinguishes between non-invasive devices, invasive devices and active devices. Software is explicitly recognized as an *active device* in MDR Article 2(4), meaning it is subject to specific classification rules. Softwares used for clinical decisions are generally class IIa, but classified higher (IIb or III) if the risk associated can cause irreversible or serious deterioration to the patient's health, or death.[46] Software monitoring physiological processes is also class IIa, unless it monitors vital parameters with immediate risk, making it class IIb. All other software is class I.[47]

Therefore, softwares used for a specific medical purpose will typically qualify in class IIa or higher regardless of whether it is SaMD, software driving or influencing or an accessory. However, if the

[42] Danish Medicine Agency, 'Medical Devices', <https://laegemiddelstyrelsen.dk/en/devices/> Visited on 28 February 2025.
[43] See Illustration 1 in Bibliography.
[44] MDR, Article 5(1).
[45] MDR, recital 40.
[46] MDR, Annex VIII, Chapter III, 6.3 (Rule 11).
[47] Ibid.

software falls out of the scope presented above, typically if it is used for more general or broad purposes, it will qualify as class I. All SaMD will therefore qualify as higher than IIa, as they are characterized by their specific medical purpose.

Below is illustrated the various requirements in MDR for different classes:



[48]

All medical devices must include a clinical evaluation report ("**CER**") and a post-market surveillance plan ("**PMSP**").[49] Class I devices submit a basic post-market report ("**PMSR**")[50], while higher-risk classes must submit more extensive and regularly updated safety reports ("**PSUR**").[51] Only higher-risk devices require a summary of safety and clinical performance ("**SSCP**"), aimed at informing users.[52] All devices must also have a plan for post-market clinical follow-up ("**PMCF**") to monitor real-world performance and safety. The PMCFs are similar to pharmacovigilance for medicine, and refer to the collection and evaluation of user data in order to detect unknown errors or side-effects of the devices.[53]

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[48] See Illustration 2 in Bibliography.
[49] CER, cf. MDR, Article 61 & Annex XIV part A. Class IIb and III are required to update their clinical evaluation report annually. PMSP cf. MDR, Article 84, & Court L, 'Ultimate Guide to Device Class Requirements under EU MDR', <https://www.greenlight.guru/blog/device-class-requirements-eu-mdr> Visited 16 May 2025.
[50] MDR, Article 85 & Medical Device Coordination Group, MDCG 2019-15 rev.1: Guidance notes for manufacturers of class I medical devices, (MDCG 2019-15 rev.1, July 2020 rev.1), p. 21.
[51] MDR Article 86. For class IIB and III it has to be updated annually, while class IIa can settle with updating their plan at least every two years.
[52] MDR, Article 32, and Court L, 'Ultimate Guide to Device Class Requirements under EU MDR', <https://www.greenlight.guru/blog/device-class-requirements-eu-mdr> Visited 16 May 2025.
[53] MDR, Annex XIV, Part B.

The differences in statutory requirements across classes relate more to the frequency than the scope of obligations. Nonetheless, the classification remains significant for manufacturers. For example, class III devices are subject to particularly stringent requirements, which may incentivise manufacturers to avoid designing software in a way that keeps them in a lower class.[54]

Under Annex I in MDR it is required that medical devices are designed in a way that makes them safe and effective for their intended purpose.[55] To the extent this safety cannot be mitigated by design, other safety measures, such as alarms, warnings, instructions or training, should be provided, similar to the requirements under the PLD as will be addressed later on.[56] However, as opposed to the PLD, the MDR acknowledges that the reduction of risks cannot extend to measures that adversely affect the risk-benefit ratio.[57] This allows for a more pragmatic approach to what may be considered safe enough for the market based on risk-benefit analysis for the manufacturer's business, even though it might not correlate with the safety assessment under liability rules, such as the PLD, to which we will return.

[54] MDR, Annex VIII, Chapter III, 6.3 (Rule 11).
[55] MDR, Annex I, 1.
[56] MDR, Annex I, 4, b-c. See Section 3.3.4.
[57] MDR, Annex, 2.

2.2 Artificial Intelligence and Machine Learning

The thesis will examine medical devices that incorporate AI. Therefore, it is necessary to discuss the concept of AI, define ML, and assess regulatory framework on the subject.

2.2.1 What Is Artificial Intelligence?

AI has evolved alongside technological advancements, progressing from early inventions such as calculators to more sophisticated devices like computers and smartphones. We have seen gadgets such as Siri, impersonating a personal assistant whom you can communicate with on Apple devices via voice control.[58] Siri helps holders of Apple devices to carry out everyday chores and requests, just like a real assistant, though somewhat limited.[59]

Today, technological advancements have increasingly blurred the line between human cognition and machine capabilities.[60] Modern AI systems operate at unprecedented speeds, executing complex computations far beyond human capacity. For instance, an AI model can process calculations in one second that would take an individual billions of years to complete.[61]

Today, AI has firmly established itself in the market, with nearly half of global companies actively integrating AI technologies and over 80% engaging with AI in some capacity.[62]

AI refers broadly to:

> "*the capability of machines or computer programs to perform tasks that typically require human intelligence, such as learning, problem-solving, and decision-making.*"[63]

Additionally, AI is described as working by:

> "*processing large amounts of data, identifying patterns and relationships, and using that information to make decisions or take actions. This process is made possible by algorithms that are designed to learn from the data they are fed.*"[64]

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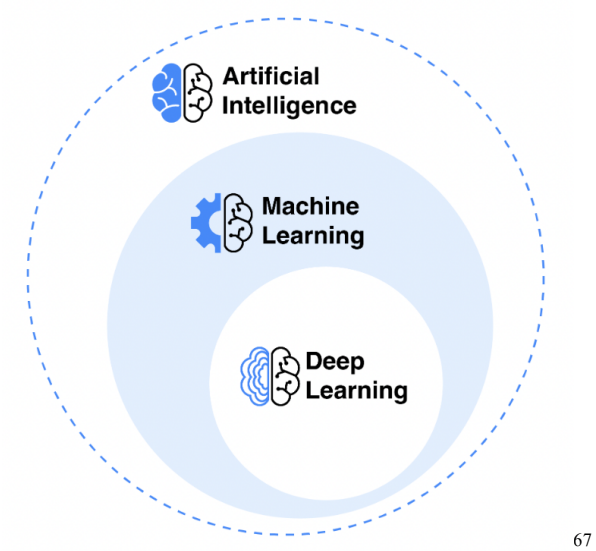
[58] Apple, 'User Manual for iPhone: Use Siri on iPhone'', <https://support.apple.com/da-dk/guide/iphone/iph83aad8922/ios> Visited on 5 March 2025.
[59] Nielsen N, 'Alt om Siri > Fremtiden indenfor Virtuel Assistance', <https://www.avxperten.dk/blog/hvad-er-siri/> Visited on 5 March.
[60] McKinsey & Company, 'What is AI (artificial intelligence)?', <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-ai> Visited on 5 March 2025.
[61] Ibid.
[62] Kumar N, 'How Many Companies Use AI In 2025? (Global Data)', <https://www.demandsage.com/companies-using-ai/> Visited on 5 March.
[63] Banafa A, Introduction to Artificial Intelligence (AI) (River Publishers 2024), p. 3.
[64] Ibid.

As these definitions indicate, AI simulates aspects of human intelligence, demonstrating extensive knowledge processing capabilities and a high degree of autonomy compared to traditional computing systems, such as calculators.

2.2.2 What Is Machine Learning?

ML is a specialized branch of AI that focuses on the development of models and algorithms capable of recognizing patterns, making predictions, and generating decisions based on data.[65] Unlike traditional software that follows explicitly programmed instructions, ML systems improve their performance over time by analyzing vast datasets and learning from the outcomes.[66] ML is therefore a subset to AI as illustrated below:



[67]

ML can be further divided into subfields, including deep learning ("**DL**"), which involves multi-layered neural networks that autonomously extract and learn features from data.[68]. DL is distinguished from other neural network-based approaches by its ability to identify intricate patterns within complex datasets without manual feature selection. This allows AI models to refine their decision-making processes, enabling them to make increasingly accurate predictions and recommendations over time.[69]

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[65] Ibid. p. 4.
[66] Ibid.
[67] See Illustration 3 in Bibliography.
[68] Banafa A, Introduction to Artificial Intelligence (AI) (River Publishers 2024), p. 6.
[69] McKinsey & Company, 'What is AI (artificial intelligence)?', <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-ai> Visited on 5 March 2025.

Put simply, DL and ML allows AI-systems to not only act as if it has human intelligence, but furthermore stimulate intelligence by continuously learning from its input.

2.2.3 The Black Box Problem

One of the primary challenges associated with AI is the black box problem, which refers to the lack of explanation and justification of how outcomes are reached.[70] This hinders transparency, flexibility, thereby impacting the level of trust in AI.[71] AI models, particularly those utilizing DL, are trained on vast datasets to identify complex patterns. However, the internal logic behind their output is often difficult to interpret, making it challenging to assess the reasoning behind a particular decision.[72]

This lack of transparency presents significant risks in medical applications. AI models may exhibit biases, resulting in unfair or inaccurate outcomes. For example, researchers discovered that an AI model used for skin cancer detection was biased due to inadequate training data, leading to less accurate assessments for individuals with darker skin tones.[73] If the AI produces an incorrect diagnosis or recommendation, it may be difficult to determine the cause of the error or implement corrective measures, if it is hidden in a black box.

2.2.4 Current Legal Framework: AI Act

The increasing integration of AI across industries has necessitated regulatory measures for governing AI. In response, the European Union adopted Regulation (EU) 2024/1689, commonly known as the AI Act ("**AI Act**").[74] This regulation establishes harmonized rules for AI systems within the EU and will be implemented progressively from 2024 to 2026.[75]

The AI Act seeks to promote AI in Europe in a sustainable and responsible manner which protects fundamental rights, promotes transparency and responsibility, while preventing market barriers and

[70] Banafa A, Introduction to Artificial Intelligence (AI) (River Publishers 2024), p. 18.
[71] Ibid.
[72] SEON, 'Blackbox Machine Learning', <https://seon.io/resources/dictionary/blackbox-machine-learning/> Visited on 5 March 2025.
[73] Davis N, 'AI skin cancer diagnoses risk being less accurate for dark skin - study', <https://www.theguardian.com/society/2021/nov/09/ai-skin-cancer-diagnoses-risk-being-less-accurate-for-dark-skin-study> Visited on 5 March 2025.
[74] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (...), [2024] OJ L 2024/1689 ("AI Act").
[75] Dansk Erhverv, 'AI Act: EU's nye forordning om kunstig intelligens', <https://www.danskerhverv.dk/branche/digitalisering-teknologi--tele/ai-act-eus-nye-forordning-om-kunstig-intelligens/> Visited 5 February 2025.

protecting innovation.[76] One of its objectives is to address the black box problem, however the EU acknowledges that not every challenge of AI governance has yet been solved with the AI Act.[77]

2.2.4.1 Legal Definitions of AI-systems

The AI Act provides a legal definition of AI-systems in Article 3(1):

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

Furthermore, the AI Act stipulates that the key characteristics of an AI system is the capability to infer from outputs and derive algorithms or models that can impact physical and virtual environments.[78]

Additionally, ML is mentioned as a technique for enabling inference by allowing the AI system to learn from data how to achieve certain objectives and build knowledge.[79] The adaptiveness and self-learning capabilities that allows a system to change while in use are thus a characteristic of an AI-system in a legal sense.[80]

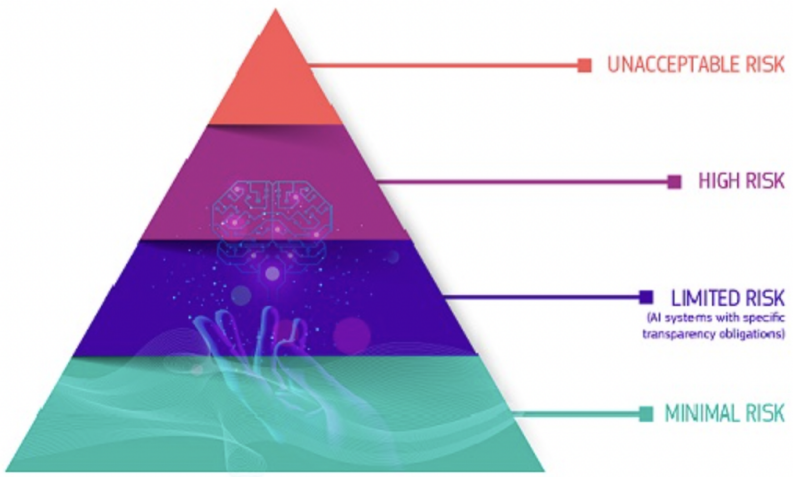
Another key characteristic of AI systems is their level of autonomy.[81] AI systems are defined to have some degree of independence of actions not involving human intervention.[82]

Conclusively, the legal definition of AI systems are that they have the capability to i) infer, ii) learn from data, iii) adapt, and moreover iv) have a certain level of autonomy.

[76] AI Act, recital 7.
[77] European Commission, 'AI Act', <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai> Visited on 5 February 2025.
[78] AI Act, recital 12.
[79] AI Act, recital 12, 5th punctuation.
[80] AI Act, recital 12, 12th punctuation.
[81] AI Act, recital 12, 11th punctuation.
[82] Ibid.

2.2.4.2 Risk-Based Classification under the AI Act

The AI Act applies broadly to all stakeholders involved in the development, use, import, export, distribution, and production of AI systems.[83] The regulation adopts a risk-based approach, categorizing AI systems according to their potential risks, much like the classification framework in MDR. AI systems are divided into four risk levels as illustrated below:



[84]

Risk-categories:[85]

Unacceptable risk: AI applications deemed a threat to fundamental rights or safety, such as AI-based deception, manipulative techniques, exploitative practices, and social scoring. These systems are strictly prohibited under Article 5 of the AI Act.

High risk: AI systems used in critical sectors, including healthcare, law enforcement, and administration of justice, where failures could pose significant risks to life, safety, or democracy. These systems must comply with strict documentation, transparency, and monitoring requirements.

Limited risk: AI applications such as chatbots and deepfakes that require transparency measures, ensuring users are aware they are interacting with AI-generated content.[86]

Minimal risk: AI systems used in video games, spam filters, and other low-risk applications, which remain largely unregulated but may voluntarily comply with best practices.

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[83] Dansk Erhverv, 'AI Act: EU's nye forordning om kunstig intelligens', <https://www.danskerhverv.dk/branche/digitalisering-teknologi--tele/ai-act-eus-nye-forordning-om-kunstig-intelligens/> Visited 5 February 2025.

[84] European Commission, 'AI Act', <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai> Visited on 5 February 2025.

[85] Ibid.

[86] EU Artificial Intelligence Act, 'High-level summary of the AI Act', <https://artificialintelligenceact.eu/high-level-summary/> Visited on 7 March 2025.

The level of risk is covered by rules setting adequate requirements for the system. A high risk-system is therefore covered by stricter requirements, such as logging of activity to ensure traceability of results[87], while the minimal risk-system is not subject to any requirements in the AI Act, although they can voluntarily abide by certain requirements.[88] The AI-systems that fall within the category of unacceptable risk are as the name suggests not allowed.[89]

2.2.4.3 Classification of AI-based Medical Devices

The AI Act explicitly classifies AI-driven medical devices as high-risk AI systems.[90] Consequently, such devices are subject to a dual CE-marking procedure under both the MDR and the AI Act.[91] Although both frameworks require CE-marking process, these do not mutually excuse the other, as the MDR addresses essential health and safety requirements related to medical devices that are not covered in the AI Act, whilst the AI Act covers more technical issues that are not addressed in the MDR.[92]

The requirements relevant for high-risk systems are set down in the AI Act Chapter III, specifically Articles 9 to 14, as well as frameworks mentioned in Section A of Annex I.[93] The latter merely refers to the MDR, but it is specified in AI Act Article 8(2), that documentation prepared under the MDR may also be used in the procedure under the AI Act.

We will go over these requirements and do a general comparison between the two CE-procedures. A more detailed discussion of the statutory requirements, their coherence, and the differences in procedures is not considered relevant for answering the thesis question.

2.2.4.4 Dual CE-procedures

The requirements for high-risk AI systems, such as medical devices, include:

I. risk management system[94]: a continuous lifecycle process for identifying, evaluating and mitigating risks,

[87] AI Act, Article 12(1) & 12(2).
[88] Dansk Erhverv, 'AI Act: EU's nye forordning om kunstig intelligens', <https://www.danskerhverv.dk/branche/digitalisering-teknologi--tele/ai-act-eus-nye-forordning-om-kunstig-intelligens/> Visited 5 February 2025.
[89] AI Act, Article 5.
[90] AI Act, recital 50, last punctuation.
[91] AI Act, recital 129 and Article 23(1)(c) & Article 24(1).
[92] AI Act, recital 64.
[93] AI Act, Article 8(1-2).
[94] AI Act, Article 9.

II. data governance[95]: data used for training must be relevant, representative, free of errors, and managed under robust data governance procedures to detect and mitigate bias,
III. technical documentation[96]: technical documentation must be prepared before putting on the market in accordance with Annex IV, which includes a general description of the AI system as well as a detailed description of its elements and the process for its development,
IV. logging[97]: systems must keep record (log results) to ensure traceability and monitoring post-market,
V. transparency[98]: the system should be transparent enough that the user understands the outputs and what they are based on (e.g. by providing instructions),
VI. human oversight[99]: the systems should be designed to ensure that human oversight is still possible (e.g. to override or intervene in the AI systems actions).

Although both the MDR and the AI Act recognize that requirements should be proportionate to the type of device or system, they do differ in focus when it comes to requirements.

While the classification under the MDR focuses primarily on the healthcare sector; how invasive the device is, which health risks it entails and other criteria relating to the patient's safety, the AI Act focuses on more general societal consequences of the AI systems. The classification is based more on ethical implications for society rather than the specific individual using the system.

Furthermore, the requirements for obtaining the two CE-markings have some similarities, particularly with respect to risk management. While the AI Act mandates a risk management system be set up, as well as other supplementary systems of logging, transparency and data governance, the MDR stipulates requirements for PSMR and PSUR, as well as the PMCF, which ensures the evaluation, identification and mitigation of post-market risks. In addition, the MDR's requirement for a SSCP to be made available to physicians and other healthcare professionals are required to promote transparency, and thus aligns with the principles of transparency promoted in the AI Act.

As stated in the AI Act Article 8(2), some of the procedures and documentation required for the MDR may be reused for the CE-assessment under the AI Act. This is intended to reduce the administrative burden. Nevertheless, some stakeholders argue that overlapping requirements still create legal

[95] AI Act, Article 10.
[96] AI Act, Article 11.
[97] AI Act, Article 12.
[98] AI Act, Article 13.
[99] AI Act, Article 14.

uncertainty and give rise to criticism of regulatory overreach.[100] Furthermore, stakeholders consider the cost for complying with both regulations too high.[101]

2.3 Conclusion on Chapter II

Medical devices incorporating AI can take various regulatory forms under the MDR, depending on their intended use. Such software may qualify as SaMD, as software driving a hardware medical device, or as an accessory. Each qualification affects the classification of the device and the corresponding statutory requirements under the MDR. While AI-based software can fall into every class under the MDR, the same cannot be said for classification under the AI Act. According to the AI Act, every AI-system that is incorporated in a medical device is automatically considered a high risk AI-system. The AI-driven medical devices discussed in this thesis are therefore always subject to a dual CE-marking procedure.

The MDR imposes requirements relating to the device's clinical safety, performance, and interaction with the patient, whereas the AI Act focuses on the broader societal risks posed by the system, including ethical concerns and data security.
Despite their differing scopes, the two frameworks share common objectives: both aim to ensure risk surveillance, reduce or mitigate harm, and enhance transparency for users.

Having now outlined the statutory requirements applicable to AI-based medical devices, we may turn to the core focus of this thesis: the liability implications of placing such devices on the market.

[100] "Balogun, E. and others, 'Exploring key stakeholders' perspectives on integrating the EU AI Act with the MDR for certifying AI medical devices', [2025] AI Ethics, vol. 5, pg. 2999-3013, p. 7 & 9.
[101] Ibid., p. 9.

Chapter III

3. A Patient's Path to Compensation

When a patient is harmed by a medical device, there are three legal possibilities for compensation in Denmark: (1) the patient may raise a claim against the physician; (2) a claim under national compensation or insurance schemes for patients; or (3) a claim against the manufacturer of the device under the PLD. While this thesis focuses primarily on product liability it is crucial to also establish the central figure in this legal constellation: the injured party. The patient who suffers harm due to, or in connection with, the use of AI-enabled medical devices constitutes a core concern of this analysis. Moreover, the legal interplay between national schemes and EU rules of compensation can constitute a challenge for the practical implication of PLD as we will see.

The following section focuses in particular on the Danish system and the compensation options available in Danish health care. Patient compensation outside the scope of product liability is largely governed by national laws, with many EU Member States having implemented insurance-based compensation schemes or relying on general tort principles.[102]

3.1 Medical Professional Liability

Firstly, we must address the liability of the physician. As the patient does not have a contractual relationship to the physician or the hospital, but only an agreement by virtue of other health initiatives typically proposed by the state, the liability for a physician is determined by non-contractual schemes of liability. This means that the physician is liable on the basis of culpable conduct or omission.[103]

In line with Danish, French, and German tort law traditions, four cumulative conditions must be met in order to be compensated in cases of non-contractual damage:

1) Fault (culpability),
2) Actual damage,
3) Causal link,
4) Adequacy (foreseeability)[104]

[102] European Commission, Expert Group on Liability and New Technologies - New Technologies Formation, 'Liability for Artificial Intelligence and other emerging technologies", [2019] ("EU Report on emerging technologies"), p. 15.
[103] von Eyben B and Isager H, Lærebog i erstatningsret, (10th Edition, Djøf, 2024), p. 451.
[104] Adäquanztheorie in German law or Prévisibilité du dommage in French law.

First, the injured party must prove the existence of a loss, and that this loss was caused by the physician's action or omission, as well as establishing a causal link between the two. Finally, liability is limited by the doctrine of adequacy, which bars compensation for losses that could not reasonably have been foreseen by the tortfeasor.

The term "culpability" refers to situations in which a person has acted either with intentional fault or with negligence. Intentional fault, as the term implies, involves conduct carried out with the intention to cause harm or a wrongful outcome. Such actions are inherently culpable. Negligence, on the other hand, is typically assessed using the *bonus pater familias* standard.[105] Bonus pater translates to "the good family father", and the concept serves as a benchmark for determining whether an act was negligent by comparing it to what a reasonably prudent person would have done under the same circumstances.[106] The bonus pater is a fictional standard; it does not accommodate the fact that real individuals may occasionally make mistakes.[107] Liability is therefore based on the risks that this idealised person would have foreseen and consequently avoided.[108]

In tort law, it is common to apply a different culpa standard to professional liability compared to general bonus pater-benchmark.[109] Typically liberal professions, such as attorneys, physicians and accountants are subject to a more strict duty of care. In some jurisdictions, specific legislation has even been adopted to govern medical liability in particular.[110] The rationale behind this approach lies in the assumption that such professionals possess specialised academic knowledge, which both enables them to practise their profession and justifies holding them to a higher standard.[111] In other words, they are expected to act in accordance with their expertise; heightening the standard of their duty of care.

As will become clear in the following section, however, it is often of little practical relevance to the patient whether the physician is held liable under the ordinary rules of non-contractual liability. This is because the Danish patient compensation scheme can provide compensation independently of any

[105] von Eyben B and Isager H, Lærebog i erstatningsret, (9th Edition, Djøf, 2019), p. 96.
[106] Ibid., p. 97.
[107] Ibid.
[108] Ibid., p. 99.
[109] Bussani M and J. Sebok A, Comparative Tort Law: Global Perspectives, (2nd Edition, Edward Elgar, 2021), p. 226.
[110] E.g. Patient Rights Act (Patientenrechtegesetz) in Civil Code in the version promulgated on 2 January 2002 (Federal Law Gazette [Bundesgesetzblatt] I page 42, 2909; 2003 I page 738), last amended by Article 1 of the Act of 10 August 2021 (Federal Law Gazette I p. 3515) "BGB" Section 630 a-h.
[111] Ulfbeck V, Erstatningsretlige grænseområder, (3th Edition, DJØF, 2021), p. 28.

finding of fault on the part of the physician.[112] Furthermore, as we will see in the following section, the hospital will typically be liable for the physician's actions or omissions.

3.1.1 Vicarious Liability

The possibility of holding the employer exempt for the employee's actions arises from national rules on vicarious liability.[113] Vicarious liability rules dictate when someone (the principal) is liable for the conduct of another (auxiliary). In Denmark Article 3-19-2 of Act no 11000 of 15 April 1683[114] establishes that a principal who has the ability to instruct, supervise, and control an auxiliary may be held liable for the auxiliary's actions, provided those actions are not of an abnormal nature.[115]

Notably, it is relevant to explore whether this rule could apply for AI-systems being the auxiliary or for the physician's interaction with AI-systems. Naturally, the principal is equally liable for their auxiliary regardless of what source of information their harmful decisions are routed in, be it AI, the internet or something else. Therefore, some have discussed whether AI should in itself be considered an auxiliary by analogy of rules on vicarious.[116] This would be particularly relevant when AIs become more autonomous. However, in jurisdictions discussing this approach to AI, the issue of determining which benchmark the AI should be held to is yet too difficult.[117] Moreover, the fear that such a rule would discourage the use of AI, which is ironically often deemed safer than the human auxiliary's actions, seemingly keeps rules on vicarious liability for AI in the future for now.[118]

Moreover, Danish law currently offers patients a much more straightforward route to compensation through the national patient insurance scheme. It may be argued that the Danish insurance scheme serves as a sort of strict vicarious liability scheme, as it is a way of insuring the patients as well as the physicians and hospitals by making the state-based compensation system bear the burden in certain circumstances.

[112] See Section 3.2.1.2.
[113] Vicarious liability is common in many jurisdictions in the EU, cf. EU Report on emerging technologies, p. 24 ff. with reference to H Koziol, 'Comparative Conclusions' (fn 54), p. 795 ff.
[114] King Christian the Fifth's law of Denmark.
[115] von Eyben B and Isager H, Lærebog i erstatningsret, (9th Edition, Djøf, 2019), p.161 ff.
[116] EU Report on emerging technologies, p. 25.
[117] Ibid.
[118] Abbott R, 'The Reasonable Computer: Disrupting the Paradigm of Tort Liability', [2018], 86 Geo. Wash. L. Rev. 1, p. 31.

3.2 National Patient Insurance

3.2.1 Denmark's Complaints and Compensation Act

In Denmark, as well as in other jurisdictions, national insurance schemes have been established to compensate patients within the healthcare system.[119] The purpose of these schemes are to ease the burden on patients who suffer treatment-related injuries. Specifically, the Danish rules aim to: (i) allow for compensation without the need to prove the physician's fault, and (ii) reduce administrative burdens by lowering the time and cost associated with the claims process.[120] The Danish rules are set out in chapter three of the Danish Klage- og Erstatningsloven, translated to the Complaints and Compensation Act ("**CCA**").[121]

The rules cover all people sustaining injuries within the Danish healthcare system.[122] This includes all hospitals, public as well as private, and other institutions of treatment, even hospices and mental institutions.

Furthermore it is only personal injuries physically or psychologically that are covered by the rules for compensation.[123] Property damage and purely financial losses are thus not covered under these rules. Consequently, claims for loss of income or expenses related to the support of a child, such as in cases where a termination of pregnancy fails, are not eligible for compensation.[124]

The insurance scheme is currently subject to an excess of 7.971,00 DKK.[125]

3.2.1.1 "Additional harm" and the Threshold for Causality

The CCA covers injuries sustained in relation to *treatment*.[126] Treatment is to be understood broadly including consultation and examination as well as any surgery etc.[127] However, the coverage only

[119] Dixon A and Poteliakhoff E, 'Back to the future: 10 years of European health reforms', [2012], Health Economics, Policy and Law. 2012;7(1):1-10, p. 4-5.
[120] Hybel U, Bak Mortensen P and Lindhardt A, Læge & Loven, (1st Edition, Munksgaard, 2015), p. 280.
[121] Lov om klage- og erstatningsadgang inden for sundhedsvæsenet (Consolidated Act No. 962 of 16 August 2024 concerning complaints and compensation mechanisms within the healthcare system) (Denmark) ("CCA").
[122] CCA § 19.
[123] CCA § 19.
[124] cf. Decision in the Danish Patientforsikringsforening with the number: PFF 1993.33 (loss of income) & PFF 1995.41 (failed termination of pregnancy). Although, in the case of the failed termination of pregnancy, the court found that the failed abortion in itself was not an injury in the sense of the CCA.
[125] CCA § 24(2) & (7).
[126] CCA § 19 and Hybel U, Bak Mortensen P and Lindhardt A, Læge & Loven, (1st Edition, Munksgaard, 2015), p. 282.
[127] Hybel U, Bak Mortensen P and Lindhardt A, Læge & Loven, (1st Edition, Munksgaard, 2015), p. 282. In the decision of 13 March 2008 in case B-2436-05, published in the Danish Ugeskrift for Retstidende 2008 on pg. 1528 ("U 2008.1528 V"), a Danish court even found that two physicians from different hospitals discussing a specific patient's health is within the definition of "treatment".

extends to injuries exceeding what would naturally result from the underlying illness or from the side effects of the treatment. Moreover, compensation is not dependent on what *should* have been avoided, but what *could* have.[128]

This principle was confirmed in the Danish Supreme Court judgment U 2011.2487 H, where back pain was considered a typical consequence of spinal degeneration, not attributable to the treatment.[129] The ruling highlights that compensation requires the injury to be both avoidable and directly caused by the treatment provided or omitted.

The case also illustrates the requirement for proof of causation as there must be proven a link between the injury and the treatment. Under the CCA this requirement has been relaxed requiring only a predominant probability, i.e. more than 50% likelihood.[130] However, in practice causality has not always been easy to prove.

In FED 2004.1878, a woman was denied compensation after childbirth due to symptoms like pain, cognitive issues, and visual disturbances.[131] Despite no clear alternative cause, the court found no sufficient link to the delivery or treatment, noting that multiple causes could not be excluded. Without a clear causal connection, compensation was denied.

The claimant's inability to establish a precise causal connection combined with the assumption that the injury did not exceed what could be expected from childbirth, meant that no compensation was awarded.[132]

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[128] Hybel U, Bak Mortensen P and Lindhardt A, Læge & Loven, (1st Edition, Munksgaard, 2015), p. 282.
[129] Decision of 1 June 2011 in case 299/2008, published in the Danish Ugeskrift for Retstidende 2011 on pg. 2487 ("U 2011.2487 H").
[130] von Eyben B and Isager H, Lærebog i erstatningsret, (10th Edition, Djøf, 2024), p. 457 ff.
[131] Decision published in the Danish Forsikrings- og Erstatningsretlig Domssamling 2004, p. 1878 ("FED 2004.1878").
[132]Currently, developments are taking place within the Danish complaint boards - namely, the Insurance Appeals Board (Ankenævnet for Forsikring) and the Equal Treatment Board (Ligebehandlingsnævnet) - concerning insurance companies' obligation to recognise birth-related injuries. For many years, such injuries were either categorically rejected or explicitly excluded in insurance terms and conditions, cf. Danish Equal Treatment Board decision no. 9202 of 25 March 2021.

This development is pushing insurance companies toward a more inclusive coverage of women's childbirth-related conditions, which arguably reflects an evolution in the equality debate. The insurance cases referred primarily address the concept of 'accident' in insurance law.

In light of this development, it is conceivable that the national patient compensation scheme may, going forward, adopt a less restrictive approach to awarding compensation for complications arising in connection with pregnancy as opposed to the decision published in the Danish Forsikrings- og Erstatningsretlig Domssamling 2004, p. 1878 ("FED 2004.1878").

Other factors relevant to the awarding of compensation are listed in § 20 of the CCA. This provision stipulates, generally, that compensation is only granted for injuries that actually could have been avoided if the treatment had been performed differently.

For instance, in FED 2007.161 V, the relatives of a deceased patient were not awarded compensation after a physician failed to do a brain scan that could have raised early suspicion of encephalitis, which condition the patient suffered death from.[133] This was because surgery for the encephalitis would not, in any case, have improved the patient's condition, and it was therefore not deemed more likely than not that the scan could have prevented the patient's death.

Although the CCA does not require that the physician acts in a culpable way in order to grant the patient compensation, case law and literature suggests that acting culpable will affect the assessment of causality. It is thus generally assumed that if the physician acts in a culpable way the need to prove causality will be presumed unless otherwise rebutted.[134]

This was illustrated in FED 2016.95 V, where a diagnosis of endocarditis was delayed because the physician failed to perform an echocardiogram.[135] This omission was deemed a culpable error that established causality. In this case, earlier initiation of surgery could have prevented additional harm.

Compared to the aforementioned case[136] about the failure to provide a brain scan, it is clear that the causality requirement is not waived if the injury was unavoidable. Even where the requirement is relaxed due to medical error, some causal analysis is still needed to assess whether the conduct affected the outcome.

In conclusion, the requirement for causality remains, and the patient still needs to demonstrate a predominant probability that the injury sustained was caused by the physician's treatment or lack thereof, and not the underlying condition or disease, or unavoidable consequences of the necessary treatment. Moreover, this causality requirement may be presumed in cases involving culpable conduct, however, only in situations where the culpable conduct demonstrably prevented timely treatment that could have altered the course of the patient's condition.

[133] Decision published in the Danish Forsikrings- og Erstatningsretlig Domssamling 2007, p. 161 ("FED 2007.161 V").
[134] von Eyben B and Isager H, Lærebog i erstatningsret, (10th Edition, Djøf, 2024), p. 459.
[135] Decision published in the Danish Forsikrings- og Erstatningsretlig Domssamling 2015, p. 95 ("FED 2016.95 V").
[136] FED 2007.161 V.

3.2.1.2 Grounds for Compensation

Moving on from the scope of which injuries are covered, we now discuss the grounds for compensation under the CCA. Going into detail with § 20 of the CCA, it lists four pathways to obtain compensation.

Although fault is not required, the standard of liability is not an objective liability either.[137] Certain risks associated with medical treatment must be accepted as the necessary cost for achieving a cure. Especially when the alternative is the risks of invalidity or death.[138] The following paragraph will examine the four pathways to compensation under CCA § 20. Particularly relevant for this thesis is the rule about device-related injuries in CCA § 20(1)(2) which will be more thoroughly examined.

The first pathway to compensation allows the patient to obtain compensation if a specialist, the most skilled physician in the relevant medical field, would have acted differently in a way that could have prevented the injury, cf. CCA § 20(1)(1). This liability standard does not merely refer to the conduct of a competent physician, but to that of a specialist in the field.[139]

Even though the standard is based on the conduct of a specialist, it is not required that a specialist was actually available at the hospital in question. The specialist standard merely serves to illustrate the benchmark of what care the patient can expect.

While the specialist standard is applied to determine eligibility for compensation under the CCA, it does not correspond to the professional standard as described in Section 3.1. Under the physician's general professional culpa standard the physician is only expected to have specialist knowledge where the physician is, or claims to be, a specialist. Under the CCA § 20(1)(1) it is assumed that the fictitious person that sets the benchmark for compensation is a specialist in the area of relevance, which significantly broadens the patient's access to compensation.

Moreover, the assessment must be based on the medical knowledge available at the time of treatment. It cannot be held against the hospital or physician that later research has shown an alternative method that might have alleviated the patient's condition more effectively.[140]

[137] von Eyben B and Isager H, Lærebog i erstatningsret, (10th Edition, Djøf, 2024), p. 460.
[138] Ibid.
[139] Ibid., p. 461.
[140] Madsen H, Comments for LBKG 2024-08-16 no. 962 (CCA) in Karnov Group, (renewed continuously), note no. 132.

The rule in CCA § 20(1)(1) operates with a strict liability framework. However, it must be kept in mind that the claim is not directed at the physician, but at the compensation system financed by the hospital.[141] The hospital may, however, pursue a right of recourse against the physician in conditions are met, cf. the Danish Liability for Damages Act § 27.[142]

The second pathway to compensation is where a technical device fails during treatment and causes injury to a patient, cf. CCA § 20 (1)(2). The assessment of whether the device is faulty is not the same as the assessment of a defect in the PLD.[143] For this reason, hospitals are held liable for device-malfunctions almost no matter which type, and even if dangers of the device were not known, when the device was put into use.[144]

The rule covers the vast majority of medical devices, including both therapeutic instruments and more complex apparatuses such as anaesthesia and X-ray machines, respiratory equipment, as well as utensils and similar tools.[145]

Under the CCA, all device failures are covered; regardless of whether the cause of the failure is known.[146] Furthermore, the rule applies regardless of whether the malfunction is due to the inherent properties of the device or external circumstances at the hospital, such as a power outage, cf. case no. 07-5634.[147] Accordingly, the incorrect use of devices may also give rise to compensation, which could mean that incorrect use of a CDSS could result in compensation even if the CDSS is not faulty.

Although the PLD's concept of "defect" is not applied when assessing whether a device has failed under the CCA, it is nevertheless relevant for the patient's ability to pursue claims. Patients are not precluded from bringing claims against the manufacturer under the rules on product liability, cf. CCA § 28, even if they pursue the claim under the CCA. However, the patient cannot obtain compensation from the manufacturer to the extent that they are already compensated through the patient insurance scheme, cf. CCA § 26 and the Danish principle against unjust enrichment. As a result, the patient

[141] Or the Danish state as that finances the Danish hospitals.
[142] Bekendtgørelse af lov om erstatningsansvar (Consolidated Act No. 1070 of 24 August 2018 on Liability in Damages) (Denmark).
[143] Jakobsen P, Askjær K and Hjortnæs N, Erstatning inden for sundhedsvæsenet, (2nd Edition, Karnov Group, 2017), p. 208 f.
[144] As opposed to the development-risk defence under the PLD as discussed in Section 3.3.6.4.
[145] Madsen H, Comments for LBKG 2024-08-16 no. 962 (CCA) in Karnov Group, note no. 136, including decisions in the Danish Patientforsikringsforening with the number: PFF 2000.39 (anaesthesia machine), PFF 1994.36 (anaesthesia and respiratory equipment), and PFF 1995.51 (medical aids/surgical forceps).
[146] Cf. Decision in the Danish Patientforsikringsforening with the number PFF 1997.51 where a medical plate was inserted but broke for unknown reasons.
[147] Case no. 07-5634 (as cited in the book: Hybel U, Bak Mortensen P and Lindhardt A, Læge & Loven, (1st Edition, Munksgaard, 2015)).

insurance scheme serves as the primary compensation system. Additionally, hospitals may bring recourse claims against manufacturers under CCA § 28 in conjunction with § 27, although such claims are rarely pursued in practice.[148]

In light of this legal framework, a key question emerges: does the national insurance scheme de facto shield manufacturers of medical devices from liability, particularly when these devices incorporate AI?

Taken together, the generous rules on compensation for medical devices in CCA, the limitation of claims under § 26, and the infrequent use of recourse actions suggest that manufacturers are effectively shielded from liability in most cases. This legal position leaves manufacturers with limited incentives to ensure or improve patient safety in device design and development for hospitals in Denmark.

The patient's access to compensation for malfunctions in medical devices are in Denmark, by design, broader than the hospital's scope for recourse, as we will see in detail in Section 3.3 regarding PLD.

The legal asymmetry is exacerbated by the implementation of ML-based AI systems. These algorithms not only evolve over time but are continuously trained on new data during use. As a result, the device effectively becomes more advanced, meaning that the product originally CE-marked and approved for market entry may be substantially different from the version that ultimately causes harm to the patient. As the CCA does not require harm to be foreseeable based on the state of the art at the time of hospital integration[149], patients will find it significantly easier to obtain compensation, while hospitals may find it increasingly harder to pursue recourse against the manufacturer. This leads to a legal imbalance in which the Danish healthcare system continues to bear the risk of claims arising from defects in the manufacturer's product, thus leaving the healthcare system to absorb the financial burden of defective products.

Although this outcome may not differ substantially from the present situation, given the already generous scope of CCA § 20(1)(2), the risk remains that the growing complexity of AI-based systems will further entrench an unequal distribution of liability.

The final two pathways to compensation under the CCA concern situations where neither the specialist nor the device is to blame. The first of these is commonly referred to as the *hindsight rule*,

[148] Jakobsen, Askjær & Hjortnæs. 2. udgave., p. 209.
[149] Which is otherwise required under the CCA, see section 3.3.6.4 on development-risk defence.

found in CCA § 20(1)(3). This provision applies in cases where a patient cannot obtain compensation under the specialist standard in CCA § 20(1)(1), as the specialist would not, at the time, have acted differently. However, with the benefit of hindsight, it becomes evident that another available treatment would have better corresponded to the patient's response, and the specialist would, in retrospect, have chosen that alternative. This allows the patient compensation, even if nothing can be blamed on the physician for their original choice of treatment.

The fourth-and-final pathway is the *catch-all rule* in § 20(1)(4), which allows compensation for rare and serious complications that exceed what a patient should reasonably be expected to endure, even if no fault can be found and no better treatment was available.[150] The severity and rarity of the complication are assessed in light of the condition being treated, though no fixed statistical threshold exists.[151][152]

AI systems will though have little to no relevance for two final rules.

Finally, it should be noted that under Directive 2011/24/EU on cross-border healthcare, the CCA also applies to EU citizens receiving treatment in Denmark.[153] Conversely, Danish citizens treated in other EU/EEA countries may benefit from similar national schemes. This reflects the broader EU principle of free movement of services and ensures a degree of cross-border consistency in patient protection.[154]

3.2.2 Conclusion on National Compensation Structures

Overall, the Danish national compensation scheme plays a significant role in ensuring that patients receive compensation in a wide range of cases involving medical treatment that results in long-term injury. The framework is particularly favourable to the patient, as the criteria for compensation are relatively broad compared to traditional tort law standards. The main challenges for patients typically lie in establishing that the injury exceeds what can ordinarily be expected from the underlying disease (additional harm), and in demonstrating a causal link between the harm and the treatment.

Importantly, however, this structure also gives rise to a systemic challenge in the context of liability for defective AI medical devices. In practice, the scheme tends to shield manufacturers from liability, despite the fact that the CCA formally preserves the hospital's right of recourse against manufacturers

[150] Ibid., p. 286 f.
[151] Madsen H, Comments for LBKG 2024-08-16 no. 962 (CCA) in Karnov Group, note no. 146.
[152] Nonetheless, legal literature has suggested that a complication should occur in 2% or fewer of cases to qualify as rare, cf. Erstatning inden for sygehusvæsenet 246 f. og Pommer B, Patientskadeerstatning: Dækningsområde og ansvarsgrundlag, (1st Edition, DJØF, 2011), p. 112 f.
[153] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 88/45., Article 7.
[154] Reflected in the Consolidated version of the Treaty on the Functioning of the European Union (TEUF) Article 56 on free movement of services, on which the cross-border directive is based.

and allows patients to pursue separate claims under product liability rules. When the injury is caused by a medical device, these legal pathways theoretically remain open. However, the ease and accessibility of the public scheme often render such additional actions redundant, particularly given the high burden of proof, complexity and costs associated with establishing product defect and fault under PLD. As a result, the burden of device-related injuries often rests with the Danish healthcare system itself, rather than with the party responsible for manufacturing the defective product.

This outcome raises a broader concern: the risk that product liability for AI may be displaced by national no-fault schemes, leaving the national healthcare systems to absorb costs that arguably ought to fall on the manufacturer of the AI medical device. As such, this interaction between national structures and the PLD may stipulate a challenge that remains to be solved in order to ensure adequate addressal of liability and holding relevant actors accountable in cases involving AI-enabled medical devices.

3.3 Product liability

While the Danish patient insurance scheme provides an accessible and generous route to compensation for patients harmed by medical treatment or malfunctioning devices in the Danish health care system, it represents only one side of the regulatory landscape. The central legal framework for this thesis is the PLD as it establishes the EU-rules on product liability.

As the use of AI in medical devices continues to grow, the PLD's ability to adequately address harm caused by increasingly autonomous and opaque technologies is brought into question. Recently the PLD has been revised in order to keep the rules to speed with the digital age.[155] The following section will examine how the challenges of AI-driven medical devices have been met with the revision of the PLD, and moreover how this has changed from the former directive. When referring to "**1985-PLD**" the thesis refers to the first product liability directive from 1985.[156] Any other mention of "PLD" refers to the current revised version.[157]

3.3.1 EU Harmonized Rules: The Product Liability Directive

Both the 1985-PLD and the revised PLD represent a regime of total harmonisation across Member States.[158] Under the 1985-PLD total harmonisation was stipulated in Article 13, however as CJEU made clear in the 2000s such harmonisation does not hinder additional liability schemes that do not interfere with the rules under PLD.[159]

In the revised PLD, 1985-PLD's Article 13 has been replaced by PLD Article 3, which also prohibits Member States from introducing stricter or more lenient national rules regarding matters that the PLD regulates, unless it is explicitly allowed. The PLD therefore continues to stipulate full harmonisation, meaning that the rules cannot be derogated unless otherwise provided, or if the rules do not interfere with the rules under PLD. However, CCA and other additional schemes of liability are still allowable, as long as they do not interfere with the rules in PLD.

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[155] European Parliament, 'New Product Liability Directive: In 'A Europe Fit for the Digital Age"', <https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-new-product-liability-directive> Visited on 12 May 2025.

[156] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L 210/29 ("1985-PLD").

[157] May be referred to as the "new PLD", "revised PLD" or the "current PLD" as opposed to the former PLD from 1985 as will be explained below.

[158] Iversen T, Obligationsret 2. del, (2nd Edition, DJØF, 2019), p.327 & C-52/00, Commission v France

[159] This was confirmed by the CJEU in 2000 in cases C-52/00, C-154/00, and C-183/00. In C-52/00, Commission v France, pr. 22 stated: "*The reference in Article 13 of the Directive (...) must be interpreted as meaning that the system of rules put in place by the Directive, which in Article 4 enables the victim to seek compensation where he proves damage, the defect in the product and the causal link between that defect and the damage, does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects*.".

3.3.2 Purpose and Scope

PLD is a legal framework designed to protect users of products within the EU and to ensure the proper functioning of the internal market for goods.[160] As mentioned the recent revision of the PLD aimed to address new technologies such as AI to create a level playing field.[161]

Thus, the revised PLD explicitly includes software in the definition of products, as opposed to the 1985-PLD which only included "all movables" naturally leading to questions of what new technology fell within that definition.[162] It is clear now, that software does, cf. PLD, Article 4(1): "'*product' means all movables, (...) and software*".

Accordingly, there is no longer any doubt that software is covered under the scope of the PLD. This applies even where software is integrated into another device. Therefore, AI software used for medical purposes falls within the directive, regardless of whether it is embedded in physical medical hardware or not.[163]

Now that we have determined that software falls within the scope of the PLD, meaning that AI-driven medical devices are covered by the PLD, we will now move on to the next question of who may be held liable for harm caused by such products.

3.3.2.3 Legal Subjects

Under Article 8 of the new PLD, liability applies not only to the manufacturer of the defective product, but also to the manufacturer of any defective component that was integrated into or inter-connected with the final product under the manufacturer's control. [164] This means that the implementation of software in a medical device will constitute a component for which the manufacturer of that software is liable for.

Moreover, any party that substantially modifies a product and places it on the market is considered a manufacturer for the purpose of the directive.[165] This implies that the modification of an AI-software,

[160] PLD, recital 1.
[161] PLD, recital 3.
[162] Directive 85/374/EEC, Article 2.
[163] Furthermore, recital 13 states: "*Products in the digital age can be tangible or intangible. Software, such as operating systems, firmware, computer programs, applications or AI systems, is increasingly common on the market and plays an increasingly important role for product safety. Software is capable of being placed on the market as a standalone product or can subsequently be integrated into other products as a component, and it is capable of causing damage through its execution. In the interest of legal certainty, it should be clarified in this Directive that software is a product for the purposes of applying no-fault liability, irrespective of the mode of its supply or usage,* (...)"
[164] PLD, Article 8(1)(a-b).
[165] PLD, Article 8(2).

e.g. by training or inserting data, could lead to liability for the modifier. In AI-driven medical devices this is particularly relevant as hospitals may train devices for their intended use and thereby somewhat modify the product to their own benefit. This could lead to liability for the hospital, if their training or insertion of data is significant enough to establish a substantial modification to the original product, as we will return to later.[166]

The scope of which manufacturers are liable under the PLD are evidently very extensive, meaning that almost every commercial supplier of AI software-products will be liable under PLD.

3.3.3 Into the Course of a Commercial Activity

Another criterion for liability under the PLD is that the product must have been put into service in the course of a commercial activity.[167] Indications of commercial activity may include situations where the software is exchanged for payment, or where personal data is processed for purposes beyond merely enhancing security, but can extend to other non-financial activities as well.[168]

3.3.3.1 Are Hospitals a Commercial Setting?

The updated wording in the PLD thus confirms that a product is considered to be placed in the course of a commercial activity regardless of whether it is supplied for payment or free of charge, provided that the supply has an economic or business character.[169] The PLD thereby clarifies that "commercial activity" is not limited to traditional sales, but also encompasses other economically motivated forms of distribution.

Under the 1985-PLD, the question of whether products made on hospitals could fall within the scope of the product liability framework gave rise to legal uncertainty. The uncertainty was settled with the *Veedfald*-case, C-203/99, which found that a perfusion fluid used to flush a kidney before transplantation was a product placed on the market under the 1985-PLD.[170] The revised PLD codifies and establishes the principles of the Veedfald-case.

In 2011, the CJEU addressed a related issue in C-495/10, *CHU de Besançon*, where a child had suffered burns during surgery due to a defective heating mechanism in a mattress he was laid on.[171] Unlike in *Veedfald*, the product had not been produced by the hospital. The question was therefore

[166] See Section 3.3.6.1.
[167] PLD Article 2(1-2) and recital 26.
[168] PLD, recital 14.
[169] PLD, recital 26.
[170] C-203/99, Veedfald, pr. 17.
[171] C-495/10, CHU de Besançon, pr. 11.

whether the hospital could be liable as a manufacturer, and, if not, whether national law could impose liability even in the face of full harmonisation under the 1985-PLD.

The CJEU found that the hospital was merely a service provider, and not a manufacturer, as was the case in *Veedfeld*-case.[172] Since the hospital was not part of the production or distribution chain, it could not be held liable under the 1985 directive.[173] CJEU therefore deemed that the hospital did not bear liability for products they merely make available to customers. They did, however, not reject the imposal of liability on other grounds, as long as these did not hinder the possibility of raising claims under the rules of PLD.[174] Therefore, supplemental rules, such as rules for exercising due care when selecting devices for patient treatment, are allowed.

As the revised PLD still does not address service providers, the judgement in C-495/10, *CHU de Besançon* will apply going forward, meaning that hospitals merely providing, e.g. an AI system for their patients to use, are not be liable under the PLD as a service provider, unless otherwise provided (e.g. they manufactured or modified it).[175]

3.3.4 The Notion of Defect

The concept of defect is central under the PLD, as it forms the basis for a no-fault liability regime for products that can be proven defective at the time of injury. [176] Under both the previous and current product liability directives, the notion of defectiveness is assessed from the perspective of what a person is entitled to expect, traditionally grounded in the reasonable expectations of the consumer.[177] This includes how the product is expected to perform, considering factors such as its function and purpose.

PLD Article 7(1) defines a defective product as one that: "*does not provide the safety that a person is entitled to expect or that is required under Union or national law*.".

The provision is elaborated in Article 7(2), which lists a range of relevant factors (a-i), many of which were already present under the 1985-directive. One such factor is the way the product is presented,

[172] Ibid., pr. 36-38.
[173] Ibid., pr. 27-28.
[174] Ibid., pr. 39.
[175] The PLD do address service providers, but only fulfillment service providers which performs the same functions as an importer but does not correspond to the traditional definition thereof, cf. PLD recital 37 and Article 4(13). This type of service provider is not comparable or relevant, and the fact that it is defined narrowly confirms the assumption that other service providers are still exempt from PLD.
[176]Lett G and Macholm N, Produktansvaret i praksis: Erstatning og forsikring, (Forsikringshøjskoles Forlag, 2002), p. 21 & PLD recital 6.
[177] Ibid., p. 15 & PLD Article 7(1).

which remains central to the assessment of defectiveness.[178] This includes labelling, instructions, warnings, and marketing.[179]

3.3.4.1 Presentation of the Product

A key factor in assessing defect is reasonably foreseeable use, which considers how the product is likely to be (mis)used in practice.[180] This is closely tied to the product's function, e.g. a vaccine must be able to inject fluids.

If a product's very purpose is to prevent damage the defectiveness is assessed by taking into account the product's failure to fulfil its purpose.[181] Thus, a product that fails to perform its essential safety function may, by that fact alone, be presumed defective. This is in alignment with the defectiveness being determined by what safety that can be expected from that specific product.[182] The PLD frames the assessment as an objective evaluation of public expectations, not the individual consumer's expectation.[183]

Furthermore, the determination of defect must take into account the intended purpose.[184] The Danish case FED 2002.1856 illustrates such purposive interpretation of a product's defectiveness.[185] In this case, a man was injured when he dropped a chainsaw onto his thigh while wearing trousers marketed as safety pants. Despite complying with all legal safety requirements and relevant public regulations, the pants failed to prevent the chainsaw from penetrating the fabric and causing personal injury. The court held that the claimant was entitled to expect the product to offer protection in precisely such a situation, as the very purpose of safety pants is to prevent injury in the event of accidents involving dangerous tools. On this basis, the product was deemed defective.

Furthermore, defectiveness can be assessed with regard to the product's user group.[186] This could include taking into account that CDSS may be used by professionals that already have a certain knowledge and expertise in their field. This could arguably heighten the threshold for what may constitute a defective CDSS under the PLD. However, this remains to be settled by courts.

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[178] PLD, Article 2(a).
[179] 1985-PLD, Article 6.
[180] PLD, Article 7(2)(b).
[181] PLD, recital 33.
[182] PLD, Article 7(2)(f).
[183] PLD, recital 30.
[184] Ibid.
[185] Decision published in the Danish Forsikrings- og Erstatningsretlig Domssamling 2002, p. 1856 ("FED 2002.1856").
[186] PLD, recital 30.

3.3.4.2 Inherent Risks in AI-systems

Furthermore, the assessment under the revised PLD of the safety of a software-product also take into account the inherent risks of putting products into service that has the ability to learn or acquire new features:

> "*The effect on a product's safety of any ability to learn or acquire new features after it is placed on the market or put into service should also be taken into account to reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour. Consequently, a manufacturer that designs a product with the ability to develop unexpected behaviour should remain liable for behaviour that causes harm. (...)*."[187]

This may have significant implications for ML-based AI software in general, and particularly in the context of medical devices. The expected level of safety is already heightened due to the personal and potentially irreversible nature of harm in medical treatment. However, the fact that the software continues to learn from patient data after being put into service adds an additional layer of complexity. This dynamic nature of ML must therefore be factored into the assessment of the product's safety at the time of use. Accordingly, manufacturers of ML-driven medical devices are compelled to anticipate and address foreseeable or emerging risks, such as algorithmic bias or the risk that the system, through reinforcement, learns to replicate and amplify erroneous outcomes.

Thus, the notion of defect under the PLD is shaped by a range of factors that collectively determine whether a product fails to meet the expectations the public is entitled to. Importantly, the PLD extends this assessment to account for new technologies, such as AI-based ML systems, that may evolve over time after. By doing so, the PLD broadens the manufacturer's accountability to extend beyond where the product is put into service if it continues to develop beyond this point. This issue will be revisited in the following sections on exemptions from liability.

In addition, the directive codifies that potential defects, such as those identified in products from the same production series, may suffice to establish defectiveness, particularly where heightened safety expectations apply.

3.3.4.3 Compliance with Statutory Requirements

It was commonly assumed under the 1985-PLD, and is reinforced in the new PLD, that failing to comply with statutory requirements, such as the MDR or AI Act, will lead to the presumption of

[187] PLD, recital 32.

defectiveness and/or causation.[188] In the PLD recital 46 states explicitly that: "*In order to reinforce the close relationship between product safety rules and liability rules, non-compliance with such requirements should also result in a presumption of defectiveness* (...)". On the contrary, compliance with statutory requirements does not exempt the manufacturer from liability.[189]

Thus, a lack of compliance with statutory requirements can give rise to a presumption of defectiveness, shifting the burden to the manufacturer to demonstrate that the product was not defective.

In practice, it is unlikely that a medical device would have entered into service without having obtained the CE-marking. A more relevant scenario is one in which the claimant can prove that the product underwent substantial changes after its initial conformity assessment, thereby requiring a new CE-marking procedure under the MDR, Article 75.

In such cases, the defendant would be required to argue that the specific component or feature that was altered, and which triggered the obligation for renewed conformity assessment, was not causally linked to the harm suffered. This issue is particularly relevant in relation to AI-based medical devices with self-learning capabilities, as such systems are inherently dynamic and likely to change substantially over time. To rebut an allegation of non-compliance, the manufacturer would need to disclose the internal workings of the algorithm and demonstrate that the changes had no bearing on the injury. Given the so-called black box nature of many ML systems, combined with the vast and often opaque datasets they rely on, such a defence may prove exceptionally difficult to establish. Moreover, the manufacturer might be more interested in keeping the algorithm secret than sparing the cost claim.

Consequently, a claimant's argument that an AI-based medical device should have undergone a new CE-marking procedure may carry considerable weight in future litigation and could significantly influence the development of case law in this area.

3.3.4.4 Warnings and Instructions

When assessing whether a product is defective, warnings and instructions can play a key role.[190] Such information may contribute to limiting the manufacturer's liability to the extent that specific warnings

[188] As an example in the Danish decision of 11 February 1997 in case B-1072-92, published in the Danish Ugeskrift for Retstidende 1997 on pg. 648 ("UfR 1997.648 Ø") concerning a defect in a medical device, it was crucial whether the device had obtained the required CE-marking.
[189] Lett G and Macholm N, Produktansvaret i praksis: Erstatning og forsikring, (Forsikringshøjskoles Forlag, 2002), p. 27.
[190] PLD, Article 7(2)(a) and recital 31.

have been issued against certain uses. However, the mere supply of a warning do not exempt the manufacturer from liability.[191]

The PLD explicitly refers to "reasonably foreseeable use", which obliges the manufacturer to consider both the intended use and reasonably foreseeable misuse of the product, and to take reasonable steps to prevent associated risks.[192] This assessment may include the characteristics of the target group, e.g. children are less likely to read or comprehend detailed instructions, or as discussed above physicians may need less instructions.[193] In general, it is required that the manufacturer takes all reasonable steps to make the product safe in itself, meaning that a warning is not sufficient if the risk in question could reasonably have been eliminated through design or production choices.[194]

Moreover, a product should not only include adequate warnings at the time of placement on the market, it may also require the issuance of new or updated warnings post-market, if new risks are discovered, cf. the Danish decision U 2000.870 H.[195] Additionally, cultural or linguistic differences may influence the effectiveness of warnings and should be considered in the defect assessment.[196]

Instructions, like warnings, may also impact the defectiveness assessment. If the product has inherently hazardous features, the instructions must provide clear and sufficient guidance to mitigate these risks.[197] Accordingly, inadequate instructions may themselves give rise to liability.

It follows that manufacturers of AI-based software can be expected to provide guidance aimed at reducing the risk of improper use. For instance, where the system incorporates ML, it may be necessary to instruct users on how to avoid performance degradation or harmful bias. This could include information on how to ensure that the data used for training or updating the system does not systematically skew the algorithm's outputs. However, as discussed in Section 3.3.4.2 it remains unclear if manufacturers can ever be exempt from liability for a defect, when it arises from a product that has self-learning capabilities, such as AI-software.

[191] PLD, recital 31.
[192] Ibid.
[193] Ibid.
[194] Lett G and Macholm N, Produktansvaret i praksis: Erstatning og forsikring, (Forsikringshøjskoles Forlag, 2002), p. 18.
[195] Decision of 18 January 2000 in case 144/1998, published in the Danish Ugeskrift for Retstidende 2000 on pg. 870 ("U 2000.870 H") as mentioned in Ulfbeck V, Erstatningsretlige grænseområder, (3th Edition, DJØF, 2021), p. 267 f.
[196] Ibid., p. 20.
[197] Iversen T, Obligationsret 2. del, (2nd Edition, DJØF, 2019), p. 326.

3.3.4.5 Systemic Failures

Similar to warnings and instructions, it is also relevant to consider the notion of systemic failures. These are characterised by the fact that the defect is inherent in the system itself and de facto cannot be avoided.[198] Moreover, the defect must be both commonly known and societally accepted.[199] In essence, it should not come as a surprise to the consumer that the product carries such inherent risks, as these are considered part of the product's nature. The doctrine of systemic failure is not directly codified in the PLD, but it has been recognized and enforced through case law in many EU-countries.[200]

The concept of systemic failure is closely tied with the definition of a defect determined by what the customer can reasonably expect. If the general customer cannot expect a safe product, but has accepted this nonetheless, the product has a systemic failure. This exempts the manufacturer from liability, as the systemic failure does not conflict with consumer expectation. However, no matter the societal knowledge and acceptance, harm stemming from a manufacturing defect can never qualify as a systemic failure.[201]
The exemption is thus related to the definition and classification of the product, and not a specific exemption for an otherwise defect product.

Classic examples of products having systemic failure include cigarettes or alcohol, which by their nature contain harmful elements. Nevertheless, they may be lawfully placed on the market without creating liability for conditions such as lung cancer.

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[198] Ulfbeck V, Erstatningsretlige grænseområder, (3th Edition, DJØF, 2021), p.283
[199] Ibid.
[200] E.g. France has implemented such restrictions to product liability for tobacco in the French Supreme Court's decision of 8 November 2007 (as cited in Hogan Lovells, 'France' in Product Liability 2010: Cross-border Handbook (Practical Law Company, Law Business Research Ltd 2010) <https://www.hoganlovells.com/-/media/hogan-lovells/pdf/publication/pl10chapter23france_pdf.pdf> Visited on 28 May 2026, p. 161.

In German case law finds that failure to supply warnings for alcohol, tobacco and chocolate bars was not a breach of duty to warn under the German GBG, cf. Higher Regional Court (OLG) of Frankfurt am Main, judgment published in NJW-RR 2001, p. 1471 (Neue Juristische Wochenschrift - Rechtsprechungs-Report, 2001, page 1471) and OLG of Hamm, judgment published in NJW 2001, p. 1654 and OLG of Düsseldorf of 20 December 2002, Case No. 14 U 99/02.

Also the Norwegian lawyer Ole Steen-Olsen also talked about "systemic failure" as something that was known and unavoidable, which made it "unlikely (...) that the courts will impose responsibility for productions failure that is commonly accepted and which affects most users of the product, such as is the case with the use of alcohol and cigarettes", cf. Steen-Olsen O, 'Produktansvaret i norsk ret', Norsk forsikringsjuridisk forenings publikasjon nr. 63, Oslo 1977 and NOU 1980: 29, 'Produktansvaret' (as cited in Kjønstad A, 'Tobacco and Tort Liability' published in Stockholm Institute for Scandinavian Law 1957-2009).
[201] Ibid.

To stipulate a systemic failure, and exempt defectiveness, it is a requirement that the defect must be both widely known and socially accepted. In the Danish case U 2003.2288 V a liability claim was raised concerning salmonella-contaminated eggs.[202] Although it was generally known and accepted at the time that salmonella outbreaks in eggs were a common issue, the court found the manufacturer liable. In that case, the eggs had been marketed as "salmonella-controlled", potentially giving consumers the impression that these particular eggs, unlike others, offered safety against salmonella infection.

Importantly, general acceptance must be derived from the public at large, not merely from the individual claimant in the case.[203] Moreover, such acceptance must exist at the time the product is placed on the market.[204]

At present, the use of AI in medical devices is still relatively novel. Despite its rapid development, one cannot yet claim that the associated risks are widely known or accepted by society. Nevertheless, it is foreseeable that AI systems will become increasingly prevalent, particularly in sectors where administrative burdens hinder efficiency, such as in hospitals. Over time, the risks associated with using AI-based systems may become both generally known and socially accepted. This could eventually support an argument that AI software constitutes a systemic failure, the risks of which fall outside the scope of liability, particularly where the self-learning functionality is essential to the product's performance and cannot be retained without the accompanying uncertainty. In such cases, the manufacturer may possibly be exempted from liability.

3.3.5 The Causation Requirement

Besides proving defectiveness, the claimant must also establish the causal link between the defect and the damage suffered, cf. PLD Article 10. How causality is assessed is primarily a national matter, and the PLD merely states that it has to be proven. However, in the new PLD some situations regarding emerging technology give rise to presumption of causality.

As such, the revised PLD addresses particular challenges posed by technical complexity, especially in relation to highly sophisticated technologies such as AI. Generally, the complexity of the systems are so high that claimants often face a significant disadvantage in accessing evidence and understanding how AI products operate.[205] This information asymmetry may be especially detrimental in cases

[202] Decision of 15 July 2003 in case B-2595-01, published in the Danish Ugeskrift for Retstidende 2003 on pg. 2288 ("U 2003.2288 V").
[203] Blomstrand S and others, Produktansvarslagen, (3th Edition, 2012), p. 81.
[204] Ulfbeck V, Erstatningsretlige grænseområder, (3th Edition, DJØF, 2021), p. 286.
[205] PLD, recital 42.

involving complex digital products and algorithms.[206] To account for the imbalance of information between the claimant and the manufacturer, Article 9 allows national courts to order disclosure of relevant evidence that may assist in establishing defectiveness or causation. Moreover, courts may order that such evidence be provided in an accessible and understandable format, subject to appropriate safeguards.[207]

If the manufacturer refuses to comply with a disclosure request it may lead to a presumption in the claimant's favour on defectiveness, but not causality.[208] However, not complying with the court's or the claimant's requests for disclosure of evidence in situations where one part is the only one possessing the evidence, and where evidence is of substantial value, will naturally affect the reliability of the part who rejects.[209]

Moreover, a new rule in PLD Article 10(4)(a) allows courts to presume causality (or defectiveness) on a case-by-case basis if the claimant faces excessive difficulty to prove defectiveness or causation due to the technical complexity of the case. Furthermore, the threshold for proving causal link is relaxed after Article 10(4)(b) as it will suffice to prove that it is likely that the product has caused damage. It is evident from the recitals on what constitutes a technically complex case that these rules may prove particularly important in cases concerning AI products:

> "*the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; (...) or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system*."[210]

While the claimant must present arguments to indicate that such difficulties are present, they are not required to prove them. Thus, the claimant is not expected to explain the technical structure of the AI system, which may even be hidden in a black box.

Naturally, Articles 9 and 10 could have a significant impact on both the burden of proof and the assessment of causality when it comes to AI-driven medical devices, and may prove decisive for the outcome of such cases.

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[206] Ibid.
[207] Ibid.
[208] PLD, Article 10(2)(a).
[209] European Law Institute and Unidroit, ELI - UniDroit Model European Rules of Civil Procedure, (2021, ELI), p. 202.
[210] PLD, recital 48.

3.3.6 Exemptions from Liability: Available Defences

Assuming that there is found a defect and a causal link, the PLD still provides situations where manufacturers can be exempt from liability some of which will be examined in the following section.

3.3.6.1 Modifying the Product

Although the following section does not concern the exemptions listed in Article 11, it still describes a situation in which the manufacturer may be exempt from liability. Namely, the new PLD prescribes that liability may attach to a person performing a substantial modification of the product, instead of the manufacturer.[211]

This raises the question of whether a hospital that trains an AI-based software device to fit a specific clinical context can be held liable for any defects resulting from that training. Another question is whether the mere act of providing local data, thereby influencing what the system learns, could itself give rise to liability.

To answer that we must assess what constitutes a substantial defect. Under the PLD Article 4(18)(b) modifications which change the product's performance, purpose or type, without that change being accounted for in the manufacturer's risk assessment, are substantial. Moreover, a change in the nature of hazard that may increase the level of risk can be considered a substantial modification. Finally, the PLD allows for national interpretations of the term.[212]

For training carried out in a hospital to qualify as a substantial modification, it must fundamentally change the product in a way that the manufacturer could not reasonably have foreseen. The underlying principle seems to be that manufacturers should not be held liable for risks they could not anticipate. However, training an algorithm or using it with institution-specific data is unlikely to fall outside what the manufacturer could foresee, at least to some extent.

Therefore, under the PLD, hospitals that merely use AI-based medical devices are seemingly not held liable for resulting defects. However, they can be liable for training AI-driven medical devices provided that such training alters the product's performance, purpose, or type, or otherwise fundamentally affect the risk profile accounted for by the manufacturer. National interpretations and case law may help shape and nuance this rule in the future.

[211] PLD, Article 8(2) and recital 39.
[212] PLD Article 4(18)(a).

3.3.6.2 Defectiveness After Time of Release

PLD Article 11(1)(c) states that if it is probable that the defect found to have caused damage did not exist at the time the product was put into service, or that the defectiveness came into being after that moment, the manufacturer is not liable.

An example could be: an AI-software with self learning capabilities develops a defect on the basis of the data it has been fed by or the training it has been given by the person who has acquired the product. Presuming that a manufacturer does not get through with the argument that the product-user, possibly the claimant themselves, had modified the product, it would be obvious to claim that the product had changed after deployment in a way that caused the defect.

If the for example a AI-software for determining skin cancer was implemented in a medical device and consecutively was used primarily on white people, causing problems of diagnosing skin cancer on black skin, it would be plausible for the manufacturer to claim that the defect was in fact not present at the time it was put into service, as required in Article 11(1)(c).

The counter-argument to this would be that it is the algorithm itself that allows for such influence that causes inaccurate diagnosis, and that this should have been taken into account by the manufacturer. This aligns with the PLD recital 32, as discussed above,[213] that states that the assessment of defects should: "*reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour.*" meaning that the manufacturer must take into account which possible defects the software could develop over time if fed specific data.

Moreover, the exemptions rely on the assumption that the product is no longer in the manufacturer's control. As we will see briefly in Section 3.3.6.4, this may not be possible to claim for systems with self learning capabilities. However, first, we must discuss the similar development risk defence in Article 11(1)(e).

3.3.6.3 The Development Risks Defence

The state of the art defence or the development risk defence known from the former 1985-PLD too,[214] is now found in Article 11(1)(e) of the PLD. It states that manufacturers are exempt from liability if:

[213] See Section 3.3.4 on Notion of Defect.
[214] 1985-PLD Article 7(e).

"*the objective state 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 within the manufacturer's control was not such that the defectiveness could be discovered*;"

The development risk defence is concerned with the state of the art at the time that the product was put into circulation or was still in the manufacturer's control. These defects exempt the manufacturer, although the defect may have been inherent in the product at the time of putting into service, but the knowledge available at the time hindered the disclosure of the defect.[215]

Distinct from the situation where the defect develops over time under the Article 11(1)(c), the development risk defence is concerned with the development of the knowledge surrounding the product.

Drawing the line on when it was possible for the manufacturer to know about the defect is not easy. According to the PLD recital 52 this is determined on the basis of the most advanced level of objective knowledge accessible, and not the actual knowledge of the economic operator in question. Thus, the crucial elements are that the knowledge was i) accessible at the time, and ii) known by the broader public, and not the operator themselves.

These principles were initially introduced in C-300/95, *EU-Commission v The United Kingdom & Northern Ireland*.[216] Here, CJEU held that the assessment of what was the most advanced scientific and technical knowledge at the time should be objectively verifiable, and in no way influenced by consideration of actual subjective knowledge of the manufacturer or his organization.[217]

The determination of what identifies as the "most advanced scientific and technical knowledge" at a given time is complex.[218] A Danish Supreme Court case offers illustrative insight.[219] The case concerned a woman who, over a number of years, had taken the weight-loss drug Isomeride and was later diagnosed with a heart valve disorder. The drug was examined in a scientific article published after Isomeride had already been placed on the market, and the article concluded that the drug could lead to such heart valve damage. As the article was only made available after the product's release,

[215] As opposed to aforementioned exemption in Article 11(1)(c).
[216] C-300/95, EU-Commission v The United Kingdom & Northern Ireland.
[217] Ibid., pr. 26.
[218] Vibe Ulfbeck argues that the concept will arguably be influenced by what knowledge can be found by using AI with time, cf. Ulfbeck V, Erstatningsretlige grænseområder, (3th Edition, DJØF, 2021), p. 293.
[219] Decision of 20 November 2011 in case 28/2009, published in the Danish Ugeskrift for Retstidende 2012 on pg. 588 ("U 2012.588 H").

the manufacturer could not have identified the defect beforehand on the basis of the most advanced scientific knowledge available at the time.

The reasoning of the court emphasised the importance of not holding manufacturers liable for harm that could not have been detected at the time the product was placed on the market, and that later scientific discoveries concerning the product's effects could not be attributed to the manufacturer.

It must be remembered that although the development risk defence can be stipulated, the manufacturer still holds some responsibility in regard to the requirement for warnings post putting the device into a commercial course.[220]

The assessment of the development risk defence, however, is also dependent on whether the product was still in the manufacturer's control at the time of defect.

3.3.6.4 Within the Manufacturer's Control

The concept of "control" plays a key role in determining whether a manufacturer can be held liable for damage. It determines at what point the manufacturer can no longer be held liable for defects occurring or new knowledge found under the exemptions in PLD Article 11.

Traditionally, and usually, the moment a product is put on the market or sold to a user, the product leaves the manufacturer's control.[221] However, newer technology allows for the manufacturer to still exercise control over the product through updates, upgrades or via ML algorithms. Accordingly, the PLD decides that the manufacturer has control when it: "*retains the ability to supply software updates or upgrades itself or via a third party*.".[222]

If the manufacturer still holds the ability to supply updates or upgrades, either directly or through a third party, the manufacturer is still in control, and can therefore be held liable. The purpose of this is to ensure that liability cannot be avoided simply by outsourcing or by delaying functionality critical to product safety.

Furthermore, recital 50 states that:

[220] The aforementioned U 2000.870 H (Section 3.3.4.4) on Warnings and Instructions.
[221] PLD, recital 50.
[222] PLD, recital 19.

> "*manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of updates or upgrades or machine-learning algorithms*.".[223]

The recital refers to the exercise of control through ML algorithms, which implies that manufacturers remain in control as long as the ML algorithm is operational. This interpretation could suggest that a manufacturer never fully relinquishes control when the AI system incorporates ML. This is particularly interesting given that such algorithms typically adapt based on user-generated data, rather than data supplied by the manufacturer. As a result, the manufacturer may be held liable not only for the functioning of the software, but also for the quality and effects of data provided by the user, and more importantly, what the AI system may subsequently learn from that data.

Thus, software with self learning capabilities may never formally leave the manufacturer's control, de facto keeping the manufacturer liable, even if information on technology changes after putting the software into service. This may completely rule out the relevance of the exemptions in Article 11 mentioned here in the context of AI, as there is never such moment for determining the state of the art or defectiveness pre- and post-marketing, as the product never leaves the manufacturer's control.

3.3.6.5 Possibilities for Derogation

An addition to the revised PLD is found in Article 18 that allows for derogation of the development risk defence. Ironically for AI manufacturers, while it appears unlikely that they can ever benefit from the exemptions due to their continuous control over the product, the EU Commission simultaneously acknowledges that some Member States may find the development risk defence to unduly limit the protection of natural persons.[224] On that background, PLD Article 18 allows Member States to entirely opt out of Article 11(1)(e) regarding the development risk defence. In addition, the PLD permits the introduction of alternative liability measures, such as extending liability for specific product categories or in particular circumstances.[225] These measures must meet three conditions: (i) they must be limited to specific categories of products, (ii) they must be justified by public interest objectives, and (iii) they must be proportionate.[226]

It is conceivable that some Member States will make use of this option to address the legal uncertainty and access to compensation in cases involving defects in AI-driven medical devices. In such instances, the objective of introducing stricter liability rules would be to promote public health.

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[223] Ibid.
[224] PLD, recital 59.
[225] PLD, Article 18(2-3) and recital 59.
[226] PLD, Article 18(3).

3.3.7 Conclusion on the PLD

The revised PLD thus established a full harmonisation regime, from which Member States can only diverge with supplemental rules that do not conflict or hinder the effective applicability of the PLD. To accommodate new technology AI software is clearly covered under the framework's scope, notably by explicitly defining software as a product and explicitly addressing AI and ML in its wording throughout.

Moreover, the broad scope of legal subject has been codified entirely by rephrasing the PLD to include any products supplied within a commercial course. Although regular market exchanges involving money for products are naturally still covered, other irregular means of supply are too covered. This clarifies that hospitals manufacturing products is too covered by the PLD, as was already established by case law under the 1985-PLD, but is now even more clear from PLD's emphasis on the commerciality of the actor and not the money or form of distribution.

When assessing defectiveness, the revised PLD also addresses the new product: AI-software. The already existing rules, known from 1985-PLD, which rely on user expectations, allows for flexible assessments taking into account: presentation, function, safety, statutory requirements, warnings and instructions. However, with regard to ML systems, as most AI systems today constitute, the notion of defect seems hard to escape if the system causes harm. Not only do self-learning capabilities seem to have an inherent risk that the manufacturer must account for, the defectiveness can even be assumed in cases where the burden of proof is highly complex, cf. PLD Article 9 and 10.

Although the notion of defect seems relaxed for AI systems currently, this may change. Over time, the risks of AI systems may become widely known and socially accepted, potentially classifying them as systemic failures beyond liability, especially when self-learning is essential to performance and inseparable from uncertainty. In such cases, manufacturers could be exempt from liability.

In relation to proving causation, this is generally a national matter. However, the revised PLD allows for presumed or relaxed burden of proof for causality, when the AI system is highly complex, and the claimant thus cannot be expected to provide an in-depth account of its connection to the harm.

With regard to exemptions for liability, the significant subject is the concept of control. Whether manufacturers can ever relinquish control of AI systems remains unclear and can be crucial to whether manufacturers can recall exemptions in PLD Article 11. Furthermore, new rules allow for Member States to entirely derogate from one of the core exemptions in specifically given circumstances.

Finally, the revised PLD provides that a person who substantially modifies a product will be held liable if the modification causes harm. Substantial modifications include changes to a product's performance, purpose, or type not covered by the manufacturer's risk assessment, or those that increase risk. If hospitals train or use AI systems in ways that alter these aspects, it could trigger liability.

The following chapter assesses how these rules apply to AI medical devices and identifies the related challenges and legal uncertainties.

Chapter IV

4. Remaining Challenges

As we have seen in Chapter III the PLD-revision seeks to codify existing case law as well as address new challenges posed by AI-software, e.g. by easing the burden of prove for complex technology[227], ensuring that ML-systems are designed to prevent hazardous behaviour[228], as well as enforcing that continuous control over AI-softwares equals continuous liability over the algorithm.[229] Finally, Member States are permitted to derogate entirely from the development risk defence under certain limited and specifically defined conditions.[230]

Although the revised PLD seemingly focuses on addressing new technology, challenges posed by AI in medical devices still remain. The following section will identify and discuss these challenges.

4.1 Liability for Selection of Devices

In the revised PLD, liability is not imposed on hospitals or other service providers who merely supply or use a medical device, as affirmed in C-495/10, *CHU de Besançon*. However, the rise of AI-integrated systems such as CDSS raises concerns that need adequate adjustment. These systems do not simply serve as passive tools but actively shape clinical decisions, sometimes with significant influence over patient outcomes. In such cases, it becomes increasingly difficult to justify a complete exemption of hospitals from liability when choosing these systems.

Therefore, when dealing with AI, it seems only logical that both manufacturers and those who select, monitor, and rely on such systems are held to a standard that ensures safety and accountability. Hospitals and physicians play a crucial role in implementing these technologies, and their responsibilities should reflect that.[231]

As noted in the EU Report on Emerging Digital Technologies, a general monitoring obligation has already emerged in national tort law for service providers.[232] Given the evolving nature of AI and its adaptability to external conditions, it is arguable that a similar vigilance should apply to those operating these systems, especially in sectors where public safety is at stake. Hospitals are uniquely

[227] See Section 3.3.5.
[228] See Section 3.3.4.2.
[229] See Section 3.3.6.4.
[230] See Section 3.3.6.5.
[231] This has also been discussed in the EU Report on emerging technologies, p. 52.
[232] EU Report on emerging technologies, p. 45.

positioned to assess clinical relevance, evaluate risk in context, and oversee proper use, yet current EU liability regimes largely ignore this role.

Moreover, patients have no control over the medical devices used in their treatment and cannot reasonably be expected to evaluate or question a physician's choices of equipment. The patient-doctor relationship is built on a foundation of trust that, arguably, should be reflected in the allocation of liability, not just nationally.

In short, the traditional division between manufacturer and user needs adjusting in the context of AI-driven devices. Whether through the PLD or another legal instrument, there is a strong case for ensuring that those who rely on such systems in clinical care also bear part responsibility for choosing and implementing these tools

4.2 Defective AI in Medical Devices

One of the key issues of AI-software in medical devices is determining their defects. The following section will discuss whether and how the notion of defect in PLD will be applicable on AI-software in medical devices. The discussion will include exemplification, as there is currently no case law in EU on AI products. One recent judgement on AI from the U.S. will though be briefly examined.

4.2.1 Exemplification: Bias in CDSS as a Defect

The section will take its starting point considering a CDSS-product as they are the more common use of AI in healthcare.[233] Furthermore, whether bias constitutes a defect is assessed, as it is one of the larger issues of AI.[234] The choice of bias as the defect serves merely to give the discussion a more specific and relevant subject, while it also allows for the author to discuss defects more generally.

[233] CDSS can take many forms, and the primary focus of AI use in healthcare currently leans more towards CDSS-type applications rather than, for example, surgical robots. Deploying CDSS will transform both administrative burdens, diagnosing and personalised treatments, and the adoption of CDSS has increased especially since COVID-19, cf. Grand View Research, (excerpt from) 'GVR Report cover Clinical Decision Support Systems Market Size, Share & Trends Analysis Report By Product (Standalone CDSS, Integrated EHR with CDSS), By Application (Drug-Drug Interactions), By Delivery Mode, By Component, By Region, And Segment Forecasts, 2025 - 2030' <https://www.grandviewresearch.com/industry-analysis/clinical-decision-support-system-market> Visited on 12 May 2025.

[234] Studies have found that most current data sets for ML are biased in various ways, cf. Tschandl P, 'Risk of Bias and Error From Data Sets Used for Dermatologic Artificial Intelligence', [2021] JAMA Dermatol. 2021;157(11):1271-1273.

4.1.1.1 User Expectations & Presentation of the Product

The notion of defect is determined by what the user may reasonably expect from a product.[235] Whether bias in CDSS is defective will therefore be based on the average consumer expectations of such systems. Because CDSSs are a whole new technology, we have not yet established a general threshold for what can be expected. We must therefore look at the sub-categories for determining defects in order to discuss when a CDSS has a defect. Particularly relevant are: i) presentation, ii) foreseeable use, iii) warnings, iv) statutory requirements, and v) systemic failure.

First of all, it must be noted that specific CDSSs may have a more specific presentation that could alter the results of this discussion. However, the main principle of a CDSS is to assist and support the physician in their decision making. The product is therefore not intended to independently rule what happens to the patient or give one single and correct answer every time. The system is merely a tool to analyze large sets of data, in order to help the physician take everything into account, and maybe present the physician with options they had not themselves thought about. A central question is therefore, whether the system ever promises to be correct and/or unbiased?

As the name suggests a CDSS is only a supporting factor for the physician's decision making. Harmful or misleading recommendations clearly compromise safety, but the degree to which a CDSS must be accurate or exhaustive is difficult to define. How many wrong outcomes can constitute a defect; will one wrong suggestion suffice? Should the system be expected to suggest any and all diseases, even those who are in theory not relevant, because the patient does not fit the usual profile? Can the device be expected to perform flawlessly?

While CDSSs promises support in decision-making, it cannot promise a bulletproof diagnostic tool. No device can yet entirely promise that. Even CT-scans or X-rays may not catch everything on the image, but that does not mean they are defective. However, while systems capturing images and measurements provide quantifiable data, the CDSS is measured on quality. Systems providing suggestions will not suffice on the basis of how many suggestions, but rather how these suggestions qualify. Although it would be possible to measure how many outcomes were correct, a general threshold for how accurate a CDSS is expected to be is hardly the appropriate approach, because no manufacturer can promise eternal correctness when putting their product on the market.

Hospitals and other users may accept a degree of inaccuracy, just as they do for other machines used in hospitals. Generally, measuring quality requires a very specific analysis of the product in question,

[235] PLD Article 7.

which amplifies the need for more specific clarity on liability for CDSS tied to the different types of AI-systems and the environment in which they are deployed.

However, if a CDSS generally provides for biased outcomes or proposes erroneous or even dangerous outcomes, it could be argued that it compromises the safety that CDSS promises. As the system is supposed to contribute to higher accuracy, a system that is generally flawed because it is biased may pass the notion of defect. As the AI systematically underperforms for certain groups, it fails to meet the general safety expectations of a clinical decision tool. This broad unreliability undermines trust and predictability, two core elements of product safety.

For this reason, presenting a diagnostic tool that generally underperforms for a whole patient group should imply defect, meaning that it would on the basis of user expectations of safety be fair to say that bias in AI constitutes defectiveness under PLD.

4.1.1.2 Foreseeable use

With regards to the foreseeable use of the product the revision of the PLD makes it very clear that manufacturers are expected to design AI products in ways that minimise foreseeable risks, including those arising from ML.[236]

It can be argued that all manufacturers know that their product will be used for both a primary and a secondary patient group depending on where it is deployed. For example, if an AI system is implemented in a hospital serving e.g. a Western society, the manufacturer should anticipate the presence of relevant minority groups and ensure that the system is adequately trained on representative data from these populations. Alternatively, CDSS could be programmed to learn about and detect bias in order to mitigate these.[237] Alternatively, the manufacturer could be expected to configure the system in such a way that it periodically requests or incorporates data on underrepresented groups to maintain balanced performance.

Ultimately, it may be argued that a manufacturer cannot claim that the development of bias over time was unforeseeable. ML systems are inherently shaped by the data they are exposed to, which will often reflect the majority population, regardless of deployment context. Therefore, failing to anticipate and mitigate such bias may constitute a failure to address foreseeable risks under the PLD.

[236] PLD, recital 48.
[237] This has been proposed in a recent study, where such a model should work by detecting algorithmic bias in medical AI models for CDS. See: Smith J and others, 'Detecting algorithmic bias in medical-AI models', [2024].

The proposed ways in which this thesis proposes that the manufacturer mitigate the foreseeable use of AI products do not account for what is realistically technically feasible. This represents one of the challenges, courts may struggle to evaluate. Nevertheless, the expectation is that developers take *all* reasonable steps to reduce known risks before putting into the commercial course.

4.1.1.3 Warnings and Instructions

Furthermore, questions regarding warnings and instructions arise in relation to AI-systems, such as CDSS, because to what extent can manufacturers guard themselves by instructing users in mitigating bias? While warnings can affect, but not exclude, liability, there might be a chance that manufacturers can influence and mitigate defects of bias by providing warnings of possibility of bias, and furthermore providing instructions on how to mitigate these.
This may be as simple as providing that the user identifies the primary minority groups, and make sure that the CDSS are trained on datasets concerning the identified minority groups. This could be a reasonable alternative, if design-solutions mitigating bias is technically unfeasible.

Recently, and relevant to the topic of warnings, US Courts have rendered their very first ruling on liability for false outcomes of OpenAI.[238] The court assessed whether ChatGPT's completely fictitious outcomes, which in the case stated fraud allegations against the plaintiff, could lead to liability for the ChatGPT.[239] The ruling was in favour of ChatGPT, as it was emphasized that ChatGPT explicitly warns users about potential inaccuracies. Moreover, the Court found that reasonable readers would not interpret ChatGPT's outputs as factual statements. The result was therefore based on both the warnings given, in combination with the general assumption that the users do not actually rely entirely on the chatbot.

Despite the fact that the case is based on an entirely different set of rules and a justice system quite far from most European jurisdictions, it implies that warnings may have quite extensive implications for AI-software. If the EU adopts a similar approach, warnings will be important for manufacturers. Although it will probably never serve as an exemption clause, it could protect the manufacturer to some extent.

Furthermore, it shows that the general acceptance and acknowledgement of a chatbot as something more or less faulty can exempt manufacturers from liability. This systemic failure-approach will be examined momentarily.[240]

[238] The Superior Court of Gwinnett County, State of Georgia, of 19 May 2025, Civil Action NO. 23-A-04860-2, Walters v OpenAI.
[239] These fictitious outcomes are also called "hallucinations".
[240] See Section 4.1.1.5.

4.1.1.4 Statutory requirements

Moreover, we have already seen that there are vast statutory requirements for AI and medical devices. This affects the assessment of defectiveness, as the lack of compliance can presume a defect, if the defect is related to the lack of compliance. In the MDR taking on measures to mitigate bias is required.[241] Therefore, if the device has a biased performance, and the manufacturer does not seek to mitigate this, it is noncompliant with statutory requirements. Furthermore, the AI Act decides that high-risk systems, such as medical devices incorporating AI, should detect, prevent and correct biased behaviour in the AI system.[242] Failing to do so will therefore also be a breach of statutory requirements in the AI Act.

Lack of statutory requirements can result in presumed defectiveness, if the lack of compliance is related to the harm in question, and if the manufacturer cannot prove otherwise. Thus, if the CDSS is found to be biased this makes the system principally defective.

4.1.1.5 Systemic Failures

That said, there is still the principle of systemic failures which may prove significant for AI-software over time. The systemic failures require that fault, such as bias, in the CDSS are generally known and publicly accepted. At present time, the risks posed by AI-systems are neither fully understood nor socially accepted. However, as AI becomes more widespread, courts may begin to accept a degree of imprecision or bias as inevitable. If that happens, systemic defect arguments could become more common in AI liability cases.

In time, ML AI-software may be expected and even allowed to provide some faulty outcomes in its capacity as a *support* system. This somehow indicates that it does not autonomously provide the full picture, but merely contributes to it.

As demonstrated in the first real case on faulty AI outcomes: U.S. Case of 19 May 2025, the fact that a "reasonable reader" would not interpret the AI's outputs as factual statements may exempt the manufacturer from liability. This supports the notion that a defect requires the user to be entitled to expect correct outcomes. Conversely, if the reasonable user cannot expect faultless results, establishing a defect becomes nearly impossible.

Moreover, an important consideration is that the medical field is inherently biased in the sense that the physician's best judgement is nevertheless always based on what is generally the diagnosis for these

[241] MDR, Annex XV, 3.6.4. decides that a clinical investigation plan must contain details on measures taken to minimise bias.
[242] AI Act, Article 10(5).

symptoms in these types of patients. This includes taking into account existing conditions, age and gender. Would it even promote more accurate diagnoses, if the system operated fully unbiased? The biased approach may very well be the reason the physician or the device comes to an accurate diagnosis, which could excuse biased systems and make their existence socially accepted.

Thus, in time, systemic failure could be a substantial argument for exemptions for liability in medical devices hindering stipulating defects for AI-devices in medical contexts under the PLD.

4.1.1.6 Conclusion on Defects

The discussion of different factors to take into account when assessing defects leaves us with a rather patchy regulation. Generally, CDSS cannot be expected to perform flawlessly, much like any other assisting device. However, a more generally biased device may be considered defective. This could be based on its lack of safety, failure to comply with statutory requirements, or its inability to prevent foreseeable misuse by design.

However, if EU courts take inspiration from recent U.S. case law, regarding OpenAI, warnings may also play a crucial role in exempting the manufacturer from liability. Nonetheless, it is clear from the PLD that an otherwise defective product cannot be exempt from liability merely because of a warning.[243] Furthermore, there may reasonably be a higher threshold for what physicians can expect from a CDSS, which is not comparable to what can be expected by the public at large using large language models, such as ChatGPT.

More importantly, the rule of systematic failure may change the assessment of AI systems over time, making it more acceptable that these do not perform flawlessly. If so, this could change the user expectation, which is fundamental to establishing a defect.

This analysis therefore finds that it is currently possible to establish defects for AI systems. Although, there are still arguments that could shield the manufacturer under the current PLD framework as should be with every product to ensure a nuanced assessment. However, in time the expectations for AI-systems may lower, essentially making it hard to establish defects for AI-systems.

[243] PLD, recital 31.

4.3 Causation

4.3.1 Is the Chain Broken?

While AI does claim to have a neural network of its own, it is not yet widely deployed in healthcare in a fully autonomous form. Surgical robots can do many things autonomously, but no AI yet is used without any human intervention in healthcare.[244] The physician will usually be the final examinant of the output of e.g. a CDSS. Therefore, the CDSS will currently never on its own make a decision of diagnosis or treatment. This breaks the chain of causality, as the physician's decision does become the final cause for possible fault.[245] The result is that it is generally close to impossible to establish a causal link between harm caused on a patient, and the device's suggestions.

However, the PLD states in Article 13, that: "(...) *liability of an economic operator is not reduced or disallowed where the damage is caused both by the defectiveness of a product and by an act or omission of a third party*.". Therefore situations of cumulative causation do not exempt manufacturer's from liability. An AI-software provider will not be exempt merely because they can claim that the physician had the final say, if their product was the reason for the physician's decision.

Authors have argued that it should not be excluded that a causal link can, in principle, be established between a defective CDSS and the harm caused by a clinical decision made in reliance on its output.[246] Van Staalduinen references the Spanish *Überlingen* case concerning a traffic alert system that supported the pilots with suggested routes in order to provide collisions.[247] Even though the pilots made the final decision of route, the system was held to have contributed to the outcome, and liability was assigned to the manufacturer.[248] On this basis, Van Staalduinen argues that decision support systems can also constitute an additional causal factor and should not be automatically excluded from liability under the product liability framework.[249]

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[244] SS&C Blue Prism, 'The Next Milestone: Agentic AI', <https://www.blueprism.com/guides/ai/agentic-ai/> Visited on 26 May 2025.
[245] Also known as: "novus actus interveniens" in latin.
[246] van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024), p. 28.
[247] Ibid., and Spanish Supreme Court judgment of 13 January 2015, Überlingen, STS (Sentencia del Tribunal Supremo) Case nr. 181 of 2015, ("Überlingen*).
[248] Überlingen, 46.
[249] van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024), p. 30.

He explicitly rejects the argument that the physician's final decision necessarily breaks the causal chain, because the clinicians are not strictly liable for the tools they use, and moreover they are expected to be influenced by diagnostic output.[250] Therefore, he maintains that causation can still be attributed to the CDSS, even if human agency intervenes.

However, the *Überlingen*-case concerned an alarm system that the pilots were almost entirely dependent on to provide collisions. The pilots would simply not have chosen the suggested route without the system. Conversely, CDSSs play a more suggestive role. Physicians typically do not treat CDSS output as their primary decision-making source, which weakens the causal link. Instead physicians will use suggestions in their considerations, and not choose their method of treatment on the sole basis of it, as with the suggested routes.

It could, though, be speculated whether physicians over time might be trained more in applying CDSSs rather than assessing the information obtained themselves. Mathematicians have similarly gone from using time on calculations, to relying on machines to do that. If physicians go through such transition, it may in years from now, develop to be a very important decisive factor for the physician, if education and practical knowledge teaches you to use systems more actively, rather than supportively. This could change how easily CDSSs can be causally linked to harm caused by decisions taken upon its suggestions. As technology advances this is not unrealistic.

Furthermore, CDSS are found to often outperform physicians.[251] This could incentivise that the physicians rely more on the device than on their own suggestions. This justifies putting more weight on the CDSS' role in the decision-making, and how it thus contributed to the harm caused by that decision. Whether this would suffice in court remains yet to be seen.

However, Van Staalduinen too acknowledges that the rule in Article 13 will not suffice to establish causal link for CDSS as of now, because of the sine qua non-test.[252] The test serves to try whether the harm would have still occurred if the CDSS was never involved. In cases where the ultimate medical decision lies with the physician, van Staalduinen argues that CDSS does not directly contribute to the damage, as the harm results primarily from the physician's action.[253] As we have just discussed, this

[250] Ibid., p. 28.
[251] E.g. in Hswen Y and Rubin R, 'An AI Chatbot Outperformed Physicians and Physicians Plus AI in a Trial - What Does That Mean?', [2024] JAMA 2025;33(4): 273-276.
[252]van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024).
[253] van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024).

could change as we advance more technically, or on the basis of the argument that CDSS can outperform physicians de facto making the CDSS more reliable than the physician themselves, causing them to be the determining factor for clinical decisions.[254]

In conclusion, although it may be argued that a broader interpretation of the sine qua non-test could eventually emerge to accommodate situations where AI systems contribute over time to an erroneous clinical decision, such an approach remains speculative at present. It is doubtful whether the mere influence on a decision is sufficient to establish cumulative causation. Accepting such reasoning could further imply that any material forming the basis of a physician's diagnosis or treatment might give rise to liability if flawed. However, for an act or omission to satisfy the legal threshold for causation, a more concrete and direct link to the harm is typically required.

4.3.2 Multiple Factors Contributing

Another challenge of proving causal link has been recognised in an EU report on AI and emerging technology.[255] The report discusses identification of the relevant causal link between the AI-product and its erroneous outcome *within* the product. Thus, it differs from the causation assessment discussed in Section 4.3.1 as it does not involve an intermediate link.

The report finds that the proof of causation is more complex with AI-technologies as the outcome may result from an interplay of factors such as: flawed input, user error, poor system design, or a faulty update. Furthermore, these can stem from different manufacturers; one providing the core algorithm, one providing an upgrade, and another the hardware or computer it is integrated to. The broad range of factors that could cause defects make it increasingly harder to isolate and identify one decisive cause for the AI to provide a faulty outcome.[256] The black box issue does not help this either. Thus, the report argues that rules should be customized to fit more multifactorial products like AI.[257]

It must be remembered that the revised PLD introduces an important evidentiary mechanism, which aims to address the difficulties claimants may face when attempting to prove defectiveness or causation in cases involving technically complex products such as AI-based medical devices.[258]

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[254] Other authors believe that it is already possible to establish causality. In Rimkuté D, 'AI and Liability in Medicine: The Case of Assistive-Diagnostic AI' [2024] Baltic Journal of Law & Politics Vol. 16, Issue 2., Rimkuté argues that the faulty CDSS will play a role in the physician's decision-making, which makes it pass the sine qua non-test (p. 77). Furthermore, he disagrees that the chain is broken, as he argues that the producer's possible fault in assuring e.g. sufficient data diversity, might be the direct link between the wrong diagnosis and the harm caused to the patient (p. 78).
[255] EU Report on emerging technologies.
[256] Ibid., p. 21.
[257] Ibid., p. 22.
[258] See Section 3.3.5.

Article 10 of the PLD thus allows for a presumed causal link where the manufacturer fails to present technical information in a comprehensible format on the request of a claimant.

While this presumption of causal link may alleviate some of the technical burdens associated with lifting the burden of proof, it does not fully address the more fundamental issue in AI-related cases: whether the chain of causation is legally broken by the physician's role as decision-maker. Whatever outcome the AI decides is only one step to finding causal connection, how the outcome affects the real world is the next. The new rule primarily assists in situations regarding multiple factors for the erroneous outcome, and not the outcomes impact on the harm occurred. Therefore, the discussion in the EU report is more relevant to more autonomous systems, such as self-driving cars, which can on its own cause harm. However, in the future, as AI becomes more autonomous, similar situations may occur, and the distribution of liability must be adequately allocated.

4.3.3 Conclusion on Causality

Thus, PLD does not yet resolve the conceptual dilemma of whether an AI system that merely supports, rather than determines, clinical decisions can be causally linked to caused harm. Therefore, even in cases where a defect is presumed, the question of liability may ultimately hinge on how the physician's actions are evaluated within the causal chain, which is a national matter. This allows for diverging approaches that can cause legal fragmentation.

4.4 Control of the product

The extent to which the manufacturer retains control over the AI-driven medical device is a key factor in determining whether liability can be attributed to them. If the device is still in the manufacturer's control, they will continuously be liable for any defect arising even after it is put in the commercial course.

In the revised PLD recital 50 suggests that ML-algorithms may never formally leave the manufacturer's control, thereby de facto making the manufacturer liable for quality and effects of data provided by the hospital and more importantly what this data may teach the AI-system. This aligns with the assessment of software products in regards to determining defectiveness, as the PLD states that the safety of a software product with the ability to learn and acquire new features shall be designed taking into account unexpected behaviour that could lead to harm.[259]

[259] PLD, recital 32.

As a result it may prove impossible to exempt liability on the basis that the AI-software is out of their control. This will be further examined in the following section, where firstly software-updates will be discussed, and then the hospital's modification or training of an AI-device.

4.4.1 Supply of updates

Whether a product remains under the manufacturer's control is defined in Article 4(5) of the revised PLD which states that a manufacturer who retains the ability to supply software updates or other modifications remains in control of the product. It is not decisive whether the manufacturer actually provides such updates, but rather whether they have the technical capability to do so, either directly or through a third party.

As a result it may become crucial whether or not it is technically feasible to provide updates in AI-systems. While it would be in each party's interest that the provider of such software can install updates to improve their system and maybe even mitigate defects, such as bias etc., it would be unfavorable for a manufacturer to retain that access, because of the implications in infers.

In practice, the manufacturer may be expected to continuously re-evaluate their software products, even after these have been deployed. In addition, they may be required to assess how each of the products have developed individually as a result of the ML processes applied within the clinical settings where they are used.

This places a considerable burden on manufacturers in terms of liability and ongoing quality control. Such a burden may exceed what is reasonable to expect. If legal frameworks want to support innovation, the liability consequences must be proportionate and must not function as a constraint on technological progress, on top of the already extensive compliance required under AI Act and MDR.

Conversely, the complexity of AI-software may justify placing the responsibility for maintaining and ensuring the quality of such systems on the manufacturer rather than the user. It is arguably neither realistic nor appropriate to expect end users, such as physicians, to oversee the technical integrity of continuously evolving AI tools. Finding a fair balance between innovation and accountability is a difficult task, as will be explored further in the proposals presented in Chapter 5.

4.4.2 Modifying the AI-system

Another important consideration is whether the hospitals that use, train, or otherwise integrate AI software can be held liable under the rules governing modification. As previously concluded, mere

use or training of an AI system does not, in itself, relieve the manufacturer of liability, as such activities do not constitute unforeseeable risks.[260]

On one hand, this rule reflects a sound principle: end-users should be able to rely on a product without assuming liability for risks inherent in its self-learning features. It is reasonable to place that responsibility on the manufacturer, provided that the risk was foreseeable and could be addressed in the design. Likewise, where a third party makes a substantial modification that the manufacturer could not have foreseen or controlled, it makes sense for liability to shift to the person making that change.

However, the current legal framework appears to rest on a binary allocation of responsibility: either the manufacturer or the modifier is liable. This all-or-nothing approach may be too rigid, especially in cases where professional users such as hospitals benefit significantly from tailoring the AI system to their clinical context. These users operate in a space between passive use and active modification, and the law does not yet adequately account for this grey zone. Moreover, PLD Article 4(18)(a) allows for national interpretations of what constitutes "substantial modifications", which risks leading to fragmentation and inconsistent application.

The concept of modification in relation to AI systems is not necessarily a flaw in the PLD, but it does present a challenge in how such modifications should be assessed. While it is relatively straightforward to determine whether a tangible product has been altered, it is far more difficult to evaluate whether an AI system has been substantially modified, especially when the "modification" may consist of nothing more than continued learning on new data.

Even where substantial modification has formally occurred, there may still be grounds for considering shared responsibility. For instance, if a hospital trains an AI system in a way that alters its effective performance or scope of application, it could arguably be fair to allocate liability between the manufacturer and the user. In such cases, a more nuanced allocation of liability would be preferable to the current binary model.

In Chapter 5 alternative approaches to schemes of shared responsibility will be proposed.

4.5 Exemptions from Liability

Although establishing defect and causation in AI software is already complex, further barriers to liability arise through the exemptions listed in Article 11 of the PLD. These exemptions are intended

[260] See section 3.3.6.1.

to protect manufacturers from liability in cases where the defect occurred after the product left their control or where the defect was unforeseeable at the time of placing the product on the market.

4.5.1 Loss of Control Exemption

Manufacturers are not liable for defects that arise after the product has left their control.[261] In the case of self-learning AI systems, this could seem like a viable defence, as such products adapt to new data from the moment they are deployed. However, for this exemption to apply, manufacturers must demonstrate that they no longer had any technical or legal control over the system post-deployment, for instance, by being unable to update or intervene. As previously discussed, the revised PLD makes it difficult, if not impossible, for manufacturers of ML-based systems to ever fully relinquish such control.[262] As a result, this exemption is unlikely to succeed in most AI-related cases.

4.5.2 Development Risk Defence

This defence applies where the defect could not have been discovered based on the state of scientific and technical knowledge at the time of market placement.[263] The defence has been found to become practically relevant for more sophisticated AI-products.[264] Although it is theoretically available, the threshold is high, particularly for advanced AI systems. Van Staalduinen suggests that the threshold may be that the manufacturer should: "*be able to argue in detail why the defence should apply, in other words: why the defect was indiscoverable, given the [explainable AI] methods available at the time*" if a high bar is set.[265]

But once again, the defence presupposes that the system has left the manufacturer's control, a condition that is impossible to meet in the context of ML AI. Moreover, under Article 18, Member States may choose to exclude this defence altogether, meaning that even if it were theoretically applicable, national choices may restrict its relevance in AI-related cases.

Overall, the defence is not a viable route to escaping liability for manufacturers of AI-based medical devices either.

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[261] PLD Article 11(1)(c).
[262] See Section 3.3.6.4.
[263] PLD Article 11(1)(e).
[264] EU Report on emerging technologies, p. 28 f.
[265] van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024), p. 27.

4.5.3 Conclusion on Exemptions

As demonstrated, the exemption's practical relevance in the context of AI-based medical devices is limited if not excluded. The PLD's concept of control leaves no realistic pathway for manufacturers of self-learning systems to escape liability. This all-or-nothing approach that was also discussed with regard to allocation responsibility between modifier and manufacturer is ill-suited to the dynamic of AI. As such, the rigidity of the current liability structure remains a challenge under the revised PLD as balance needs to be struck to promote innovation *and* ensure victims of harm.

4.6 Conclusion on Remaining Challenges

In conclusion, the notion of defect still remains to be determined by EU courts. Speculations can be given to what may or may not constitute a defect, and if EU courts follow the line laid down with recent U.S. case law, warnings may become particularly relevant in AI liability cases when determining defects. However, as of now, the determination of defects seems rather fair and paves way for a flexible and balanced approach, and thus does not constitute a remaining challenge under the PLD.

However, in time, systemic failure may gain importance as AI becomes more embedded in healthcare. If certain types of bias or imprecision are seen as inevitable or even necessary in the diagnostic process by society, and society furthermore accepts this systemic flaw, courts may begin to view the flaws not as defects, but as systemic failures. Over time, this could complicate efforts to establish defectiveness in AI-systems.

Moreover, while the PLD framework is clearly aiming to modernise product liability, it appears fragmented in its approach to AI. On the one hand, it places considerable burdens on manufacturers to foresee, prevent, and continuously monitor hazardous behaviour in AI systems. On the other hand, it offers procedural mechanisms in PLD Article 9 and 10 that seem to bypass any genuine attempt to assess the complexity of the technology.

Moreover, it appears inconsistent that establishing defect or causation in AI systems is made extremely difficult in cumulative scenarios, while rebutting liability for "singular causation" is made surprisingly easy by the PLD whenever the underlying technology is deemed too complex to assess.[266]

Overall, the PLD's approach relies on simplifications and presumptions, which suggests a reluctance from regulators to engage with the substance of the technology itself. If the aim is to strike a balance

[266] PLD, Article 9 and 10 as discussed in section 3.3.5.

between innovation and user protection, regulators must be willing to understand and engage with the systems they seek to govern, not fear the complexity of it.

Moreover, it seems stringent that manufacturers are expected to prevent behaviour that, by the nature of adaptive AI, may be unforeseeable, as well as being denied access to defences under PLD Article 11 that acknowledge that very unpredictability. Although letting manufacturer's be exempt from liability under the defences in Article 11 could be considered problematic for patient safety, the current framework also risks discouraging innovation by holding manufacturers of AI-systems to a standard that no other technology is measured against. The manufacturer's must be left with some degree of leverage when it comes to predictability of their system.

Generally, the revised PLD needs to change its all or nothing-structure, as it hinders that responsibility is allocated in a more balanced way. For example, as demonstrated, there should be some shared responsibility for hospitals, or other professional users, to exercise due care when choosing AI-systems, particularly in sectors where public health is at stake, e.g. healthcare. Furthermore, the causation assessment should recognize that both the physician and the CDSS can share the liability adequately, which, under current rules, seems unlikely.

If the ambition is to let AI transform healthcare practice, a more fair balance must be struck.

Finally, and perhaps the biggest challenge, the current rules rest on the assumption that one model fits all AI systems. This assumption does not hold. AI systems vary significantly in design and application, and the regulatory framework should reflect and accommodate that diversity.
Thus, the revision of PLD provides for a rather fragmented set of rules, that poses an all-or-nothing solution, and which do not dare to understand and individualize these highly complex systems. However, if innovation and consumer protection must exist side-by-side, regulators need to engage more specifically.

Chapter V

5. Alternative solutions

In the current chapter suggestions for alternative solutions to regulate AI-software in medical devices will be discussed. The section will present different proposals from both regulators, academics and the author of this thesis herself, and seek to evaluate and find the more suitable solution for the EU.

5.1 'A Reasonable Clinician'

As demonstrated in Chapter 4, determining causality can be challenging for several reasons. One is the potential disruption of the causal chain when a physician or another healthcare professional acts upon an AI-generated suggestion, thereby becoming the ultimate decision-maker.

While the PLD applies a relatively strict and objective standard for determining product defectiveness, establishing causality in such cases may require a more nuanced approach. In particular, AI software such as CDSS introduces intermediate links between the decision and the resulting harm, which the legal framework must be able to accommodate.

Although many academics have discussed granting AI legal personhood, similar to that of a natural person (e.g. a physician), such a move currently appears yet too drastic. If an AI were fully autonomous and capable, this could become relevant, but as of now the medical field is still not yet using fully autonomous objects. Moreover, as noted in an EU report on emerging technologies and AI, there remains significant disagreement over the legal and ethical implications of AI personhood.[267] According to the Working Group behind the report, fundamental questions must still be resolved, such as whether AI can hold assets and pay taxes etc. These issues need settlement, before liability rules can be based on AI personhood.[268]

However, Van Staalduinen proposes a more pragmatic solution in situations regarding CDSS where the AI and physician jointly determine a diagnosis, treatment, or testing strategy.[269] He suggests that causality should be assessed on the basis of a legal standard of what a 'reasonable decision-maker' would do.[270] The idea is, that the causal link is assessed by comparing what a reasonable physician

[267] EU Report on emerging technologies, p. 37 f.
[268] Ibid.
[269] van Staalduinen J and others, Digital Governance Confronting the Challenges Posed by Artificial Intelligence, chapter 2: European Product Liability for AI-based Clinical Decision Support System, (T.M.C. Asser Press, 2024), p. 35.
[270] Ibid., p. 32-34.

would have done had they been presented with correct information, as opposed to what they did with the incorrect information from the CDSS. The test is inspired by EU prospectus rules, which hold information providers liable if an investor can prove that they would not have made the same investment decision had the prospectus been accurate.[271]

Although Van Staalduinen does not define the term 'reasonable' in detail, maintaining flexibility in its interpretation seems appropriate. What is considered reasonable may evolve over time, vary across EU Member States, and differ between professional groups and sub-specialties. The assessment could be guided by principles of professional liability, specifically what can reasonably be expected of a physician based on their expertise. The core test, however, remains a form of sine qua non: would a reasonable physician have followed an alternative advice of the CDSS if presented with that instead?

This rule addresses the broken causal chain by adapting existing legal principles to new technological realities. It allows the system to bear a degree of responsibility for misleading the decision-maker, while still permitting manufacturers to rebut the presumption of causality. As manufacturers typically possess the relevant technical data and expertise, they are well positioned to challenge such claims.

5.2 Common Enterprise Liability

Another issue of causality concerns determining who bears greater responsibility when multiple entities have contributed to the development and deployment of an AI system. One party may have produced the hardware, another the software for that hardware, while a third may have supplied a specific program integrated as a component. Finally, the hospital or end-user might have modified the algorithm through additional training or configuration. This raises the question of how legislators can adequately address situations where harm arises from such a multi-contributor setting.

Unlike the earlier-discussed issue of the physician breaking the causal chain, this concern relates more directly to the technical composition of the system and the internal attribution of fault. The key question becomes: why did the AI produce the erroneous outcome, and who is to blame?

R. Sullivan and J. Schweikart have proposed a model of joint responsibility among all involved parties.[272] Their concept, termed "common enterprise liability," suggests that every actor involved in the use and implementation of the AI system should be held collectively responsible.[273]

[271] Ibid., p. 33.
[272] "Sullivan H and others, 'Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?' [2019] AMA Journal of Ethics 21(2), E160-16, p. 164.
[273] Ibid.

A similar approach is reflected in the aforementioned EU report, which proposes that corporations working on different elements within the same ecosystem may be held jointly liable if they can be considered part of a "commercial and technological unit.".[274] This aims to prevent the producers to: "*artificially splitting up the eco-system in order to obscure causal links and diluting responsibility*.", as well as ensure that either way the victim should not suffer the consequences of a complex internal structure of the device.[275]

The author of this thesis agrees that this approach may effectively address issues of causality while safeguarding victims from the burdens of complex AI-structures. Moreover, it could help clarify the legal understanding of control, which, as demonstrated, is quite complex, and seems to ultimately lay the burden on producers either way. Under a joint liability model, responsibility would no longer rest solely on a single actor but would be fairly distributed among the contributors. Importantly, the question of who precisely caused the harm would not be decisive for the victim's right to compensation. Instead, it would become more of an internal matter for the contributing parties to resolve among themselves.

5.3 Obligation to Insure

A crucial principle in the use of AI in healthcare is that patients retain access to reasonable compensation and do not bear the consequences of increased technological complexity. This has led to the relatively straightforward proposal that AI systems should be subject to mandatory insurance requirements.

Kalagi et al. suggest introducing third party liability insurance for AI.[276] Specifically, the insurance should cover potential risks arising from the inherent uncertainties and possible errors of AI systems.[277] The solution seems rather simple, although it raises questions of burdens of cost for both insurers and the insured manufacturer.

However, imposing a blanket insurance requirement on all AI systems across the European Union seems overkill. According to the EU report, a general obligation to insure is not only arbitrary but currently unfeasible.[278] First, AI will be deployed in a wide range of sectors and serve many different purposes. A universal rule requiring insurance for all systems would place an unreasonable burden on

[274] EU Report on emerging technologies, p. 56 ff.
[275] Ibid.
[276] Kalagi S, Gubbewad R and Gondal A, 'LEGAL LIABILITIES OF ARTIFICIAL INTELLIGENCE: AN OVERVIEW' [2024] SDG Journal of Law and Sustainable Development, p. 11.
[277] Ibid.
[278] EU Report on emerging technologies, p. 61.

stakeholders. The report therefore recommends that any such obligation be assessed in light of the product's specific use and only be introduced following careful analysis.[279] Second, and perhaps more importantly, the insurance market is not yet sufficiently developed to offer relevant coverage for such a wide array of AI systems.[280] As a result, mandatory insurance is simply not a viable option at this stage.

The author of this thesis agrees that a generalised insurance obligation would be too aggressive and arbitrary without careful consideration of which types of devices should fall within its scope. However, for medical devices containing AI, it would in principle be fair and proportionate to impose a requirement of compulsory insurance. Given the high risk associated with the medical context and the potentially severe consequences for patients' life and health, it seems reasonable to ensure that patients are not left unprotected due to gaps in the product liability framework. The form of this protection could follow a model similar to the Danish CCA scheme, where access to compensation is subject to certain conditions.

Whether implemented through private insurance, a national compensation scheme, or another form of protection, the essential point is that patients must be given a simpler and more reliable path to compensation in what is otherwise a highly complex and costly system.

To account for the formerly identified challenge that hospitals rarely pursue their right of recourse,[281] this thesis proposes that the PLD must be tailored more specifically for the AI-systems. Therefore, the solutions proposed here in Chapter 5 should attract hospitals to seek recourse, as the rules are more fair and sector specific. Moreover, as the solutions reflect, it is argued that hospitals may need to carry part responsibility for the development and safe deployment of AI-systems in healthcare. However, ultimately, even if the hospitals refuse to seek recourse, and thereby bears the full liability, this thesis finds that patient safety carries greater weight than whether manufacturers are in fact held liable for their products, although the two are undeniably interrelated.

5.4 Auditing and Duty of Care

As demonstrated, the question of how control over AI systems is exercised remains unsettled in case law. When, how, and if a manufacturer can ever be said to no longer exercise control over an AI device is complex. Accordingly, manufacturers might as well embrace this obligation and implement proportional control measures.

[279] Ibid., p. 61 f.
[280] Ibid.
[281] See Section 3.2.2.

Marotta suggests that an auditing process is introduced.[282] In particular, she suggests deploying an AI tool to audit for bias in healthcare contexts.[283] Recognising that even the auditing tool itself could be biased, she further recommends that such a system is subject to human oversight.[284] While neither Marotta nor the author of this thesis can confirm whether such a tool would prove fully effective, the idea of auditing represents a promising method for exercising more active control over AI systems.

More generally, systematic oversight and proactive efforts to mitigate harm is a shared goal for both manufacturers and patients. Continuous monitoring of AI-enabled products would reduce the risk of harm, although it would impose a significant burden on manufacturers. However, this burden is already embedded in the requirements in the MDR and AI Act. Manufacturers could therefore address all three obligations simultaneously through a unified auditing and surveillance system.

Building on this idea, the author of this thesis proposes coupling such active control with a conditional exemption from liability. Specifically, the manufacturer should be exempt from liability for defects they could not have foreseen even if their auditing were performed correctly. If the manufacturer had exercised active control and surveillance of their devices, and done what was technically feasible and proportionate to expect from them, they shall not be held liable for defects that were unforeseeable. The residual risk of completely unpredictable outcomes from AI must instead be (partly) borne by the one who benefits from AI, namely users.

Alternatively, a more moderate version of this proposal could involve a limitation of liability rather than a full exemption. In cases where unforeseeable harm occurs, the manufacturer's responsibility could be significantly reduced, and the burden of compensation should then shift primarily to the hospital or healthcare provider that benefits most directly from the AI system.

These considerations regarding the allocation of liability on the one who benefits will be further discussed in the following subsection.

5.5 Liability for the Beneficiary

The EU Report suggests that a new liable actor is introduced: the *operator* of the system.[285] The proposal defines the operator using two criteria: 1) who benefits from the system, and 2) who is in a

[282] Marotta A, 'When AI Is Wrong: Addressing Liability Challenges in Women's Healthcare, Journal of Computer Information Systems', [2022], Journal of Computer Information Systems, 62(6), 1310-1319, p. 1315.
[283] Ibid.
[284] Ibid., p. 1417
[285] EU Report on emerging technologies, p. 39.

better position to control the risks associated with its operation.[286] This approach aligns with other forms of no-fault liability for comparable risks, such as that imposed on car drivers.[287] Accordingly, the one who benefits from the AI, typically its user or their principal, should bear liability for the harm that is caused through their interaction with it.

However, benefit alone cannot determine liability, as it would be unjust to hold someone liable for risks they are unable to manage. For example, a private person using an AI-system provided by their physician can in no way be expected to alter the system's algorithm or similarly reduce risks of the system themselves. Therefore, the EU report argues that determining which operator is liable must also be determined by who is more in control, not of the product, but of the risks associated with the product.[288] This may point to a professional party, e.g. the hospital or the manufacturer, depending on the specific circumstances and distribution of control. Even if both parties may be liable under this model, the proposal preserves the right to recourse, allowing hospitals to seek indemnification from manufacturers where appropriate.[289]

The author of this thesis finds this proposal generally compelling, particularly in its attempt to reflect the control more specifically defined by the actual risk-control. However, it remains unclear what level of control is sufficient to establish liability, and in that respect the proposal may not move us far beyond the existing ambiguity surrounding control under the current version of the PLD. Balancing benefits and risk-control though addresses the issue of the all-or-nothing approach that either the manufacturer or modifier is liable. The operator-term is more flexible and based on more nuanced criteria. Moreover, it may also hold hospitals liable for merely providing an AI-system, when they benefit from their deployment and are the more obvious controller and maintainer of its risks.

5.6 AI Liability Directive

In 2022 the European Commission proposed an AI Liability Directive ("**AILD**") that lay down rules for non-contractual civil liability for AI products.[290] The proposal offers a rebuttable 'presumption of causality', and rules for the victim's burden of proof for establishing damage. Moreover, it gives national courts the ability to order disclosure of evidence about high-risk AI systems suspected of having caused damage.[291] However, in 2025 the proposal was nowhere to be seen on the European

[286] Ibid., p. 39-42.
[287] Ibid., p. 40.
[288] Ibid., p. 41-42.
[289] Ibid., p. 40.
[290] European Commission, Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), [2022], COM(2022) 496 final ("AILD").
[291] European Commission, European Parliamentary Research Service, 'Brief on the AI Liability Directive' [2023], p. 1.

Commission's work programme, as executives stated that there was "no foreseeable agreement".[292] However, the suggestions will be presented and evaluated in the following section.

The AILD lays down rules on the disclosure of evidence on high-risk AI systems and the burden of proof for damages in cases concerning harm caused by AI, cf. AILD Article 1(1)(a-b). The main parts of the proposal are found in Article 3 and 4.

Article 3 enables a potential claimant pursuing compensation for harm caused by AI to easier gain access to evidence. Notably, it is not the potential claimant that is entitled, meaning that even if the case has not yet been brought before the courts, a natural or legal person who is considering bringing a claim for damages before the court benefits from the rule.[293]

If the potential claimant can present facts and evidence supporting that it is plausible that a high-risk AI system under the AI Act, such as medical devices incorporating AI, caused the damage before the court, the court can order the manufacturer of the system to provide evidence at their disposal.[294] The court may only disclose the evidence to the extent that it is necessary and proportionate to support the potential claim.[295] However, the potential claimant must also demonstrate that they have taken all proportionate measures to obtain the information themselves.[296] If the provider of the high-risk system fails to comply with such an order, the courts may presume that the evidence was intended to prove for the purposes of the relevant damage claim. The provider may rebut this presumption.[297]

The rule in Article 3 of the AILD appropriately addresses the inconsistency of requiring claimants to initiate legal proceedings in order to obtain disclosure of evidence, as is the case under the PLD.[298] Given the high costs associated with litigation and the claimant's lack of technological insight to assess whether the system could actually be liable, the current requirement for raising the case before assessing evidence is unreasonable. Article 3 thus enables potential victims to better evaluate the merits of their case and make an informed decision on whether to proceed, taking into account the financial risks involved. In doing so, the directive contributes to a more equitable balance between the parties.

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[292] Kroet C, 'Lawmakers reject Commission decision to scrap planned AI liability rules' <https://www.euronews.com/next/2025/02/18/lawmakers-reject-commission-decision-to-scrap-planned-ai-liability-rules> Visited on 28 May 2025.
[293] The definition of a 'potential claimant' is found in AILD Article 2(7).
[294] AILD Article 3(1).
[295] AILD Article 3(4).
[296] AILD Article 3(2).
[297] AILD Article 3(5).
[298] PLD Article 9 about disclosure of evidence only discusses the claimant, and not the potential claimant.

However, significant barriers to access remain, as the victim must still present convincing evidence that the AI system was a plausible cause of the damage. Moreover, disclosure of evidence is limited to what is proportionate and necessary. While this provides some protection for manufacturers and ensures flexibility for Member States in implementation, it also introduces considerable legal uncertainty. The threshold for what constitutes sufficient plausibility is not clearly defined and is not further clarified in the recitals.[299] In practice, this requirement may prove to be just as burdensome as the existing evidentiary standards. Furthermore, the provision can be applied very differently in every Member State causing legal fragmentation and uncertainty.

Article 4 introduces a rebuttable presumption of causality if the following conditions are cumulatively met:

a) the claimant must demonstrate non-compliance with Union or national law intended to protect against the damage occured
b) the claimant must demonstrate that the fault to comply is linked to the AI's output
c) and that the output led to the harm in question.[300]

Furthermore, special rules for high-risk systems are laid out in 4(2-4) which determines that high risk systems can only be non-compliant as understood in the first condition (a) with regard to specific provisions of the AI Act. If the defendant, providing a high-risk system, can demonstrate that sufficient evidence to prove causality is available, the presumption will not apply.[301] Similarly for non-high-risk systems, the presumption shall only apply when it is excessively difficult for the claimant to prove causal link.[302] Finally, the AILD also allows for the defendant to rebut the assumption of causality.[303]

As is evident from the formulation of Article 4, the proposed threshold for triggering the presumption of causality is notably high. It is almost paradoxical that such a detailed and structured set of criteria must be fulfilled simply to *presume* causality, meaning that the burden of proving actual causality may be close to insurmountable for many victims of AI-related harm. Crucially, the directive outlines *what* must be proven (e.g. a breach of duty, reasonable likelihood of influence, and a link to damage), but remains silent on *how* such proof can be established. There is no guidance on the types of evidence or documents that might satisfy the criteria, leaving victims without a clear procedural path.

[299] Plausibility is mentioned in AILD recital 17, but provides no elaboration of what information could be beneficial for the victim to present.
[300] AILD Article 4(1)(a-c).
[301] AILD Article 4(4).
[302] AILD Article 4(5).
[303] AILD Article 4(7). There are also rules that specifically govern the use of AI in a personal, non-professional, context in Article 4(6) which will not be addressed due to lack of relevance for the medical sector's use of AI.

In addition, the requirement that it must be "excessively difficult" for the claimant to prove causality in order for the presumption to apply is vague and under-defined.[304] This vagueness introduces legal uncertainty and risks divergent interpretations by national courts. Ironically, if a claimant is able to gather sufficient evidence to convincingly satisfy all three conditions (a-c), they could arguably be said to already have enough evidence to prove actual causation, thus undermining the intended evidentiary relief.

Combined with the fact that the proposal is based on minimum harmonisation, which allows Member States to maintain or introduce stricter or divergent rules, the practical application of the directive is likely to be fragmented. This risks defeating the core objective of legal clarity and predictability for both victims and AI system operators across the Union.

5.6.1 Conclusions on AILD

While the AI Liability Directive proposal shows awareness of the structural challenges posed by AI-related harm, particularly in relation to causality and access to evidence, it fails to be specific and does not dare to properly address today's technology.

Article 3 makes a welcome attempt to address the evidentiary imbalance between victims and providers of high-risk AI systems. Yet even this procedural innovation is entangled in vague conditions and undefined thresholds that gives little clarity for courts and claimants. The requirement of "plausibility" is not elaborated, and the burden of showing this plausibility still lies heavily with claimants who often lack access to the technical insight required to make such assessments.

Article 4 suffers from similar issues. The presumption of causality, though framed as a legal easing, remains gated behind quite high conditions. More importantly, the AILD outlines in detail what needs to be proven but offers no guidance on how. There is no indication of what types of evidence may satisfy the test, nor how courts should evaluate such material. The result is a provision that appears to lower the burden of proof on the surface, but in practice may do little to change the evidentiary deadlock victims face under existing rules.

[304] The term 'excessive difficulties' is also used in the revised PLD's Article 10(4)(a), which determines rebuttal of defectiveness and causal link, when it is excessively difficult for the claimant to prove. The European Law Institute has equally criticized the expression for being to broad and non-specific. They stress the need for more specific guidance is what is needed for the claimant to suffice, cf. European Law Institute, "European Commission's Proposal for a Revised Product Liability Directive Feedback of the European Law Institute" [2023], p. 20 f.

These shortcomings are enhanced by the minimum harmonisation approach, which allows Member States a lot of flexibility in interpretation and implementation. This flexibility risks producing the very problem the directive was meant to solve: legal fragmentation.[305] Instead of offering a common framework for addressing AI-related harm, the directive may generate a patchwork of inconsistent national practices and continued uncertainty.

At its core, the directive shies away from making the hard choices. The Commission has chosen a generalist, one-size-fits-all model despite the fact that AI systems vary enormously in function, risk, and societal impact. The refusal to engage with the technical specificity of these systems, or to propose differentiated rules based on system characteristics, undermines the credibility and practical application of the AILD. For a regulatory instrument that promises clarity and modernisation, the end result is vague, and lacking in the concrete tools needed.

[305] AILD proposal, p. 3, 6 and recital 7.

Chapter VI

6. Conclusion

This thesis has aimed to clarify the product liability rules applicable to AI-driven medical devices in the EU and to identify persisting legal challenges. In addition, it has proposed specific solutions to address these challenges. The thesis thus has a threefold aim.

The first aim of the thesis has been to examine the current regulatory framework for liability for AI-based medical devices in the EU. The revised PLD clearly addresses AI-technology by explicitly including software in the definition of a product and acknowledging the challenges of unpredictable behaviour in self-learning systems. Furthermore, PLD acknowledges the difficulty for claimants to establish defectiveness and causality in complex technologies such as AI.

The second and third aim was to analyse unresolved legal issues and propose solutions. While the revised PLD indeed addresses AI, it takes a generalist approach that does not reflect the wide variability and societal significance of different AI systems, which also reflects the EU's approach for regulating AI in the dropped AILD. In the context of healthcare, the use of AI entails both substantial benefits and significant risks that are unique for the use of AI in healthcare and therefore demands specific attention.

The thesis identifies five key challenges and addresses them through tailored proposals for solutions:

First, the PLD imposes a disproportionately strict liability regime on manufacturers of self-learning AI systems. Under the revised rules, manufacturers are held responsible for all unpredictable developments in their products, including latent defects that emerge long after deployment. This is reinforced by the PLD's concept of control, which, in the case of self-learning systems, effectively presumes that the manufacturer remains in control indefinitely. As a result, manufacturers of AI may be unable to invoke exemptions from liability. This all-or-nothing approach may deter innovation and limit the development of advanced medical AI in the EU. To address this, the thesis proposes a conditional exemption from liability for unforeseeable harm, provided that the manufacturer has exercised active control through regular auditing and monitoring efforts.

Second, the current causation standard fails to account for intermediate actors, such as physicians making the final decision after using a CDSS. In many legal systems this would break the causal chain, as the CDSS is not the direct cause of harm. Moreover, in time, inconsistent national

approaches may risk legal fragmentation across Member States. To remedy this, the thesis proposes an EU-level standard based on a modified sine qua non test, inspired by existing rules for prospectuses, where the CDSS' influence on the physician's decision is assessed by comparison to what a 'reasonable clinician' would have done.

Third, even if causation is established, determining fault in complex systems involving multiple components, suppliers, perhaps hidden in black-box algorithms, is difficult. While the PLD allows rebuttable presumptions in complex cases, this thesis suggests a more specific solution: a common enterprise liability model whereby all contributing parties are jointly liable to the injured party. The contributing parties may then pursue internal redress based on their degree of contribution. This preserves access to compensation for patients without foreclosing recourse.

Fourth, national insurance schemes, such as the Danish CCA, and other supplementary compensation mechanisms often offer easier access to compensation than the PLD. However, hospitals rarely pursue their recourse claims against manufacturers. Although this stipulates a challenge that effectively shields producers from liability, the thesis acknowledges that such schemes are essential to ensure patient protection in healthcare. Therefore, solutions of insurance are proposed for the healthcare sector specifically. Ultimately, the protection of public health outweighs concerns about private enforcement.

Fifth, liability rules in PLD also addresses cases where hospitals substantially modify AI systems, e.g. by retraining them or providing new data. However, these rules blur the line between manufacturer and user responsibility. This thesis critiques the all-or-nothing allocation of liability and instead proposes a shared liability approach between hospitals and manufacturers where both benefit from and exert control over the risks of the AI system. This model better reflects the distribution of risk and use in professional healthcare environments and could help nuance the allocation of liability under the PLD.

In conclusion, the PLD's generalist and binary structure fails to accommodate the layered responsibility that is unique to using AI in healthcare. By imposing strict liability on manufacturers, while overlooking the role of professional users-level interactions, it creates an all or nothing approach that hinders fair allocation of liability. The solutions presented in this thesis aim to tailor liability rules to the specific context in which AI operates and to promote shared responsibility, without compromising the victim's right to effective compensation. Only by embracing sector-specific rules and providing a more flexible liability framework can the EU ensure both innovation and effective protection of patients in an AI-driven healthcare landscape.

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Illustrations

Illustration 1:

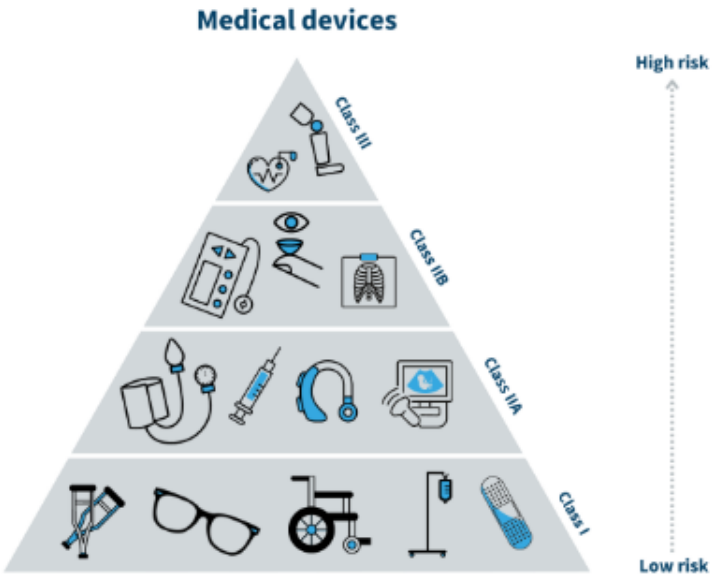

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Illustration 2:

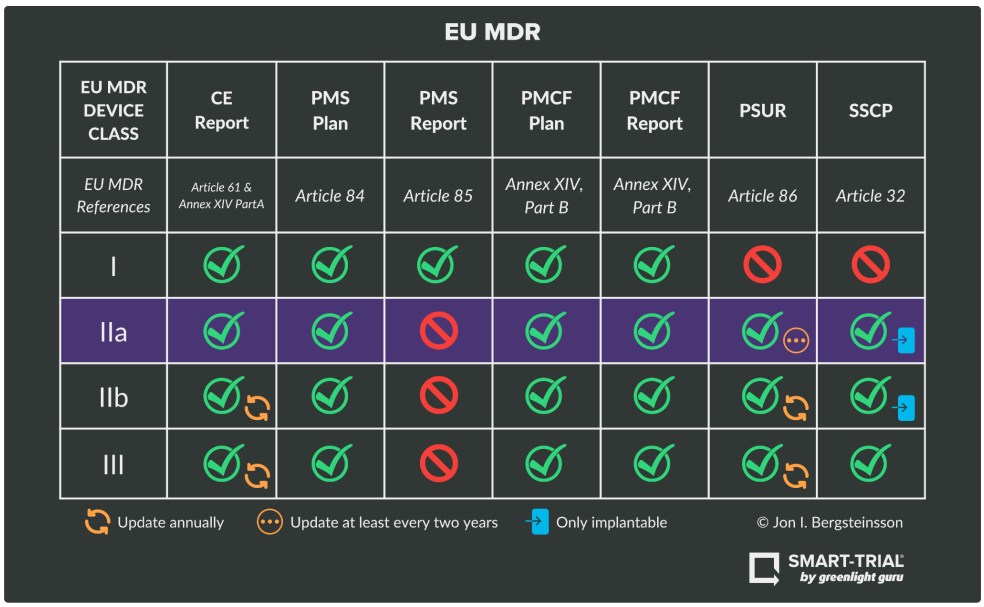

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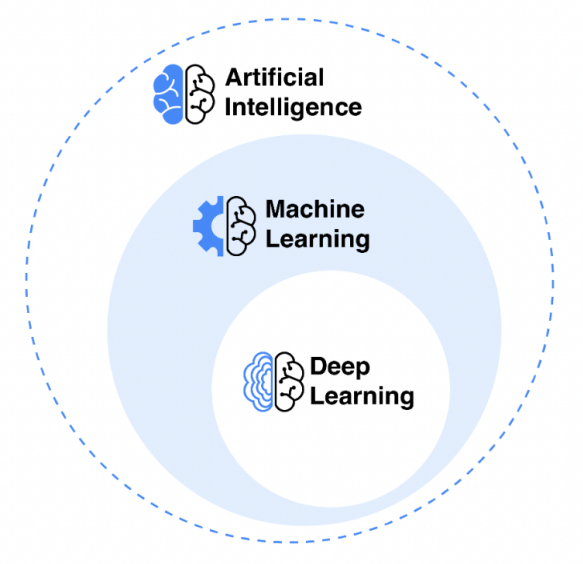
Illustration 3:



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