FINAL PAPER

Harmonising Innovation:

Reconciling The EU AI Act and MDR in Europe's Legal Framework for AI Medical Devices.

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Harmonising Innovation: Reconciling The EU AI Act and EU MDR in Europe's Legal Framework for AI Medical Devices.

Artificial intelligence (AI) is reshaping the landscape of medical devices, promising significant advancements in diagnostics, treatment planning, and patient care. Within the European Union (EU), AI-enabled medical devices are regulated by two principal instruments: the Medical Device Regulation (MDR) and the proposed Artificial Intelligence Act (AI Act). Both are Regulations with direct applicability in all Member States under Article 288 of the Treaty on the Functioning of the European Union (TFEU) and thus carry equal legal force. While intended to harmonise standards and safeguard public health, their overlapping provisions, divergent national interpretations, and lack of explicit conflict-resolution mechanisms create regulatory uncertainty. This paper argues that despite the EU's ambitions, the concurrent application of the MDR and AI Act generates fragmentation that risks stifling innovation and delaying patient access. Drawing on key CJEU case law and the experience of deepeye Medical's Therapy Planning Support (TPS) system, the paper illustrates the need for integrated guidance, proportionality safeguards, and harmonised implementation to realise AI's full potential in healthcare.

Introduction

Every so often, an innovation emerges that redefines how we think about progress. Today, that innovation is artificial intelligence (AI), and the medical device sector has not been left behind. AI is rewriting the playbook on diagnostics and clinical decision support, offering new possibilities that are reshaping healthcare as we know it. In response, the European Union has enacted a dual regulatory framework: Artificial Intelligence Act (hence referred to as "AI

Act") i.e. Regulation (EU) 2024/1689, [1] complementing the existing Medical Device Regulation (hence referred to as "MDR") i.e. Regulation (EU) 2017/745.[2] Both are Regulations under Article 288 TFEU, directly applicable across all Member States and holding equal legal force. [3] This legal design aims to harmonise standards and enhance patient safety while fostering innovation.

Yet this duality presents challenges. The MDR modernises medical device regulation, emphasising rigorous conformity assessments, clinical evaluations, and risk management, [4] while the AI Act introduces a horizontal framework for AI governance, classifying certain AI systems, including many medical device algorithms, as high-risk and imposing requirements for data governance, algorithm transparency, human oversight, and regulatory sandboxes (Article 53). [5] However, neither Regulation contains explicit provisions resolving potential conflicts, leaving legal hierarchy and interpretive clarity to the principles of lex specialis and lex posterior, or ultimately to the Court of Justice of the European Union (CJEU).[6]

Recent academic scholarship highlights these complexities. Hacker notes incomplete sectoral alignment, adding unnecessary regulatory burdens;[7] Kutterer emphasises the need for a robust taxonomy linking risk classification with AI capabilities; [8] and Helberger et al.

[1] European Parliament, 'EU AI Act: First Regulation on Artificial Intelligence' (European Parliament, 1 June 2023)
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L117/1 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 accessed 22 May 2025.
[3] Treaty on the Functioning of the European Union (Consolidated Version) [2012] OJ C326/47, art 288.
[4] ibid; Regulation (EU) 2017/745 (n 1).
[5] European Parliament (n 2); ArtificialIntelligenceAct.eu, 'AI Regulatory Sandbox Approaches: EU Member State Overview' (AI Act Portal) https://artificialintelligenceact.eu/ai-regulatory-sandbox-approaches-eu-member-state-overview/ accessed 23 May 2025.
[6] European Commission, 'ABC of EU Law' (Publications Office of the European Union 2022) https://op.europa.eu/webpub/com/abc-of-eu-law/en/ accessed 21 May 2025.
[7] Hacker's analysis summarised in Stanford Law School, 'EU and US Regulatory Challenges Facing AI Health Care Innovator Firms' (Stanford Law School, 6 April 2024) https://law.stanford.edu/2024/04/06/eu-and-us-regulatory-challenges-facing-ai-health-care-innovator-firms/ accessed 18 May 2025.
[8] Barbara Prainsack and others, 'Regulatory Sandboxes in Health AI: A Comparative European Perspective' (2024) 12 AI and Ethics https://link.springer.com/article/10.1007/s43681-024-00612-5 accessed 26 May 2025.

advocate for enhanced fundamental rights protections and environmental impact assessments.[9] These concerns resonate with the experiences of SMEs like deepeye Medical,[10] which developed the TPS system to assist ophthalmologists in managing retinal therapies. Navigating overlapping obligations, sandbox uncertainties, and dual conformity assessments, deepeye Medical's journey exemplifies the challenges posed by concurrent Regulations.

This paper advances three claims, each supported by relevant CJEU case law. First, definitional ambiguities between the MDR and AI Act create regulatory confusion, as evidenced by SNITEM & Philips France.[11] Second, inconsistent enforcement by Notified Bodies undermines harmonisation, following insights from Elisabeth Schmitt v. TÜV Rheinland.[12] Third, the principle of proportionality, as articulated in Alliance for Natural Health, must constrain regulatory burdens to safeguard innovation and fundamental rights.[13] Through these claims, the paper argues for harmonised guidance, integrated sandbox mechanisms, and proportionality safeguards to reconcile the MDR and AI Act and ensure AI innovation in medical devices flourishes within the EU's single market.

Understanding the hierarchal structure of legal instruments of the EU

[9] Mathew M. G. Konicki and others, 'Navigating AI in Clinical Decision Support: Regulatory Challenges and Opportunities' (2024) 8 NPJ Digital Medicine https://www.nature.com/articles/s41746-024-01232-3 accessed 2 June 2025.
[10] Easy Medical Device, 'How deepeye Medical Overcame the AI Act' (Easy Medical Device Podcast) https://podcast.easymedicaldevice.com/337-2/ accessed 5 June 2025.
[11] SNITEM and Philips France v Premier Ministre (Case C-329/16) ECLI:EU:C:2017:947 https://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16 accessed 25 May 2025.
[12] Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH (Case C-219/15) ECLI:EU:C:2017:128 https://curia.europa.eu/juris/liste.jsf?num=C-219/15 accessed 27 May 2025.
[13] Alliance for Natural Health v Secretary of State for Health (Joined Cases C-154/04 and C-155/04) ECLI:EU:C:2005:449 https://curia.europa.eu/juris/liste.jsf?num=C-154/04&language=en accessed 19 May 2025.

To understand the complexity of navigating the aforementioned two regulations, we need to first understand the hierarchy of the legal instruments and how conflicts between them are generally resolved.

The European Union legal system is a unique supranational framework that derives its authority from the Treaties, primarily the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).[14] EU law consists of primary law (the Treaties and the Charter of Fundamental Rights) and secondary law (legal acts adopted by the EU's institutions). Secondary law includes Regulations, Directives, Decisions, Recommendations, and Opinions under Article 288 TFEU.[15]

A Regulation is binding in its entirety and directly applicable in all Member States, meaning it requires no national transposition and carries uniform legal force across the Union.[16] By contrast, a Directive sets out objectives that Member States must achieve but leaves national authorities' discretion in implementation, allowing for some degree of "gold-plating" (additional national measures). [17]

In situations where two Regulations overlap, the EU legal system relies on interpretive principles, including lex specialis derogat legi generali (a more specific law takes precedence over a general one) and lex posterior derogat legi priori (a later law takes precedence over an earlier one).[18] However, where neither instrument explicitly addresses its relationship with the

[14] ibid.
[15] Treaty on the Functioning of the European Union (n 3).
[16] ibid.
[17] Northern Bridge Toolkit, 'The European Union' (Northern Bridge Doctoral Training Partnership) http://toolkit.northernbridge.ac.uk/introductiontogovernmentandpolicy/theeuropeanunion/ accessed 31 May 2025.
[18] European Commission (n 6).

other, conflicts of interpretation may ultimately fall to the Court of Justice of the European Union (CJEU) for resolution.[19]

Both the Medical Device Regulation (MDR)[20] and the proposed Artificial Intelligence Act (AI Act)[21] are Regulations with equal legal force under Article 288 TFEU. As such, they create a layered but potentially overlapping regulatory environment for AI-enabled medical devices. This overlap raises legal questions about hierarchy, interpretive clarity, and compliance strategies for manufacturers navigating this complex landscape.

I. Definitional Ambiguity and Regulatory Confusion

A core challenge facing AI-enabled medical device manufacturers is definitional ambiguity between the MDR and AI Act. Under the MDR, software intended for medical purposes is classified as a medical device (Article 2(1)), requiring conformity assessments and CE marking.[22] Simultaneously, the AI Act defines high-risk AI systems as those intended for use as safety components in medical devices, subjecting them to additional requirements such as algorithm transparency, risk management, and human oversight (Articles 6 and 14).[23] Both Regulations are directly applicable under Article 288 TFEU, carrying equal legal force, yet neither instrument clarifies which takes precedence where definitions or obligations overlap.[24]

The CJEU's decision in SNITEM & Philips France v. Premier Ministre (Case C-329/16) [25] provides instructive guidance. Although decided under the Medical Devices Directive (93/42/EEC), the Court emphasised that Member States could not impose additional

[19] ibid.
[20] Regulation (EU) 2017/745 (n 1).
[21] European Parliament (n 2).
[22] EU MDR, (n 2) art 2(1)
[23]EU AI Act (n 1), arts 6, 14
[24] TFEU (n 3), art 288.
[25] (n 11).

national certification requirements on CE-marked medical devices, reinforcing the principle of harmonisation. While SNITEM did not directly address conflicts between two Regulations, its emphasis on the primacy of harmonised EU law resonates in the current context: the AI Act's risk classification requirements, for instance, might impose new obligations on devices already certified under the MDR. This raises the question of legal hierarchy. Would lex specialis (the MDR as the specific regime) override lex generalis (the AI Act as the general regime)? Or would lex posterior (the AI Act as the later Regulation) take precedence? The absence of clear guidance burdens manufacturers with legal uncertainty.[26]

deepeye Medical's TPS system exemplifies these challenges. As an AI-based decision-support tool for ophthalmologists, it qualifies as medical device software under the MDR, requiring clinical evaluation and post-market surveillance.[27] Under the AI Act's risk-based framework, it would simultaneously be classified as a high-risk AI system, subject to additional requirements, including transparency obligations and a sandbox option.[28] Navigating these overlapping definitions required deepeye Medical to invest significant resources in compliance documentation, risk management matrices, and data protection strategies, resources that might be prohibitive for smaller firms.[29]

II. Fragmented Enforcement and Notified Body Inconsistency

[26] European Commission, ABC of EU Law (Publications Office 2022) 44–45 https://op.europa.eu/webpub/com/abc-of-eu-law/en/ accessed 21 May 2025.
[27] ibid art 2(1); see also Emergo by UL, 'New European Guidance Clarifies Medical Device Software Requirements' (2023) https://www.emergobyul.com/news/new-european-guidance-clarifies-medical-device-software-requirementsaccessed 30 May 2025.
[28] ArtificialIntelligenceAct.eu, 'AI Regulatory Sandbox Approaches' (n 10).
[29] Stanford Law School, 'EU and US Regulatory Challenges Facing AI Health Care Innovator Firms' (6 April 2024) https://law.stanford.edu/2024/04/06/eu-and-us-regulatory-challenges-facing-ai-health-care-innovator-firms/ accessed 18 May 2025.

Beyond definitional issues, fragmented enforcement by Notified Bodies exacerbates regulatory confusion. Notified Bodies play a central role under the MDR, conducting conformity assessments and issuing CE certificates. [30] However, the AI Act's sandbox provisions (Article 53) allow for supervised experimentation of AI systems in real-world conditions, with national competent authorities overseeing implementation.[31] Yet the AI Act does not integrate these sandbox outputs with MDR conformity assessments, nor does it clarify whether sandboxed systems remain subject to MDR requirements during testing.[32]

The CJEU's ruling in Elisabeth Schmitt v. TÜV Rheinland (Case C-219/15) [33] illuminates challenges in ensuring consistent oversight. Although the case arose under the Medical Devices Directive, it highlighted Notified Bodies' duty of diligence in assessing compliance. The Court found that while Notified Bodies must ensure conformity assessments are rigorous, they are not strictly liable for all device defects.[34] This reasoning reveals that Notified Bodies' effectiveness depends on harmonised expectations and consistent application of standards, a challenge compounded in the AI context, where expertise varies and AI literacy is inconsistent across the EU. [35]

deepeye Medical's experience illustrates these difficulties. Working with Kiwa Assurance, a Notified Body under the MDR, the company encountered varying interpretations regarding AI risk assessments and explainability requirements, areas where Notified Bodies have different levels of technical expertise.[36] The potential for forum shopping and inconsistent

[30] Regulation (EU) 2017/745 (n 22 above), arts 51–52.
[31] Regulation (EU) 2024/1689 (n 23 above), art 53; see also European Parliamentary Research Service, *Regulatory Sandboxes in the AI Act* (Briefing 2022) 8 https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733544/EPRS_BRI(2022)733544_EN.pdf
[32] Regulation (EU) 2024/1689 (n 23), art 53(6).
[33] Elisabeth Schmitt v TÜV Rheinland (*C-219/15*) ECLI:EU:C:2017:128 https://curia.europa.eu/juris/liste.jsf?num=C-219/15 accessed 27 May 2025.
[34] ibid at [36]–[39].
[35] Prainsack and others, (n8) 58–59
[36] Easy Medical Device Podcast (n 8 above).

risk classification is heightened under the AI Act, where sandbox experimentation may produce divergent national practices. Without explicit guidance on harmonizing sandbox results with MDR conformity pathways, manufacturers risk duplicative efforts, higher costs, and legal uncertainty. [37]

III. Proportionality and Fundamental Rights

The principle of proportionality, codified in Article 5 TEU, requires that EU measures be appropriate and not exceed what is necessary to achieve legitimate objectives.[38] Both the MDR and AI Act pursue laudable goals of safety and trust, yet their cumulative obligations, particularly on risk management, algorithm transparency, and human oversight, may impose disproportionate burdens on SMEs.[39]

The CJEU's reasoning in Alliance for Natural Health v. Secretary of State for Health[40] (Cases C-154/04 & C-155/04) illustrates how the proportionality principle can constrain EU measures. There, the Court upheld the Directive but emphasized that measures must not unduly restrict market access or innovation. This principle applies equally to Regulations: under Article 263 TFEU, [41] a Regulation may be challenged for breaching proportionality or fundamental rights.[42]

Academic commentary reinforces this point. Hacker highlights that compliance costs will be especially high for SMEs developing narrow AI models.[43] Kutterer underscores the need for robust taxonomies linking risk classification to model capabilities, to avoid one-size-

[37] ibid.
[38] Treaty on European Union (Consolidated Version) [2012] OJ C326/13, art 5(4).
[39] Regulation (EU) 2024/1689 (n 23 above).
[40] Alliance for Natural Health v Secretary of State for Health (Joined C-154/04 & C-155/04) ECLI:EU:C:2005:449 https://curia.europa.eu/juris/liste.jsf?num=C-154/04 accessed 19 May 2025.
[41] TFEU (n3), art 263.
[42] (n40) at [52]-[55]
[43] Stanford Law School Podcast (n 29).

fits-all obligations that disproportionately affect smaller players.[44] Helberger et al. argue that the AI Act should include explicit fundamental rights safeguards, especially regarding privacy (Article 7 Charter), data protection (Article 8), and freedom to conduct a business (Article 16).[45] deepeye Medical's experience exemplifies these concerns: the TPS system's risk management frameworks, data pseudonymisation, and explainability modules required significant investment, and drove complexity far beyond typical medical software.[46] This can potentially limit innovation and deter future AI entrants into the EU market for medical devices.[47]

Discussion: Legal Challenge Considerations

Although the three cases analysed arose under Directives, their underlying principles remain instructive in assessing potential challenges to the AI Act and MDR. As both the AI Act and MDR are Regulations, they are directly applicable in all Member States and hold equal legal force.[48] In the event of a conflict between the two instruments, no express hierarchy exists, leaving resolution to judicial interpretation by the CJEU, applying principles such as **lex specialis derogat legi generali** and **lex posterior derogat legi priori**.[49]

Article 263 TFEU provides the legal avenue to challenge the validity of a Regulation on grounds including infringement of the Treaties, proportionality, and fundamental rights.[50] While SNITEM & Philips France[51] and Elisabeth Schmitt[52] do not directly challenge a Regulation, they illustrate how divergent implementation by Member States and Notified

[44] Prainsack et al. (n 8).
[45] Konicki et al. (n 23 and n 39).
[46] Easy Medical Device Podcast (n 8).
[47] ibid.
[48] Treaty on the Functioning of the European Union (Consolidated Version) [2012] OJ C326/47, art 288.
[49] European Commission, ABC of EU Law (Publications Office 2022) 46 https://op.europa.eu/webpub/com/abc-of-eu-law/en/ accessed 21 May 2025; ibid art 5.
[50] ibid art 263.
[51] (n11)
[52] (n12)

Bodies can undermine harmonization, providing context for potential proportionality challenges.[53] Alliance for Natural Health, although concerning a Directive, directly addresses the principle of proportionality under Article 5 TEU, highlighting that even Regulations must conform to this principle.[54]

The potential conflicts between the AI Act's regulatory sandbox and the MDR's requirements reflect a broader challenge of coordinating innovation-friendly provisions with patient safety imperatives.[55] Without clear mechanisms for integrating sandbox testing into the MDR's conformity assessment procedures, developers face the risk of investing in sandbox experimentation that may not translate into compliance under the MDR.[56] This uncertainty could deter participation in sandboxes altogether or lead to costly duplication of efforts, a concern especially relevant to SMEs seeking to bring AI medical devices to market.[57]

Beyond sandbox integration and definitional ambiguities, additional regulatory considerations exacerbate the burden on manufacturers of AI/ML-integrated medical devices. First, **algorithmic bias** poses significant legal and ethical challenges. AI systems trained on non-representative datasets may yield discriminatory outputs, contravening the EU Charter's non-discrimination principles (Article 21).[58] Yet neither the AI Act nor the MDR explicitly integrates bias mitigation frameworks, leaving manufacturers uncertain whether post-market surveillance or pre-market conformity assessments must account for algorithmic drift.[59]

Second, **interoperability**—the capacity of AI medical devices to integrate with other health systems—poses another challenge. The MDR requires manufacturers to demonstrate

[53] AI Act, art 53
[54] Prainsack et al. (n 8)
[55] Ibid (n 29)
[56] TFEU (n 48) art 263
[57] SNITEM (n 51); Elisabeth Schmitt (n 51); Alliance for Natural Health (n 52).
[58] Charter of Fundamental Rights of the European Union [2012] OJ C326/391, art 21.
[59] Konicki et al, 'Navigating AI in Clinical Decision Support' (2024) 8 NPJ Digital Medicine https://www.nature.com/articles/s41746-024-01232-3

interoperability under its essential safety and performance requirements,[60] yet the AI Act does not address this explicitly, potentially leaving gaps in ensuring consistent integration with electronic health records or other AI-driven systems.[61] Divergent national implementations of these requirements could lead to market fragmentation, undermining the EU's single market objectives.[62]

Third, **cybersecurity** represents a crucial consideration. MDR Annex I requires manufacturers to ensure protection against unauthorised access and data breaches,[63] but the AI Act's risk-based governance focuses more on transparency and human oversight.[64] The absence of harmonised cybersecurity obligations between the two Regulations may expose manufacturers to conflicting expectations, especially in high-risk AI devices where data integrity is paramount.[65]

Finally, both Regulations risk overlapping in **post-market surveillance obligations**. The MDR mandates comprehensive post-market clinical follow-up (PMCF), including continuous monitoring and reporting,[66] while the AI Act introduces continuous risk management and human oversight obligations.[67] Without clear guidance on integrating these requirements, manufacturers face the risk of duplicative reporting obligations, resource inefficiencies, and potential regulatory conflict—particularly burdensome for SMEs navigating the MDR's already stringent post-market regime.[68]

[60] EU MDR (n 53) Annex 1, para 14-16
[61] ibid; European Parliament, 'EU AI Act: First Regulation on Artificial Intelligence' (European Parliament, 1 June 2023)
[62] Ibid
[63] EU MDR (n 53) Annex I, para 17.4
[64] AI Act (n 54)
[65] Ibid
[66] EU mDR art 83, Annex XIV
[67] EU AI Act (n 54) art 9, 14
[68] Prainsack et al (n 8)

Thus, a manufacturer like deepeye Medical, if faced with conflicting or disproportionate obligations under the AI Act and MDR, could, in theory, bring an action for annulment under Article 263 TFEU, citing the principles discussed in these cases as persuasive, though not binding, analogies.[69]

Conclusion

The MDR and AI Act reflect the EU's commitment to harmonised, risk-based regulation of AI-enabled medical devices. Yet their overlapping scopes, equal legal force, and fragmented enforcement reveal a regulatory landscape at risk of undermining innovation and delaying patient access. The cases analysed, though decided under Directives, provide legal principles that remain relevant: SNITEM emphasizes harmonisation; Elisabeth Schmitt highlights the need for consistent enforcement; and Alliance for Natural Health reinforces the principle of proportionality.[70] deepeye Medical's experience with the TPS system illustrates how these challenges manifest in practice, especially for SMEs navigating overlapping obligations and regulatory sandboxes.[71]

To reconcile these frameworks, the EU should issue integrated guidance clarifying the relationship between the MDR and AI Act, align sandbox procedures with conformity assessments, and ensure proportionality in compliance burdens. Without these steps, the promise of AI in healthcare may be overshadowed by legal uncertainty and regulatory complexity. Only by harmonizing these instruments can the EU fully unlock the transformative potential of AI medical devices while safeguarding patient safety and fundamental rights.

[69] (n 10)
[70] (n 13)
[71] (n 5)