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Research Paper

From user to manufacturer: How substantial modification of medical AI crosses the product liability threshold under the revised PLD☆

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ABSTRACT

The revised Product Liability Directive (rPLD) introduces a pivotal shift in the liability landscape for healthcare professionals using artificial intelligence. While existing research often focuses on professional or regulatory thresholds, this paper highlights a critical and underexplored juncture: the moment a health institution or professional's interaction with an AI system constitutes a substantial modification, thereby transforming them from a user into a de facto manufacturer under the rPLD's strict liability regime.

Drawing on the author's prior work on threshold-based liability frameworks, this paper examines how the rPLD redefines the "product" to include software and AI systems, and expands liability to any natural or legal person who substantially modifies a product outside the manufacturer's control. In clinical practice, such modifications may occur through actions such as overriding safety parameters, integrating unauthorized components, or in other manner. When these actions are not foreseen in the manufacturer's initial risk assessment, create a new hazard or increase the risk level, and are performed by a healthcare professional rather than a consumer, the health institution or professional crosses the product liability threshold, triggering strict liability for any resulting harm.

The analysis situates this threshold within the broader EU regulatory ecosystem, including the AI Act, the General Product Safety Regulation, and the Medical Devices Regulation, to demonstrate how liability becomes distributed and context-dependent. The paper argues that the rPLD does not merely complement existing fault-based regimes but creates a distinct, strict liability pathway that reallocates risk to the party with the highest degree of control over the AI system's final safety configuration.

1. Methodology

As established in prior author's work, the liability of healthcare professionals using AI can be understood through a tripartite threshold typology encompassing regulatory, professional, and product dimensions. The present paper builds upon this framework by offering a detailed doctrinal analysis of the product threshold's central mechanism: substantial modification (Ampovska, 2026).

This research addresses a single, underexplored question: under what circumstances does a health institution's/professional's interaction with an AI-enabled medical device cross the threshold of "substantial modification," thereby transforming them from a user into a de facto manufacturer under the revised Product Liability Directive (hereinafter rPLD)[1]? The inquiry proceeds through a doctrinal analysis of the relevant EU legal instruments. The research is structured in three stages.

First, the paper establishes what constitutes an AI-enabled medical device under EU law. This requires examining the interplay between the Medical Device Regulation (hereinafter MDR)[2] and the Artificial

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[1] 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, OJ L 2853, 18.11.2024.

[2] Regulation (EU), 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017

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Intelligence Act (hereinafter AI Act),[3] identifying how these instruments define medical devices, software, and AI systems, and assessing whether their definitions align or create tensions. The purpose is to determine the regulatory baseline from which any modification departs.

Second, the paper analyzes the concept of "substantial modification" across four instruments: the MDR, the General Product Safety Regulation (hereinafter GPSR),[4] the rPLD, and the AI Act. Each instrument addresses modification from a different regulatory perspective: safety, liability, and conformity assessment. The analysis compares their definitions, identifies convergences and divergences, and establishes how the rPLD's Article 8 operationalizes the threshold for liability purposes.

Third, the paper applies Article 8 of the rPLD to the healthcare context. It distinguishes between healthcare professionals (natural persons) and health institutions (legal persons) and examines the objective elements of the provision (what constitutes a modification, manufacturer's control, and market placement) alongside the subjective element (who performs the modification). The analysis then clarifies the boundary between actual transformation and off-label use, before examining the joint application of Article 8 with the exemptions under Article 11.

The research draws exclusively on EU primary law (regulations and directives), CJEU case law, and scholarly commentary on these instruments. Comparative references to US scholarship are used only where they illuminate general principles of liability allocation, not as sources of binding authority. National implementation materials, specifically the German Government Draft of December 2025, are included as illustrative examples of how the rPLD's framework translates into national law, not as sources of EU law.

The goal is not to provide an exhaustive interpretation of all possible modifications in clinical practice, but to offer an initial, structured analysis of Article 8 rPLD and its implications for health institutions and professionals who modify AI-enabled medical devices.

2. Defining medical device in the EU regulatory framework

Under Article 2(1) of MDR, a "medical device" is defined not by its technological composition, but by its intended medical purpose. The definition encompasses any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended for human beings for specific medical purposes, including diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease or injury. Crucially, a medical device achieves its principal intended action by physical or mechanical means, explicitly excluding pharmacological, immunological, or metabolic primary modes of action. This purpose-centric definition is inherently technology-neutral and future-proof, capable of accommodating technological evolution, including artificial intelligence.

Because the MDR expressly includes "software" in that definition, AI-driven software falls squarely within the scope of a medical device. Researchers note that the MDR added the purposes of "prediction" and "prognosis," which map directly onto the capabilities that AI systems provide, thereby confirming that AI-based software is treated as a software-based medical device when its intended use matches any of those medical purposes (Nüssler, 2023). Therefore doctrine defines an AI medical device as software that incorporates artificial-intelligence algorithms and is intended by the manufacturer to perform a regulated medical purpose, such as diagnosis, monitoring, prediction, prognosis, treatment or disease-alleviation, so that its classification and regulatory requirements are driven primarily by the intended use and associated risk rather than the underlying technology (Fraser et al., 2023).

The MDR further elaborates categories that are pivotal for understanding AI integration:

- Software as an Active Device (Art. 2(4)): The MDR explicitly states that *"Software shall also be deemed to be an active device."* This classification is foundational for AI systems, as it recognizes software that depends on an energy source (computing power) and acts by converting that energy, a perfect descriptor for algorithmic data processing.
- System (Art. 2(11)): A "system" is a *"combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose."* This anticipates the ecosystem nature of modern AI-enabled medical technology, where devices, software, and data streams interconnect.
- Accessory (Art. 2(2)): An accessory is an article intended to be used with a specific medical device to *"enable"* its use or *"directly assist"* its medical functionality. This could encompass specific AI modules that enhance a primary device's performance.

The manufacturer's declared intended purpose is the linchpin of the MDR regime. It determines the device's risk classification (Class I, IIa, IIb, or III), dictates the conformity assessment pathway, and establishes the safety and performance baseline.

Therefore, an AI system qualifies as a medical device under the MDR when the manufacturer intends it to be used for a defined medical purpose (e.g., analyzing medical images for tumor detection, predicting patient deterioration) and its primary mode of action is algorithmic/data-driven. Such an AI system would be classified based on its intended use and potential risk to patients, subjected to the MDR's rigorous pre-market conformity assessment and post-market surveillance requirements (The Medical Device Coordination Group (MDCG), 2025).

The MDR establishes that an AI medical device's safety and performance are legally codified in its technical documentation, conformity assessment, and intended use. For the health institution and the healthcare professional, this creates a clear regulatory boundary: using the device outside its specified conditions or authorized configurations, such as on an unvalidated platform or for an unapproved purpose, constitutes a breach of the device's legally-mandated safety parameters, directly undermining the compliance framework established by the manufacturer (Wendehorst & Duller, 2023, pp. 251–254).

The AI Act creates a horizontal, risk-based framework specifically for AI systems. Its interaction with the MDR is not one of replacement but of layered regulation. The AI Act explicitly acknowledges this layering. Recital 50 states that for high-risk AI systems that are safety components of products, or which are themselves products, falling within the scope of Union harmonisation legislation such as the MDR, the requirements of both acts apply. Recital 50 explicitly names 'medical devices' and 'in vitro diagnostic medical devices' among the products covered. Consequently, an AI system that meets the MDR's definition of a medical device is presumptively high-risk under the AI Act, subject to the two-condition test in Article 6(1): the AI system must (a) be a safety component of, or itself be, a product covered by Annex I; and (b) be required to undergo a third-party conformity assessment under that legislation. Consequently, an AI system that meets the MDR's definition of a medical device is presumptively high-risk only where it is subject to Notified Body involvement, which includes all Class IIa, IIb, and III devices, and Class I devices that are sterile, have a measuring function, or are reusable surgical instruments. Class I devices that do not require Notified Body involvement are not automatically high-risk under Article

[3] Regulation (EU), 2024/1689 of the European Parliament and of the Council of 13 June, 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L 1689, 12.7.2024

[4] Regulation (EU), 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 and Directive (EU) 2020/1828, and repealing Directive 2001/95/EC and Council Directive 87/357/EEC, OJ L 135, 23.5.2023.

6(1). For most AI-enabled medical devices in clinical practice (which tend to be Class IIa or above), the high-risk classification applies.

Nevertheless, the doctrine concludes that even after the EU AI Act is in force, the core problem remains: there is still no harmonised, risk-based framework that tells manufacturers exactly what clinical evidence, transparency and safety-assessment steps are required for AI-enabled medical devices. While the AI Act expands the regulatory landscape and acknowledges AI-driven software as a medical device, the AI Act alone does not close the gap and further alignment with MDR, detailed standards and unified definitions are still needed (Fraser et al., 2023, p. 467).

The rPLD shifts the perspective from regulatory compliance to civil liability for damage**.** It does not have a category for "medical device". Instead, a medical device becomes relevant to the rPLD only because it is a subset of "products". rPLD redefines the foundational concept of a product to explicitly include software. Under the rPLD framework, an AI system that is a medical device under the MDR and a high-risk AI system under the AI Act is also a product for strict liability purposes. The MDR's intended purpose and the AI Act's trustworthiness requirements now directly inform the rPLD's central question of defectiveness. For instance, a failure to meet the robustness standards of the AI Act could directly evidence a defect under the rPLD.

The rPLD introduces the crucial operational concept of "manufacturer's control". Under Recital 18, control extends beyond the physical product to include related digital services and components (such as software updates) only if the manufacturer actively integrates, supplies, authorizes, or consents to them, whereas merely providing the technical possibility for integration or failing to prohibit third-party services does not constitute control. Control is defined as authorizing the integration, interconnection, or supply of a component (including software updates) or the modification of the product.[5]

3. Legal definitions of "substantial modification"

The concept of "substantial modification" functions as a critical legal threshold across the evolving EU regulatory landscape for products, serving to reallocate responsibility from original manufacturers to downstream operators who alter products after their initial placement on the market. Its importance lies in the consequences that flow from crossing that threshold: a healthcare professional, health institution, or other operator who performs a substantial modification may be transformed from a mere user into a manufacturer, subject to strict liability and accountability for any resulting harm. The complexity of this determination is compounded by the coexistence of multiple legal instruments that address substantial modification from different angles and with distinct terminological variations. This section sets out the legal definitions and conditions as they appear in the relevant instruments: rPLD, AI Act, MDR and GPSR providing the necessary groundwork for the subsequent analysis of how these definitions interact and the implications they hold for healthcare professionals and health institutions who modify AI-enabled medical devices in clinical practice.

3.1. The medical device regulation (MDR)

The MDR does not contain a single, unified definition of substantial modification comparable to the AI Act or GPSR. Instead, the concept is established through a combination of provisions that operate across different contexts. Article 120 (3) provides that devices covered by transitional provisions may continue to be placed on the market only if "there are no significant changes in the design and intended purpose." This formulation, while not defining "significant change," establishes the concept that changes to design or intended purpose require renewed conformity assessment. Article 16(1), (b) and (c) treats any person who "changes the intended purpose of a device already placed on the market or put into service or who modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected" as assuming the obligations of a manufacturer. This provision establishes a lower threshold than the substantial modification concept: where a modification "may affect" compliance, the modifier becomes a manufacturer. The provision does not require that the modification actually affects compliance, only that it has the potential to do so. Article 16 (2) specifies certain activities that are not considered modifications that could affect compliance:

(a) provision, including translation, of the information supplied by the manufacturer … and of further information which is necessary in order to market the device in the relevant Member state;
(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it.

This fragmented approach to modification has drawn significant criticism from scholars who question whether the MDR itself would satisfy the standards it imposes on medical devices. Researchers argue that the MDR lacks transparency, traceability, and a coherent risk-based approach, noting that its classification rules often fail to account for the actual risk profile of individual devices, a deficiency that becomes particularly acute when assessing whether a software update or algorithm retraining constitutes a "significant change" under Article 120(3) (Haimerl et al., 2026). Manufacturers of software as a medical device face particular challenges in interpreting what constitutes a "significant" or "substantial" change under the MDR, as the regulation lacks clear criteria for software updates (Svempe, 2024). Other researchers found that manufacturers in the orthopaedic aids sector struggle with the MDR's increased requirements for documentation and quality management, which includes determining whether changes to a device, such as software updates or design adjustments, constitute a modification that triggers renewed conformity assessment obligations. The findings suggest that the lack of clear, predictable criteria for what counts as a modification under the MDR creates significant operational uncertainty for manufacturers, forcing them to invest resources in interpreting regulatory thresholds rather than in device improvement (Carl & Hochmann, 2023).

3.2. The general product safety regulation (GPSR)

The GPSR establishes the most comprehensive and detailed definition of substantial modification among the instruments examined. Article 13(2) provides that a natural or legal person who substantially modifies a product shall be deemed to be a manufacturer and subject to the obligations of a manufacturer for the part of the product affected by the modification or for the entire product if the substantial modification has an impact on its safety. Article 13(3) establishes three cumulative criteria that must be satisfied for a modification to be deemed substantial:"(a) the modification changes the product in a manner which was not foreseen in the initial risk assessment of the product; (b) the nature of the hazard has changed, a new hazard has been created or the level of risk has increased because of the modification; and (c) the modifications have not been made by the consumers themselves or on their behalf for their own use." These three cumulative criteria translate to unforeseeability in the initial risk assessment, alteration of hazard characteristics or risk level, and performance by a party other than the consumer all of which must be satisfied for a modification to be deemed substantial, a reading confirmed by the conjunctive "and" in the provision's wording (Grau, 2024, p. 34). In addition the third criterion of Article 13(3)(c) GPSR requiring that modifications not be made by or on behalf of consumers is considered to create a significant limitation on the

[5] 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, OJ L 2853, 18.11.2024, Recital 18.

concept of substantial modification, as it excludes precisely those modifications that characterize the emerging market for refurbished and remanufactured goods, where consumers commission third parties to restore products for resale (Grau, 2024).

Recital 25 of the GPSR expands the concept to encompass digital modifications, recognizing that "new technologies might substantially modify the original product, for instance through software updates." The recital establishes that such modifications "should then be subject to a new risk assessment if that substantial modification were to have an impact on the safety of the product." This provision is particularly significant for AI-enabled medical devices, where software updates and algorithmic changes can fundamentally alter product behavior without any physical intervention. On the other hand, researchers confirm that the current regulatory framework is inadequate for managing software updates and algorithmic changes in AI-enabled medical devices, with industry experts characterizing the approach as "not fit for purpose" for continuous-learning AI systems. It is further noted that the European Union lags behind other jurisdictions in addressing these challenges, underscoring the practical significance of GPSR Recital 25's recognition that software updates may constitute substantial modifications requiring new risk assessments (DuPreez & McDermott, 2025).

In addition Article 13(2) introduces a nuanced allocation of responsibility: the modifier is deemed a manufacturer "*for the part of the product affected by the modification or for the entire product if the substantial modification has an impact on its safety*." This formulation creates a modular liability structure, where the extent of responsibility corresponds to the scope of the modification's effects. Where the modification is contained to a specific component or feature, liability attaches only to that affected part, where the modification alters the overall safety characteristics of the product, full manufacturer responsibility attaches. The European Commission's Guidelines on the GPSR confirm this modular structure, stating that modification by digital means, including software updates, constitutes a substantial modification when it affects the product in a manner not foreseen in the initial risk assessment, and that the person carrying out such a modification is considered a manufacturer, but only in respect to the modified part of the product, provided the modification does not affect the product as a whole. The Guidelines further clarify that the modifier need not repeat tests or produce new documentation for aspects of the product unaffected by the modification, but bears the burden of demonstrating that the modification does not affect the product in its entirety.[6]

3.3. The revised product liability directive (rPLD)

The legislative evolution of the revised PLD reveals a significant refinement in how "substantial modification" is defined. Writing prior to final adoption, authors critiqued the initial proposal's silence on interpretive criteria for substantial modification, recommending either autonomous definition or explicit reference to the GPSR. The final rPLD followed this recommendation (Grau, 2024), as article 4(18) rPLD defines "substantial modification" in the operative provisions.[7] It establishes a two-tier structure. First, a modification is substantial where it is considered substantial under relevant Union or national product safety law (Article 4(18)(a)). This incorporates the criteria of the GPSR, the MDR, and other sectoral legislation. Second, where relevant product safety law lays down no threshold, the rPLD provides its own autonomous definition: a modification is substantial where it changes the product's original performance, purpose, or type in a manner not foreseen in the initial risk assessment, and changes the nature of the hazard, creates a new hazard, or increases the risk level (Article 4(18)(b)). Recital 39 clarifies this structure but does not replace the binding operative text. The rPLD thus contains both a deferential definition and its own autonomous definition, with the latter serving as a fallback only where product safety law is silent. For medical AI devices, product safety law does provide a threshold (consisted in GPSR and MDR). Therefore, Article 4(18)(b) does not apply in case of medical AI. The rPLD's operative definition is referential in this case as it sends us to the GPSR and MDR. On the other hand, the autonomous definition of substantial modification in Article 4(18)(b) rPLD exhibits a deliberate structural alignment with the GPSR's three cumulative criteria in Article 13(3), with one notable omission: the consumer exception. Both definitions share identical substantive cores. The GPSR requires a modification to be not foreseen in the initial risk assessment, and to have changed the nature of the hazard, created a new hazard, or increased the risk level. The rPLD's autonomous definition mirrors these requirements verbatim, demanding the same unforeseeability in the initial risk assessment and the same alteration of hazard characteristics or risk level. The sole substantive divergence lies in the third criterion. The GPSR explicitly excludes modifications made by consumers or on their behalf, a condition that reflects the regulatory context of consumer product safety.

When it comes to rPLD's correlation with the MDR, according to certain authors, the rPLD seeks to enhance coherence with the MDR by aligning key concepts, clarifying liable actors, and facilitating claims in complex technological contexts, thereby improving, but not fully achieving, harmonisation of liability for medical devices (Heikkonen & Havu, 2023). But, at the end rPLD does clarifies the range of liable actors within the MDR framework by aligning liability with the notion of "manufacturer" and extending it to additional actors such as authorized representatives and software-related contributors, thereby improving coherence between the regimes (Heikkonen & Havu, 2023, pp. 656–657).

A further limitation identified by researchers concerns the application of the rPLD's core concept of defect to autonomous medical AI. In this view, the rPLD does not adequately equip courts or claimants to distinguish between harm flowing from an AI's autonomous decision-making and harm flowing from a genuine product defect. Where an autonomous AI system operates without human medical input and causes injury, patients may be unable to hold the manufacturer accountable, as the system's op/aque reasoning could fall outside the manufacturer's control as defined by the rPLD (Solaiman & Malik, 2025, p. 20).

The German implementation of the rPLD provides a concrete illustration of how the rPLD's framework can be translated into national law. The German Product Liability Act (Produkthaftungsgesetz, hereafter referred as the German Act) as reformed by the Government Draft of December 2025 codifies the autonomous definition from Article 4(18)(b) directly into the liability regime.[8] Section 5(2) of the German Act establishes a two-part cumulative test: a modification is substantial where it changes the original performance, purpose, or type of the product in a manner not foreseen in the manufacturer's initial risk assessment, and where the nature of the hazard changes, a new hazard arises, or the risk level increases. Moreover, the German Act operationalizes the rPLD's distinction between modifications made with and without the original manufacturer's control. Section 5(1) provides that a

[6] Commission Notice, *Guidelines on the application of the EU general product safety legislative framework by businesses*, C/2025/6233, *Official Journal of the European Union*, C series, 21 November 2025, section 3.4.4., p. 39.

[7] "substantial modification' means a modification of a product after it has been placed on the market or put into service:

(a) that is considered substantial under relevant Union or national rules on product safety; or

(b) where relevant Union or national rules on product safety lay down no threshold on what is to be considered a substantial modification, that:

(i) changes the product's original performance, purpose or type, without that change having been foreseen in the manufacturer's initial risk assessment; and

(ii) changes the nature of the hazard, creates a new hazard or increases the level of risk."

[8] Deutscher Bundestag, *Entwurf eines Gesetzes zur Moder.nisierung des Produkthaftungsrechts (Regierungsentwurf)* (December 2025), §§ 5, 8(2), 9(4).

person who substantially modifies a product without the manufacturer's consent becomes the manufacturer of the modified product, while Section 8(2) clarifies that a manufacturer retains control, and therefore remains liable, where it consents to such modifications. Significantly, the German Act also provides a modular defence under Section 9(4), allowing the modifier to escape liability for defects relating to parts of the product unaffected by the modification, a direct implementation of the rPLD's exemption for modifiers who can prove that the damage is unrelated to the modified component.[9]

The German implementation process illustrates that even within a single Member State, the precise contours of substantial modification remain contested. In its statement of October 2025, the European Justice Forum (hereafter the EJF) proposed a significant tightening of the definition set out in § 5(2) of the Government Draft. While the draft requires that a modification be substantial where the nature of the hazard changes, a new hazard arises, or the risk level increases, the EJF argued that this threshold is set too low. Grounded in the principle *de minimis non curat praetor* (the law does not concern itself with trivialities), the EJF recommended that each of these elements be qualified by the requirement of significance: the nature of the hazard must change *significantly*, a *significant* new hazard must arise, or the risk level must increase *significantly*.[10] This proposal reflects industry concerns that the current draft may capture minor or routine modifications, such as small software updates or adaptations that do not materially alter the product's safety profile, under the substantial modification regime, thereby exposing modifiers to strict liability for changes that are not genuinely transformative. The EJF's intervention underscores that the rPLD's delegation of definitional criteria to product safety law does not resolve all interpretive questions; rather, it shifts the debate to how those criteria are operationalized at the national level, where competing interests seek to calibrate the threshold between capturing genuinely new products and preserving a space for routine maintenance and incremental improvement.[11]

The abovementioned clearly shows that the precise scope of substantial modification remains contested among legislators and scholars. Another aspect was contested in the phase of the proposal of rPLD discussions when the European Law Institute had cautioned that the term "substantial modification" as originally proposed did not clearly encompass refurbishment, noting that refurbishment aims to restore a product to its original quality while a substantial modification pursues fundamentally different goals (European Law Institute, 2023). Recital 39 provides interpretive context for Article 4(18), affirming that when a product is substantially modified and thereafter made available on the market, it is considered a new product, while repairs and other operations that do not involve substantial modifications remain outside the Directive's liability scope.[12] On the other hand there are views that acknowledge the conceptual distinction between repair, refurbishment, and remanufacturing but also conclude that for liability purposes, the effect is the same**:** all three can constitute substantial modification if they meet the criteria of Article 13(3) GPSR. According to the same doctrine, a fundamental challenge in determining substantial modification lies in the tension between the GPSR's requirement that modifications be performed outside the consumer sphere and the reality that refurbishment and remanufacturing are typically carried out by commercial operators precisely because consumers commission such services, creating a gap where interventions intended to extend product life cycles may fall outside the substantial modification framework while simultaneously triggering manufacturer liability under the rPLD's distinct definitional approach (Grau, 2024).

3.4. The artificial intelligence act (AI Act)

The AI Act defines substantial modification in Article 3(23) as: "*a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed*." This definition differs from the GPSR formulation in several key respects. First, it is anchored in the conformity assessment framework rather than the risk assessment framework. The critical question is whether the change was "foreseen or planned in the initial conformity assessment", a forward-looking determination that gives providers the ability to pre-approve anticipated changes and thereby avoid reclassification. Second, the trigger for substantial modification is either (a) an effect on compliance with the requirements of Chapter III, Section 2, or (b) a modification to the intended purpose. Article 43(4) provides a crucial clarification: "*For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation … shall not constitute a substantial modification*."

Article 96(1)(c) of the AI Act explicitly mandates the Commission to develop guidelines on the practical implementation of the provisions related to substantial modification. The Medical Device Coordination Group, in its June 2025 guidance on the interplay between the MDR and the AI Act, confirms that "substantial modification" is an autonomous concept under the AI Act but does not provide a corresponding definition under the MDR. The guidance acknowledges that further assessment is needed to determine how the AI Act's definition applies to medical devices, and explicitly states that pre-determined changes assessed at the time of conformity assessment do not constitute a substantial modification under the AI Act, while leaving open whether such changes would trigger a new conformity assessment under the MDR.[13]

4. Health institution and healthcare professional's liability

For the purposes of this analysis, the term health institution is used to denote the legal person, whether public or private, whose primary purpose is the care or treatment of patients, as defined in Article 2(36) of the MDR. This term distinguishes the organizational entity capable of assuming legal personality and economic operator status from the natural persons (healthcare professionals) who act within its framework.

Based on the previous author's research, healthcare professional liability for AI use in the EU is governed by a tripartite, layered system derived from few core legal instruments: the preventive and compliance-based Regulatory Threshold (AI Act, MDR, GDPR), the fault-based Professional Threshold (national malpractice law), and the strict liability Product Threshold (rPLD). This framework demonstrates that liability is not monolithic but conditional and role-dependent: it migrates between fault-based professional standards and strict producer liability based on whether the professional acts as a user, overseer, or substantial modifier of the AI system. Consequently, the same individual can face different liability regimes, from negligence for inadequate oversight to

[9] Deutscher Bundestag, *Regierungsentwurf Produkthaftungsrecht* (December 2025), § 5, 8 and 9.

[10] European Justice Forum (EJF), *Stellungnahme zum Entwurf eines Gesetzes zur Modernisierung des Produkthaftungsrechts, hier zum Gesetz über die Haftung für fehlerhafte Produkte (ProdHaftG)*.

[11] Ibid.

[12] 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, Recital 39.

[13] Medical Device Coordination Group (MDCG) & Artificial Intelligence Board (AIB), *Interplay between the Medical Devices Regulation (MDR) &* In vitro *Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA)*, MDCG 2025–6 / AIB 2025–1, June 2025, p. 23.

strict liability for unauthorized modifications, depending on their specific interaction with the technology (Ampovska, 2026). On the other hand, liability for harm caused by medical AI is not concentrated on a single actor but is distributed across multiple parties, including developers, health institutions, and individual practitioners, with the allocation of responsibility shaped by how the AI system is developed, acquired, and integrated into clinical workflows. For example, when a health institution system co-develops an AI system, trains it on its own patient data, or develops the technology entirely in-house, the institution assumes a role beyond that of a mere user, which fundamentally alters the legal landscape of accountability (Price II et al., 2024). This is a foundational principle recognized across EU member states: that health institutions assume independent responsibility for the organizational decisions that determine how medical technologies are integrated into clinical practice, including the selection of devices, the training of personnel, and the design of supervision protocols that can either mitigate or exacerbate the risks inherent in AI-enabled medical products. Existing researches emphasize that this institutional responsibility operates alongside individual professional liability, creating a dual framework in which the same patient injury may give rise to claims against both the treating practitioner for deviation from the *lex artis* and the medical center for systemic failures in device management, a principle that aligns with the broader EU trend toward allocating liability to the actor best positioned to prevent harm (Servera, 2023).

4.1. Analises of Article 8 of the rPLD

The legal mechanism that operationalizes this dual framework is found in Article 8 of the revised Product Liability Directive. Under this provision, any natural or legal person that substantially modifies a product outside the original manufacturer's control and thereafter makes it available on the market or puts it into service shall be considered a manufacturer of that product for the purposes of strict liability. This provision is significant because it does not distinguish between individuals and institutions: both a healthcare professional acting in their personal capacity and a health institution acting as an organization can cross the threshold from user to manufacturer if their actions constitute a substantial modification. The rationale underlying this allocation is well-established in comparative legal scholarship. As researchers observe in the US context, liability should migrate toward the actor with the greatest capacity to coordinate, monitor, and integrate medical technologies into clinical workflows, the actor that can see the "big picture" and implement systemic safety improvements that transcend individual practice (Price II et al., 2024, pp. 357–360). Similarly, on EU grounds researchers note that within the EU framework, health institutions are better positioned than individual practitioners to manage the risks associated with medical devices through systematic oversight, aggregate data analysis, and organization-wide risk management measures, yet individual professionals retain direct responsibility when their personal conduct falls below the accepted standard of care (Servera, 2023).

As we mentinod earlier, the European Commission is required to develop guidelines on the practical implementation of the provisions related to substantial modification. As of July 2026, these guidelines have not yet been issued. The Medical Device Coordination Group has acknowledged that once such guidelines are published, further assessment will be necessary to determine their application to medical devices.[14] The absence of formal Commission guidance means that the interpretation of substantial modification currently rests on the legal texts themselves and scholarly analysis, including the examination undertaken in this paper.

In our view, the application of the provision under Article 8 can be analyzed through a combination of objective and subjective criteria. Objective criteria concern the modification itself and the circumstances surrounding it. First, the modification must be substantial, a determination that, as Recital 39 clarifies, is made according to criteria laid down in relevant Union and national product safety law, including Regulation (EU), 2023/988. Where no such criteria exist, modifications that change the original intended functions of the product, affect its compliance with applicable safety requirements, or change its risk profile are considered substantial. Second, the modification must occur outside the original manufacturer's control**.** This objective element distinguishes between modifications that are authorized or integrated by the manufacturer, in which case the original manufacturer remains liable, and those undertaken independently by downstream actors, who then assume manufacturer status. Third, the modified product must be made available on the market or put into service after the modification, a requirement that situates the liability trigger within the commercial or operational life of the product rather than in purely private or non-commercial contexts.[15] Subjective criteria concern the identity of the modifier. Article 8 applies to both natural persons (healthcare professionals) and legal persons (health institutions). When an individual professional performs a substantial modification that professional assumes personal manufacturer liability, transforming from a user subject to fault-based standards into a producer subject to strict liability. When a health institution performs a substantial modification, the institution assumes manufacturer status.

However, a critical clarification is necessary regarding the scope of Article 8 of rPLD. Substantial modification requires an actual transformation of the product, a physical or digital alteration that changes the product's safety features, risk profile, or functionality in a manner not foreseen in the manufacturer's initial risk assessment. Mere off-label use, even where it deviates from the intended purpose, does not constitute a substantial modification. Such use falls within the concept of foreseeable or known misuse and remains governed by product safety law and, where harm occurs, by fault-based professional liability under national law. Consequently, a healthcare professional who merely uses an AI system outside its intended clinical purpose, without altering the system itself, does not become a manufacturer under Article 8. Liability for such off-label use, if any, would be determined under national medical malpractice law, requiring proof of fault (deviation from the lex artis). By contrast, a professional or institution that undertakes an actual transformation of the AI system, such as retraining the algorithm, modifying the software, or physically altering the device, may cross the Article 8 threshold and assume strict manufacturer liability. The distinction between substantial modification and mere use outside intended purpose finds support in the negative definitions scattered across EU legal instruments. Under the MDR, for instance, Article 16(2) explicitly excludes the provision of information and changes to outer packaging from the concept of modification, confirming that only alterations affecting a device's compliance or safety characteristics trigger manufacturer obligations. Similarly, the GPSR excludes modifications made by consumers themselves from the definition of substantial modification, though authors critique this limitation as unduly narrow (Grau, 2024). Read together, these provisions establish a clear negative boundary: activities that leave the product's physical and digital integrity intact including off-label use that does not involve retraining algorithms, modifying software, or physically altering devices do not constitute substantial modification under the rPLD.

[14] Medical Device Coordination Group (MDCG) & Artificial Intelligence Board (AIB), *Interplay between the Medical Devices Regulation (MDR) &* In vitro *Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA)*, MDCG 2025–6 / AIB 2025–1, June 2025, p. 23.

[15] 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, Article 8.

4.2. Exemptions from liability under rPLD

The preceding analysis of Article 8 established when a healthcare professional or health institution crosses the threshold from user to manufacturer. However, Article 8 alone does not determine the full scope of liability. It must be read together with Article 11 of the rPLD, which provides exemptions from liability. The joint application of these provisions creates a systematic framework for allocating responsibility between the original manufacturer, the modifier, and other economic operators. Article 11(1)(g) rPLD provides the most directly relevant exemption for modifiers: a person who modifies a product under Article 8 (2) shall not be liable if they prove that "*the defectiveness that caused the damage is related to a part of the product not affected by the modification.*" This provision establishes that the modifier assumes liability only for defects arising from the modified part of the product. The original manufacturer remains liable for defects in unmodified parts, subject to the general defences in Article 11(1)(a)-(f). Article 11(2) rPLD imposes an important limitation on the general defence in Article 11(1)(c) (which allows the manufacturer to escape liability by proving the defect arose after placement). Where the defectiveness is due to a related service, software (including updates or upgrades), the lack of necessary security updates, or a substantial modification of the product, the economic operator cannot rely on the defence that the defect did not exist at the time of placement, provided these elements are within the manufacturer's control. This provision effectively creates a continuing obligation for manufacturers to maintain product safety through updates, even after the product has been placed on the market.[16] While Article 11 (2)(b) excludes software-related defects from the later defect defence, the development risk defence (Article 11(1)(e)) remains available. This creates an originary defect recharacterisation incentive whereby manufacturers, including those who become manufacturers through substantial modification, may argue that the defect was present from the outset but unknowable, thereby escaping liability that the software exclusion was designed to impose (Parziale, 2025).

In addition to this understanding, health institutions that act as importers, authorized representatives or fulfilment service providers are "economic operators" under the rPLD. When a health institution installs or authorizes a software update to a medical device that constitutes a substantial modification (e.g., a new AI algorithm that changes clinical performance), the device is treated as newly placed on the market, and liability for any resulting harm falls on the party who performed the modification. If the health institution itself makes the change, it must demonstrate that the damage is unrelated to the modified component to obtain exemption (European Commission, 2022). Moreover, manufacturers cannot avoid liability for failures to provide necessary security updates; thus, a health institution that relies on outdated software may still claim compensation from the manufacturer, because the defect is attributed to the manufacturer's omission rather than the health institution's use (European Commission, 2022, pp. recital 37–38).

To illustrate the operation of Article 8 rPLD and the modular defence under Article 11(1)(g), we created the following hypothetical scenario that reflects emerging patterns in clinical AI deployment. A European hospital purchases a CE-marked AI system for detecting lung nodules on CT scans. The manufacturer's intended purpose is for the AI to be used on the general population. The system is Class IIb under the MDR and, consequently, a high-risk AI system under the AI Act. The hospital's radiology department, concerned about the AI's performance on its predominantly elderly, high-risk patient population, retrains the algorithm on 5000 local CT scans. The hospital then redeploys the modified AI system into clinical practice. Six months later, the modified AI fails to detect a nodule in a 72-year-old patient. The patient's cancer progresses undetected, resulting in significant deterioration in health and the patient brings a claim. The first question is whether the hospital's retraining constitutes a "substantial modification" under the GPSR, to which the rPLD defers (Article 4(18)(a) rPLD; Recital 39 rPLD). In the scenario all three criteria are satisfied (not foreseen in initial risk assessment, new hazard / increased risk and not made by consumers). The modification is "substantial" under the GPSR. This is not mere off-label use because the hospital did not simply use the AI differently but it transformed the product through retraining. The hospital becomes a de facto manufacturer under Article 8(2) rPLD. The hospital cannot invoke Article 11(1)(g) to escape liability. Under that provision, a modifier is not liable if the defect relates to a part of the product not affected by the modification. The defect—bias introduced during retraining—relates directly to the modified part. Article 11(1)(g) does not provide a defence because the hospital cannot prove the damage was unrelated to its modification. The burden is on the hospital to establish that the damage was unrelated to the modified part. This scenario thus demonstrates how the rPLD achieves its intended allocation of risk: the party with the highest degree of control over the AI system's final safety configuration bears the liability.

4.3. Relationship between article 8 of the rPLD and national medical liability regimes

The relationship between Article 8 of the rPLD and national medical liability is best understood through the principle of functional separation. Article 8 refers to the act of substantial modification that creates a new product risk, imposing strict liability on the modifier (whether individual or institution). National professional liability, by contrast, refers to the conduct of care, imposing fault-based liability on healthcare professionals who deviate from the *lex artis* and the standard of care. As the Court of Justice established in Commission v. Denmark (Case C-327/05),[17] the Product Liability Directive is fully harmonising and exhaustive as to strict product liability. Member States may not introduce strict liability regimes that go beyond those provided in the Directive. Denmark adopted national legislation that made intermediaries in the distribution chain liable under the same conditions as a manufacturer. By adopting and maintaining in force provisions which make intermediaries in the distribution chain liable under the same conditions as a manufacturer, contrary to Article 3(3) of 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, the Kingdom of Denmark has failed to fulfil its obligations under that directive. This judgment confirms the full harmonisation nature of the Product Liability Directive.

The principle of full harmonisation affirmed in Commission v Denmark now underpins Article 3 of the rPLD, which expressly prohibits Member States from introducing or maintaining divergent strict liability regimes, while Article 2(4)(b) preserves national fault-based liability rules - a distinction that remains central to determining when a healthcare professional's modification of an AI medical device crosses the threshold into manufacturer liability under Article 8(2).

5. Conclusions

The analysis confirms that an AI system qualifies as a medical device under the MDR when its intended purpose is medical, with software expressly included and the AI Act layering high-risk classification on top. While no fundamental contradiction exists between the two instruments, a gap remains: the precise clinical evidence and transparency requirements for AI-enabled medical devices are still not fully

[16] 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, Article 11.

[17] Judgment of the Court of Justice (First Chamber) of 05 July 2007, *Commission of the European Communities v Kingdom of Denmark*, Case C-327/05, ECLI:EU:C:2007:409, paragraphs 24–27.

harmonised. For the purposes of this paper, however, the essential baseline is established: an AI medical device is a product with a declared medical purpose, subject to conformity assessment, and its safety parameters are fixed at the moment of placing on the market. Turning to substantial modification, four instruments approach the concept from different angles. The MDR addresses it indirectly through significant changes and modifications affecting compliance. The GPSR provides the most detailed definition, requiring three cumulative criteria: unforeseeability in the initial risk assessment, alteration of hazard characteristics or risk level, and performance by a party other than the consumer. Article 4(18) rPLD establishes a two-tier definition: a deferential definition that incorporates product safety law (Article 4(18)(a)), and an autonomous residual definition that applies where product safety law provides no threshold (Article 4(18)(b)). For medical AI devices, the GPSR and MDR provide thresholds, so the autonomous definition is not triggered. The rPLD thus remains definitionally dependent on the GPSR and MDR for medical AI devices.

The AI Act defines substantial modification through the conformity assessment framework rather than the risk assessment framework, creating a divergence: the GPSR asks whether the change was foreseen in the original risk assessment, while the AI Act asks whether it was foreseen in the original conformity assessment. The result is a layered and not fully unified definitional landscape.

With the definitional framework established, the analysis then turns to Article 8 of the rPLD. The provision does not distinguish between natural and legal persons. Both a healthcare professional and a health institution can become manufacturers if they substantially modify a product. The objective criteria are three: the modification must be substantial (assessed under the GPSR criteria), it must occur outside the original manufacturer's control, and the modified product must be made available on the market or put into service. The subjective criterion is the identity of the modifier. A critical boundary separates actual transformation of the product, which triggers Article 8, from off-label use, which does not. Healthcare professionals who merely use an AI system outside its intended purpose, without altering the system itself, remain within national fault-based liability. Those who retrain algorithms, modify software, or physically alter devices cross the threshold. The joint application of Articles 8 and 11 establishes modular liability where under Article 11(1)(g), the modifier is liable only for defects arising from the modified part, while the original manufacturer remains liable for unmodified parts. Article 11(2) prevents manufacturers from escaping liability for software-related defects by claiming they arose after placement.

The paper set out to determine when a health institution's or healthcare professional's interaction with an AI-enabled medical device constitutes a substantial modification under the rPLD. The answer flows from the analysis. Substantial modification is defined by the GPSR criteria. Article 8 then attaches liability consequences to that finding. The threshold is crossed when the professional performs an actual transformation of the product, physical or digital, that changes its safety features, risk profile, or functionality in a manner not foreseen in the manufacturer's initial risk assessment, outside the manufacturer's control, and followed by making the product available on the market or putting it into service. Mere off-label use does not qualify and routine clinical judgment does not qualify as well. But retraining an algorithm, installing unauthorized software, or integrating the system into clinical workflows in ways that alter its safety baseline does. At that moment, the healthcare professional or health institution crosses the threshold and becomes a de facto manufacturer, subject to strict liability under the rPLD. This outcome will not occur in most clinical interactions, but when it does, the legal consequences are significant and remain largely unexplored.

CRediT authorship contribution statement

Marija Ampovska: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

Ampovska, M. (2026). *Thresholds of agency in medical artificial intelligence: A liability framework for healthcare professionals under European Union law* (pp. 109–127). Vestnik of Saint Petersburg University. Law 1.

Carl, N., & Hochmann, N. (2023). Impact of the new European medical device regulation: A two-year comparison. *Biomedical Engineering*, 1–10.

DuPreez, J. A., & McDermott, O. (2025). The use of predetermined change control plans to enable the release of new versions of software as a medical device. *Expert Review of Medical Devices, 22*(3), 261–275.

European Commission. (2022). Explanatory memorandum to the proposal for a directive on liability for defective products. From https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0495.

European Law Institute. (2023). *European Commission's proposal for a revised product liability directive: Feedback of the European law institute*. Vienna: European Law Institute (in Vienna).

Fraser, A. G., Biasin, E., Bijnens, B., Bruining, N., Caiani, E. G., Cobbaert, K., & Vasey, B. (2023). Artificial intelligence in medical device software and high-risk medical devices – A review of definitions, expert recommendations and regulatory initiatives. *Expert Review of Medical Devices, 20*(6), 467–491.

Grau, I. (2024). Producer liability for substantial modification of products through repair, refurbishment and remanufacturing. *European Review of Private Law, 32*(1), 9–40.

Haimerl, M., D'Agosto, M., Fornefett, M., Kubon, M., & Schiepp, T. (2026). Deficiencies of the EU medical device regulation when applying its own rules. *Frontiers in Medicine, 12*, 1–18.

Heikkonen, S., & Havu, K. (2023). Liability for medical devices – How clear and harmonised is it? *Europarättslig tidskrift*, 651–668.

Nüssler, A. (2023). The new European medical device regulation: Friend or foe for hospitals and patients? *Injury, 54*.

Parziale, A. (2025). AI-powered medical devices and the development risk defense under the revised product liability directive. In *, 7. Enabling and safeguarding personalized medicine. Data science, machine intelligence, and law* (pp. 279–291). Springer.

Price, N., II, Gerke, S., & Cohen, G. (2024). Liability for use of artificial intelligence in medicine. In *Research handbook on health, AI and the law* (pp. 149–168). Cheltenham: Edward Elgar.

Servera, P. G. (2023). La responsabilidad (civil o patrimonial) del personal médico, de los centros sanitarios y de las administraciones sanitarias por los daños causados por un producto sanitario defectuoso. *Bioderecho.es, 17*, 10–15.

Solaiman, B., & Malik, A. (2025). Regulating algorithmic care in the European Union: Evolving doctor–patient models through the artificial intelligence act (AI-Act) and the liability directives. *Medical Law Review, 33*, 1–22.

Svempe, L. (2024). Exploring impediments imposed by the medical device regulation EU 2017/745 on software as a medical device. *JMIR Medical Informatics, 12*, Article e58080.

The Medical Device Coordination Group (MDCG). (2025). *Guidance on qualification and classification of software in regulation (EU) 2017/745 – MDR and regulation (EU) 2017/746 – IVDR*. European Commission.

Wendehorst, C., & Duller, Y. (2023). Safety and liability related aspects of software. In *Civil liability for artificial intelligence and software* (pp. 185–318). Berlin, Boston: De Gruyter.

Legal sources and guidelines

Directive (EU). (2024). *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, OJ L 2853*.

Regulation (EU). (2017). *2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117*.

Regulation (EU). (2023). *2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 and Directive (EU) 2020/1828, and repealing Directive 2001/95/EC and Council Directive 87/357/EEC, OJ L 135*.