

THE NEW EUROPEAN UNION LEGAL FRAMEWORK ON DEFECTIVE DIGITAL MEDICAL DEVICES: ALLEVIATING THE PATIENT'S BURDEN OF PROOF

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Abstract Digitalisation has changed the medical sector, introducing sophisticated digital medical devices (such as software as a medical device and devices assisted by Artificial Intelligence systems). Innovations in medicine present potential for improving diagnosis and treatment. Simultaneously, they raise certain questions about civil liability and the legal position of the patient who has suffered harm caused by a defective digital product. This paper examines whether the modernized EU liability rules for defective digital medical devices can alleviate the evidentiary burden patients face in civil litigation, thus strengthening their position. The author focuses on the adequacy of the new rules on disclosure of evidence and burden of proof. The key findings show that the new rules strengthen patients' position by alleviating the burden of proof and imposing an obligation to disclose relevant evidence. The author proposes drafting guidelines to resolve existing ambiguities, ensuring the new evidentiary framework is applied consistently and effectively.

Keywords

burden of proof,
defective digital medical
device,
Directive (EU)
2024/2853 on liability
for defective products,
disclosure of evidence,
patient

1 Introduction

The application of digital technologies in medicine offers many benefits. At the same time the use of digital medical devices can present risks to life, health, or property. Digitalization is perceived as the main factor in the global transition from traditionally industrial to digital, based on technology model (Zhao, Wallis & Singh, 2015, p. 734). It has been noted that the COVID-19 pandemic further accelerated the digital transformation of healthcare (Wickramasinghe, 2024, p. 2). AI systems are often believed to be able to make decisions faster and more accurately than human practitioners. This has led to their widespread implementation across the medical field (Devenney & Howells, 2025, p. 118). AI applications and other digital technologies are often recognized to be able to significantly improve healthcare, making delivery more efficient, accurate, and personalized (Steinhauser, 2025, p. 87). However, like any powerful technological change, digitalisation introduces significant risks and perils associated with the use of defective digital medical products. One such risk is the risk of harm a patient may suffer due to a defective digital medical product. Under such circumstances, the existing product liability system was increasingly struggling to keep pace with rapid technological development. This has created significant legal inconsistencies and uncertainty in this specific legal area (Gsell & Mayrhofer, 2025, p. 205).

The European legislator identified the need for reform, given recent tech advances, new circular economy business models and new global supply chains. Therefore, the European Union has recently established a comprehensive regulatory framework consisting of the Medical Devices Regulation,¹ Regulation (EU) 2024/1689,² Product Liability Directive³ and Regulation (EU) 2024/2847 on cybersecurity for products with digital elements⁴ and AI Act to govern the safety and accountability

¹ 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 (hereinafter: MDR).

² 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, 2024/1689 (hereinafter: AI Act).

³ 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, 2024/2853 (hereinafter: PLD).

⁴ Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) OJ L, 2024/2847 (hereinafter: CRA).

of digital medical devices. The new PLD came into force in 2024. The Member States must implement the new PLD rules into their national laws by December 2026. Patients currently face significant hurdles when claiming compensation for defective medical devices. These difficulties stem from restrictive rules and the complexity of proving liability, especially new technologies (Recital 3, PLD). To address this, the PLD introduces major reforms. Among its key changes are mechanisms of disclosure of evidence and rebuttable presumptions regarding defect and causation. The new measures are aimed at adjusting the standard of proof to be less demanding for the patient as a claimant.

There is a significant existing literature on defective product liability in the EU. The aim of the paper is to complement the field by employing both normative dogmatic and comparative methods. This paper examines whether modernized EU rules on liability for defective digital medical devices can ease the evidentiary burden patients face in civil litigation. It provides a critical assessment of the former and current regulatory frameworks for defective digital medical devices. By comparative analysis of the European Union and Croatian case law, the paper also examines judicial standards of interpretation concerning the patient's evidentiary burden and the legal definition of product defectiveness. The central part of the paper examines the newly enacted mechanisms for the disclosure of evidence and rebuttable presumptions, providing a comparative analysis of the standard of proof under the previous and new PLD regimes. Implementation challenges and potential legal uncertainties surrounding these mechanisms are also being addressed. Finally, the concluding section of the paper synthesizes the key findings of this research.

2 Legal Framework for Medical Digital Products

2.1 Digital Medical Devices Under the MDR

A regulatory framework in the European Union was developed to guarantee that medical devices meet safety and performance standards before being placed on the market. In the European Union, the governance of medical products is primarily managed by MDR. This regulation established stringent new rules focusing on enhancing the safety, traceability, and overall compliance of medical devices throughout Europe. These regulations are typically structured around the risk a device poses to the patient. The framework is designed to guarantee patients access

to high quality, safe, and effective devices. In the European Union, this is achieved through an integrated system of premarket safety requirements and post market monitoring and reporting duties, whereby the responsibility for safety and reporting is shared among manufacturers, certification organizations, and competent national authorities (Cappelli, 2024, p. 531). The MDR defines a medical device as any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used for medical purposes such as diagnosis, prevention, monitoring, treatment, or alleviation of disease (MDR, Article 2(1)). It requires that all medical devices meet the general safety and performance requirements detailed in Annex I.⁵ Devices must be designed and made to perform as intended without jeopardizing the safety of patients or users. Furthermore, the regulation enhances transparency and traceability through provisions like the mandatory Unique Device Identification (UDI) system (Article 27), ensuring authorities and the public have better access to vital device information and post-market surveillance data.

Regulation (EU) 2017/746,⁶ or the In Vitro Diagnostic Medical Device Regulation (hereinafter: the IVDR), represents a revision of the European Union's legal framework of in vitro diagnostic products that imposes stricter requirements for the safety and efficacy of those products. The legislation requires specified person that would be responsible for compliance. Compliance is a prerequisite for institutional accountability. The IVDR introduces the Unique Device Identification (UDI) marking system to enhance transparency and traceability throughout the whole healthcare sector. It also mandates registration within the European Database on Medical Devices (EUDAMED),⁷ and the adoption of common specifications. What is more, manufacturers are liable to higher standards of maintaining clinical evidence and post market surveillance under the new rules of the IVDR.

⁵ MDR, Annex I, Section 3.

⁶ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) OJ L 117.

⁷ EUDAMED is, under Article 30 IVDR, a centralized secure IT system designed to improve transparency, traceability, and coordination of information regarding medical devices, including in vitro diagnostics on the European Union market.

In 2025, the European Commission introduced a new regulatory proposal aimed at simplification of the existing MDR and IVDR. This initiative, which represents the most significant reform since the original adoption of these regulations, is designed to make the regulatory environment more efficient, agile, and digital-first while maintaining a high level of patient safety. As a core component of the broader Choose Europe for Life Sciences⁸ strategy, the reform seeks to bolster the European Union's global standing. For the pharmaceutical and biotech sectors, this transition promises a substantial reduction in administrative hurdles, particularly for the development of companion diagnostics and combination products. Moving forward, the proposal will enter the ordinary legislative procedure, where it will undergo review and potential amendment by the European Parliament and the Council. The European Union has established a comprehensive and symbiotic regulatory framework consisting of the PLD, the CRA, and the AI Act to govern the safety and accountability of high-risk AI systems and other digital medical devices. The AI Act sets a foundational standard for safety and quality, while the revised PLD ensures that failures to meet this standard result in effective compensation for injured patients. The PLD and the AI Act complement the MDR, as discussed in the next section.

3 The MDR'S Interplay with Other European Union Regulations

3.1 New Liability Rules for Defective Products Under the PLD

The New PLD represents a fundamental overhaul of European product liability rules, replacing the outdated Directive 85/374/EEC (hereinafter: PLD 1985).⁹ The PLD aims to address the shortcomings of PLD 1985 and to modernize the European Union's product liability law. That way the rules would become relevant for the digital age, circular economy practices, and suitable to complex global supply chains (De Luca, 2023, p. 1). It is suggested that the new PLD modernizes and broadens the liability framework but retains the core principle of strict producer defective product liability (Masnada et al., 2024). The new PLD addresses several

⁸ Choose Europe for Life Science is a flagship strategy launched by the European Commission in July 2025. It serves as a comprehensive roadmap to restore Europe as a global leader in health, biotechnology, and medical technology by the year 2030. Retrieved from: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en (accessed: December 30, 2025).

⁹ 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, OJ L 210.

key questions. The questions include the classification of software as a product, liability distribution within complex supply chains, and the mitigation of procedural hurdles for patients (Devetzis, 2025, p. 112). The new legislation expands the definitions of both product and product defectiveness to better adjust to product digitalisation. The new PLD, therefore, allows to hold manufacturers liable for damages caused by an AI based defective product (Asensio, 2024, p. 89). Under the PLD 1985 product was defined unfairly narrow, essentially as movable goods and electricity (Lee & Schutte, 2023, p. 592). The new PLD's expanded product definition now captures many digital features of the product. It encompasses software (from standalone mobile apps to embedded operating systems) and an AI system, independently or as integrated components. The definition further encompasses digital production files, provided they contain the functional information required to manufacture a physical item. It also covers digital connected services that are so integral to a product that it would lose its core functions without them.

PLD integrates cybersecurity failures directly into the definition of defectiveness. A product is, therefore, considered defective if it does not provide the safety level a person is entitled to expect, considering, among other factors,¹⁰ the cybersecurity requirements and features of the product (Article 7(2)(f)). This liability is not limited to the point of sale. Manufacturers are also liable if the defect is caused by a failure to provide necessary software updates or upgrades, including addressing cybersecurity vulnerabilities, where they retain control over such updates (Article 7(2)(e)). This aligns with the obligations established in The MDR Annex I establishes obligation for manufacturers to manage information security to prevent any unauthorized access. While the core definition of defectiveness remains somewhat vague (Howells, Spindler & Wilhelmsson, 2020, p. 150), others argue that the product definition is just as ambiguous. Such ambiguity is unavoidable because judges must assess each situation on an individual basis (Machnikowski, 2024, p. 42).

The PLD expands manufacturer liability for defective digital products. Manufacturers can now be held accountable for damage resulting from a product defect caused by insufficient cybersecurity, thereby encompassing the risks of the

¹⁰ Article 7 of the PLD also defines other criteria for determining whether a product is defective. These criteria include an assessment of its design, labeling, foreseeable use, and any post-market updates or interconnections with other products. A product is not considered defective because a newer or superior version has been released.

contemporary digital environment. Furthermore, liability is no longer limited to the moment the product is placed on the market, it also extends to failures in issuing software updates or upgrades if these failures subsequently cause a defect. Regarding compensation, the PLD, for the first time, ensures that the destruction or corruption of data used for private purposes caused by a defective digital product is now recoverable damage. In this way, the PLD ensures the application of the principle of strict liability across the entire supply chain, consistently integrating digital elements which are an integral part of nearly every modern product into the legal liability framework. Additionally, the minimum financial threshold of €500 for property damage is abolished, making it easier to pursue damages, including potential mass actions. Simultaneously, the list of entities strictly liable for damages has been substantially expanded; in addition to manufacturers and importers, it now includes fulfillment service providers and online platforms in cases where they mislead consumers about the identity of the actual supplier. This expanded liability aims to hold all relevant economic operators accountable, especially given the continuous nature of digital products, where manufacturers retain control even after the initial placement on the market through updates. The PLD also introduces a significant change that, in our opinion, weakens the development risk defense for manufacturers (Article 11(e) of the PLD). The development risk defense, or the unknown risk exception is the manufacturer's argument that the defect was unknowable at the time the product was placed on the market, given the state of scientific and technical knowledge. The new PLD still lists the development risk defense as one of the circumstances where a manufacturer is exonerated from liability. However, the new PLD explicitly allows Member States to decide whether to retain or abolish this defense when transposing the PLD into national law. If a Member State chooses to abolish it, a manufacturer operating in that country would be subject to absolute strict liability, removing this key defense completely (Article 18 of the PLD). This optionality presents a significant issue, as it leads to legal fragmentation across the EU, potentially subjecting manufacturers to different liability standards depending on the Member State. Ultimately, the construction of Article 18 of the PLD can be interpreted as a compromise between individual protection and the need for scientific innovation. It principally preserves the development risk defense, but its optional nature might result in unnecessary legal fragmentation. This lack of full harmonization is a deficiency that needs to be addressed. In our opinion, such fragmentation undermines the goal of an internal single market and creates uncertainty for both consumers and producers.

The PDL operates in parallel with existing national contractual and non-contractual liability rules as it is not intended to replace them. Consequently, individuals harmed by defective medical devices may choose to seek compensation through national legal system. Because of this, we expect that the actual legal outcome will, in the future, still vary considerably, depending on which country the claim was filed in.

3.2 Cybersecurity as an Essential Digital Medical Devices Safety Requirement

The CRA makes cybersecurity an essential part of product safety for all digital devices. This new requirement works in tandem with the expanded definition of a defective product found in the PLD. Once the CRA has full effect, manufacturers must guarantee that every product with a digital element is protected against cyber threats. Some experts argue that under the CRA manufacturers now must incorporate strong cyber protection onto digital products. This should be based on potential risk assessment. Crucially, they must also provide regular updates to those cyber protections to maintain continuous product cyber security (Schoo, 2024, p. 245). The digital transformation in medicine resulted in a complex system of interconnected digital devices. While such digital medical product connectivity offers enhanced precision, it simultaneously introduces new risks of physical harm to patients' health and life. In this context, the CRA mandates are not just another technical feature. They are crucial for the patient's safety. Under Article 6 of the CRA and Annex I, product safety now includes security by design, the elimination of exploitable vulnerabilities and the preservation of data integrity. Furthermore, the CRA requires that manufacturer manages said vulnerabilities and provide continuous security updates. Otherwise, the CRA enforces heavy fines to ensure the product's cybersecurity requirements are met.

3.3 Compliance Standards for Digital Medical Devices under the AI Act

Incorporating AI systems into medical devices promises personalized and improved healthcare for patients (Braun & Harasimiuk, 2023, p. 1). However, its integration in medical devices raises significant ethical questions that need to be addressed (Bertarini, 2023, p. 82). The AI Act supplements the MDR and introduces an additional set of standards necessary for the secure use of digital medical devices with integrated AI systems. Under the AI Act, medical devices with integrated AI

system require third-party conformity assessment (as regulated under the MDR). Such medical devices are classified as high risk, which triggers strict compliance obligations. Therefore, manufacturers must maintain a continuous product risk management system, as mandated by Article 9 of the AI Act. Failure to comply with these provisions can be directly interpreted as evidence of a defect under the new PLD. Under Article 10, the AI Act imposes strict data governance requirements. These provisions mandate high standards for training, validation, and testing datasets. Poor-quality data leads to flawed analytics, such as misdiagnosis. This can form a basis for a liability claim. Furthermore, human oversight obligations for high-risk artificial intelligence systems (Article 14 of the AI Act) as well as an obligation to maintain detailed technical documentation (Article 11 of the AI Act), record keeping (Article 12 of the AI Act) and logging capabilities (Article 19 of the AI Act) are not merely compliance paperwork for manufacturers. These provisions could represent essential pieces of evidence for plaintiffs pursuing legal action. The new PLD rules on liability supplement, but do not replace the strict safety requirements established by the MDR. The MDR ensures the *ex ante* compliance of digital medical devices with quality, safety, and performance requirements before they are even placed on the market. Failures to comply with the MDR and the CRA, therefore, will be a strong indicator of product defectiveness under the PLD. Violations of a manufacturer's obligations under the AI Act may facilitate the proof of defectiveness and causation in court, as explored further in this paper.

4 Patients' Standard of Proof Under the European Union Legal Framework on Liability for Defective Digital Medical Devices

After nearly 40 years the European Union updated its product liability framework in 2024. The new PLD aims to ease the evidentiary burden for patients when establishing manufacturer liability in compensation claims. Prior to examining how the patient's standard of proof has changed under the new PLD rules, we will provide an overview of the patient's position in court proceedings under the PLD 1985., Croatian Obligations Act¹¹ and relevant European and national case law.

¹¹ Obligations Act, Official Gazette, no. 35/2005, 41/2008, 125/2011, 78/2015, 29/2018, 126/2021, 114/2022, 156/2022, 145/2023, 155/2023.

4.1 Patients' Standard of Proof Under the PLD 1985

Moving away from traditional medical litigation that required proof of negligence, the PLD 1985 introduced a strict liability framework under Article 1, holding manufacturers accountable for damages regardless of whether intent or fault can be proven. According to some scholars, the application of the concept of manufacturer's strict liability for damage caused by a defective product, independent of fault, is the most significant innovation introduced by PLD 1985 (Misita, 2019, p. 369). This protection is supported by Article 2 of the PLD 1985, which classifies products as all movables, including those incorporated into other movable or immovable properties. The definition specifically extends to electricity.¹² Under Article 4 of the PLD 1985, the burden of proof rested on the injured patient, who had to successfully demonstrate the existence of a defect, the resulting damage, and a clear causal link between the two. However, once these elements were established, the manufacturer was held liable by default, removing the nearly impossible requirement for an individual to prove specific intent or negligence. The main practical evidentiary challenges for the injured patient were the defendant's practice of retaining technical documentation and design specifications. The patient often lacked specialized knowledge and resources to prove the defect. In the case of technically complex products or pharmaceuticals, it was virtually impossible to isolate the exact defect that caused harm. Furthermore, scientific uncertainty magnified the patient's difficult position, as it was rather challenging to prove that a specific product had caused the sustained damage in situations when there was no scientific consensus on the matter.

In several judgments, the Court of Justice of the European Union (hereinafter: the CJEU) established the use of indirect evidence and a rebuttable presumption of defect, bypassing the rigid PLD 1985 requirements associated with the burden of proof. In the *Boston Scientific case*¹³ the CJEU, exploring ways to ease the burden of proof in complex product cases, ruled that if a specific batch or model of a product

¹² In *VT v KRONE-Verlag case*, the CJEU rejected the idea that inaccurate health advice in a newspaper constitutes a "defective product" under the PLD 1985. The case concerned a physical newspaper that published inaccurate health advice regarding a herbal treatment, which subsequently caused physical injury to a reader. The CJEU reasoned that the defect must be inherent to the physical characteristics of the product itself (such as the paper or ink) rather than the intellectual content or service provided within it. Judgment of 10 June 2021, C-65/20, *VT v KRONE-Verlag Gesellschaft mbH & Co. KG*, ECLI:EU:C:2021:471, paras. 34–36.

¹³ Judgment of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, ECLI:EU:C:2015:148.

(such as a pacemaker) has a significantly high failure rate, every individual unit in that group can be legally classified as defective. Consequently, a patient does not need to prove that their specific device was actually broken or malfunctioning, the potential risk inherent to the product group is enough to establish a defect under the law.¹⁴

One of the most significant cases regarding the patient's burden of proof (under the PLD 1985) is the *W and Others v Sanofi Pasteur case*¹⁵ (C-621/15), which centered on the alleged link between a hepatitis B vaccine and the onset of multiple sclerosis. The central legal challenge arose from the lack of a definitive scientific consensus regarding the connection between the vaccine and the disease. In its ruling, the CJEU held that national courts may accept evidence based on serious, specific, and consistent indicia to establish causation. The CJEU held that if the link between the administration of a vaccine and a suspected side effect is neither proven nor disproven as a matter of medical science, then no inferences can be drawn about its existence for the purposes of adjudication.¹⁶ A requirement of scientific proof would be contrary to the objective of the PLD to apportion risks fairly between the injured person and the producer.¹⁷

European case law, as is evident from examples above, has made it considerably easier for the injured person to demonstrate a causal link between the product defect and the damage. The condition outlined by the CJEU is that such alleviation does not undermine the PLD 1985 provision that places the burden of proof on the injured person and that the free assessment of evidence by the courts must be preserved.¹⁸

The rules on liability for defective products from PLD 1985 have been transposed into the Croatian Obligations Act. Under the provision of Article 1073(1) of Obligations Act a manufacturer who places a product on the market is liable for damage caused by a defect in that product, regardless of fault. The burden of proof is regulated according to the provision of Article 1073(8) of Obligations Act, which rests with the injured patient. To be entitled to compensation for damages, the

¹⁴ *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, paras. 39-41.

¹⁵ Judgment of 21 June 2017, C-621/15, *N. W and Others v Sanofi Pasteur MSD and Others*, ECLI:EU:C:2017:484.

¹⁶ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 55.

¹⁷ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 32.

¹⁸ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 54.

patient is required to prove the defect in the product, the damage incurred, and the causal link between the product's defect and the damage. Croatian judicial practice further affirms these requirements through established interpretive standards. For instance, The County Court in Zagreb held that a patient is not required to prove the fault of the physician or the manufacturer if the damage resulted from a defective medical device. The Court accepted the existence of a causal link based on the entirety of the medical documentation and the expert witness findings. Evidence also included official correspondence and registries. The Court maintained that any challenges to the causal link that lack firm evidence do not affect the legality of the judgment. Also, the Court stated that the manufacturer's liability is based on the principle of strict liability, without the need to prove fault.¹⁹ In another case, the Supreme Court of the Republic of Croatia emphasized that the injured patient must prove the product defect, the damage, and the causal link. However, in this particular case, the claimant failed to prove that the endoprosthesis she used to be defective, nor did she prove a causal link between the defect and the resulting damage. The lack of evidence regarding the defect and the product's withdrawal from the market led to the dismissal of the claim. The Court also highlighted the importance of precisely determining the safety of the specific product in relation to its characteristics and the individual patient.²⁰

The new PLD introduces new rules regarding the disclosure of evidence in technically demanding cases and sets out rebuttable presumptions. The application of these presumptions is intended to alleviate the burden of proof for the injured patient, as it is further discussed below.

4.2 Patients' Standard of Proof Under the New PLD

The new PLD aims to place the patient in more favorable evidentiary position than under the PLD 1985 regime. While the fundamental principle of strict liability remains, the PLD introduces several mechanisms designed to overcome the difficulties patients historically faced in proving the defect, harm and the causal link. The most critical change to the patient's position is the introduction of rebuttable

¹⁹ Judgement of 3.6.2025, The County Court in Zagreb, case no. *Gž-133/2025-2*. Retrieved from: <https://www.iusinfo.hr/sudska-praksa/ZSRH2025ZgGzB133A2> (accessed: March 15, 2026).

²⁰ Judgement of 1.2.2023., The Supreme Court of the Republic of Croatia, case no. *Rev 1785/2019-2*. Retrieved from: <https://www.iusinfo.hr/sudska-praksa/VSRH2019RevB1785A2> (accessed: March 15, 2026).

presumptions regarding the defect and causation, as well as a disclosure mechanism. They are perceived as a shift in doctrine towards facilitating private enforcement of product liability-based claims (Jacquemin, 2024, p. 130). The presumption of defect (Article 10(2) of the PLD) is triggered if and when the defendant fails to comply with a court ordered disclosure obligation, or the damage results from an obvious malfunction during reasonably foreseeable use. The presumption of causation is triggered when the product is established to be defective, and the damage is of a kind typically consistent with that defect (Article 10(3) of the PLD). The patient's burden of proof is simplified in technically complex cases (Casarosa, Gennari & Rossi, 2025, p. 3). A court can presume defectiveness, causal link, or both in situations where the patient faces excessive difficulty in proving the defect or causation, (due to technical or scientific complexity of the product) and has demonstrated that the defect or causal link is likely (Article 10(4) of the PLD). The most debatable aspect of this presumption, in our opinion, is the lack of a clear definition of what constitutes excessive difficulty. Recital 48 of the new PLD does not provide closer guidelines on how this term should be interpreted. It only states that the assessment of the excessive difficulties should be made by national courts individually. This could, in our view, potentially undermine legal certainty. Similarly, some maintain that the rules on rebuttable presumptions explicitly rely on national courts to evaluate circumstances and apply presumptions discretionarily and case-by-case (Buiten, 2024, p. 241). Therefore, we believe that the issuance of interpretative guidelines regarding these vaguely defined terms would be highly beneficial. Such guidance would prevent divergent interpretations in similar cases.

The new PLD also introduces a disclosure mechanism (Article 9 of the PLD) aimed at facilitating patients' access to evidence. If a patient makes a sufficiently plausible claim for compensation, the national court can now oblige the defendant (the manufacturer) to disclose relevant and necessary evidence concerning the product's function, design, or production process. This, indeed, represents a major advantage for the patient as it forces the manufacturer to provide documents necessary to establish the defect or causation. We find these provisions particularly important for the medical digital devices sector. It is often very difficult for patients to understand or prove defects in complex digital systems, especially when technical documentation is often exclusively available to the manufacturer. The refusal to disclose evidence allows the court to presume the manufacturer's liability, serving as an effective mechanism to compel defendants to comply with disclosure orders. At

the same time, the manufacturer's obligation is limited to what is necessary and proportionate (Article 9(6) of the PLD). The legislator does not further specify the criteria for necessity and proportionality. Instead, access is limited to prevent non relevant searches and to ensure the protection of confidential data. There is, again, significant uncertainty regarding the effectiveness and the practical application of this provision. In the author's view, the lack of precision and the absence of a clear definition as to when a measure is deemed necessary and proportionate represent a significant deficiency. This ambiguity creates a risk of arbitrary interpretation and ultimately undermines legal certainty.

5 Conclusion

The use of digital medical devices enhances the accuracy of medical diagnoses and treatments by meeting the specific needs of individual patients. Thus, medicine becomes significantly more precise (Amaral et al., 2024, p. 20). However, all of this, simultaneously, exposes patients to novel risks that can result in damage. The European Union's response to the obsolescence of the product liability 1985 system was a comprehensive overhaul of its defective product liability framework. The new PLD structure is believed to permit adjustments to the new appearing risks (Steindl, 2024, p. 8). The findings of this research suggest that the new PLD, in conjunction with the MDR and the CRA strengthens the legal position of the injured patient. This is accomplished by broadening the definition of a product and its defectiveness, as well as establishing cybersecurity as a core product's safety requirement. Furthermore, the process is aided by simplifying the burden of proof in technically complex cases (Casarosa, Gennari & Rossi, 2025, p. 3). This paper examined the extent to which the modernized European Union liability regime alleviates the evidentiary burden faced by patients in civil litigation. The study showed that these updated rules effectively strengthen the patient's position by lowering the evidentiary threshold. By introducing evidence disclosure and easing the burden of proof with new rebuttable presumptions, the new PLD provides mechanisms that enhance procedural parity. Furthermore, practical implementation of these mechanisms could simplify the path for patients seeking compensation for damage caused by defective digital medical devices. Conversely, the certain ambiguity surrounding the presumptions of the burden of proof in technically complex cases may result in legal uncertainty and disparity in interpretations across national case laws. Therefore, we advocate for the introduction of guidelines on how to interpret the ambiguities

identified in certain provisions. The goal is to establish a framework that, by addressing these deficiencies, ensures the uniform interpretation of provisions and the full functionality of the new evidentiary mechanisms.

Legal Acts, Case-law

- 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 2024/2853.
- 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, OJ L 210.
- Judgement of 1 February 2023, The Supreme Court of the Republic of Croatia, *Rev 1785/2019-2*.
- Judgement of 3 June 2025, The County Court in Zagreb, *Gž-133/2025-2*.
- Judgment of 10 June 2021, C-65/20, *VI v KRONE-Verlag Gesellschaft mbH & Co. KG*, ECLI:EU:C:2021:471.
- Judgment of 21 June 2017, C-621/15, *N. W and Others v Sanofi Pasteur MSD and Others*, ECLI:EU:C:2017:484.
- Judgment of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, ECLI:EU:C:2015:148.
- Obligations Act, Official Gazette, no. 35/2005, 41/2008, 125/2011, 78/2015, 29/2018, 126/2021, 114/2022, 156/2022, 145/2023, 155/2023.
- 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.
- Regulation (EU) 2017/745 on medical devices, European Parliament and Council (2017) 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 117/1.
- 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 2024/1689.
- Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) OJ L 2024/2847.

References

- Amaral, C., Paiva, M., Rodrigues, M. R., Veiga, F. & Bell, V. (2024). Global Regulatory Challenges for Medical Devices: Impact on Innovation and Market Access. *Applied Sciences*, 14(20), 1-24.
- Asensio De Miguel, P. (2024). *Conflict of Laws and the Internet*, Second Edition. Cheltenham: Edward Elgar Publishing.
- Bertarini, B. (2023). *European Union Digital Single Market Legal Framework and Challenges*. Milano: Franco Angeli.
- Braun, T. & Harasimiuk, D. (2023). AI deployment in medical devices-ethical and regulatory reflections, beyond data protection and bias - EU perspective, *2023 IEEE Conference on*

- Computational Intelligence in Bioinformatics and Computational Biology*. Eindhoven: Netherlands, 1–6.
- Buiten, M. C. (2024). Product Liability for defective AI. *European Journal of Law and Economics*, 57, 239–273.
- Cappelli, V. (2024). Medical Device Liability. Challenges and Proposals for a Safer Regulatory Environment for Patients in the EU. *Osservatorio del diritto civile e commerciale*, 2, 531–561.
- Casarosa, F., Gennari, F. & Rossi, A. (2025). Introduction. In Casarosa, F., Gennari, F. & Rossi, A. (eds.) *Enabling and Safeguarding Personalized Medicine*. Berlin: Springer.
- De Luca, S. (2023). *New Product Liability Directive Proposal*, EPRS: European Parliamentary Research Service. Retrieved from: <https://coilink.org/20.500.12592/c0vdc> (accessed: November 11, 2025).
- Devenney, J. & Howells, G. (2025). Developing product liability networks for AI systems in the medical context. *Legal Quarterly*, 76(1), 118–139.
- Devetzis, D. (2025). The New EU Product Liability Directive. Interaction with Parallel EU Initiatives: Proposed AI Liability Directive, Digital Services Act and Digital Markets Act. In Devetzis, D., Volesevic, D. & Sotiropoulos, L. (eds.). *Digital Landscapes: Artificial Intelligence, Cybersecurity and the New European Order*. Bucharest-Paris-Calgary: ADJURIS- International Academic Publisher.
- European Commission, Research and Innovation, Strategy for European Life Sciences. Retrieved from: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en (accessed: December 30, 2025).
- Gsell, B. & Mayrhofer, A. K. (2025). The New Product Liability Directive 2024: Missed Updates or Upgrades for the Interplay with National Liability Rules and for Service Liability. *Journal of European Consumer and Market Law*, 14(5), 205 – 216.
- Howells, G., Spindler, G. & Wilhelmsson, T. (2020). *European Product Liability: Theory and Practice*. Abingdon, Oxon: Routledge.
- Jacquemin, Z. (2024). Product Liability Directive: Disclosure of Evidence, the Burden of Proof and Presumptions. *Journal of European Tort Law*, 15(2), 126–129.
- Li, S. & Schutte, B. (2023). The Proposal for a Revised Product Liability Directive: The Emperor's New Clothes? *Maastricht Journal of European and Comparative Law*, 30(5), 573– 596.
- Machnikowski, P. (2024). The Principles of European Tort Law and Product Liability. *Journal of European Tort Law*, 15(1), 31–43.
- Masnada, M., Pacciti, A. & Ecanova, C. (2024). *EU introduces comprehensive digital-era Product Liability Directive*. Retrieved from: <https://www.hoganlovells.com/en/publications/eu-introduces-com> (accessed: October 31, 2025).
- Misita, N. (2019). *Evropska unija: zaštita potrošača*. Fojnica: Revicon.
- Parziale, A. (2025). AI-powered Medical Devices and the Development Risk Defense Under the Revised Product Liability Directive. In Casarosa, F., Gennari, F. & Rossi, A. (eds.). *Enabling and Safeguarding Personalized Medicine*. Berlin: Springer.
- Schoo, P. (2024). Navigating the CRA: A Brief Analysis of European Cyber Resilience Act and Resulting Actions for Product Development. *Proceedings of the 9th International Conference on Internet of Things, Big Data and Security*, 245–251.
- Steindl, E. (2024). Consumer neuro devices within EU product safety law: Are we prepared for big tech ante portas? *Computer Law & Security Review*, 52, 1–8. doi.org/10.1016/j.clsr.2024.105945.
- Steinhauser, S. (2025). Human-computer interaction: paths to understanding Artificial Intelligence. In Lerzynski, G., Plugmann, J., Pape, P., Glauner, P. & Plugmann, P. (eds.), *Health Care, game changers in digitalization, technology, AI and longevity*. Berlin: Springer Nature.
- Wickramasinghe, N. (2024). *Digitalization and the Transformation of the Healthcare Sector*. Hershey: IGI Global Scientific Publishing.
- Zhao, F., Wallis, J. & Singh, M. (2015). E-government development and the digital economy: A reciprocal relationship. *Internet Research*, 25(5), 734–766.

Povzetek v slovenskem jeziku

Digitalizacija je spremenila zdravstveni sektor z uvedbo naprednih digitalnih medicinskih pripomočkov (kot so npr. programska oprema, medicinski pripomočki in pripomočki, ki jih podpirajo sistemi umetne inteligence). Inovacije v medicini ponujajo potencial za izboljšanje diagnoze in zdravljenja. Hkrati pa sprožajo določena vprašanja o civilni odgovornosti in pravnem položaju pacienta, ki je utrpel škodo zaradi okvarjenega digitalnega izdelka. Članek preučuje, ali lahko posodobljena pravila EU o odgovornosti za okvarjene digitalne medicinske pripomočke olajšajo dokazno breme, s katerim se pacienti soočajo v civilnih sporih, in s tem okrepijo njihov položaj. Avtor se osredotoča na ustreznost novih pravil o razkritju dokazov in dokaznem bremenu. Ključne ugotovitve kažejo, da nova pravila krepijo položaj pacientov z zmanjšanjem dokaznega bremena in uvedbo obveznosti razkritja relevantnih dokazov. Avtor predlaga pripravo smernic za rešitev obstoječih nejasnosti, s čimer bi se zagotovila dosledna in učinkovita uporaba novega dokaznega okvira.

