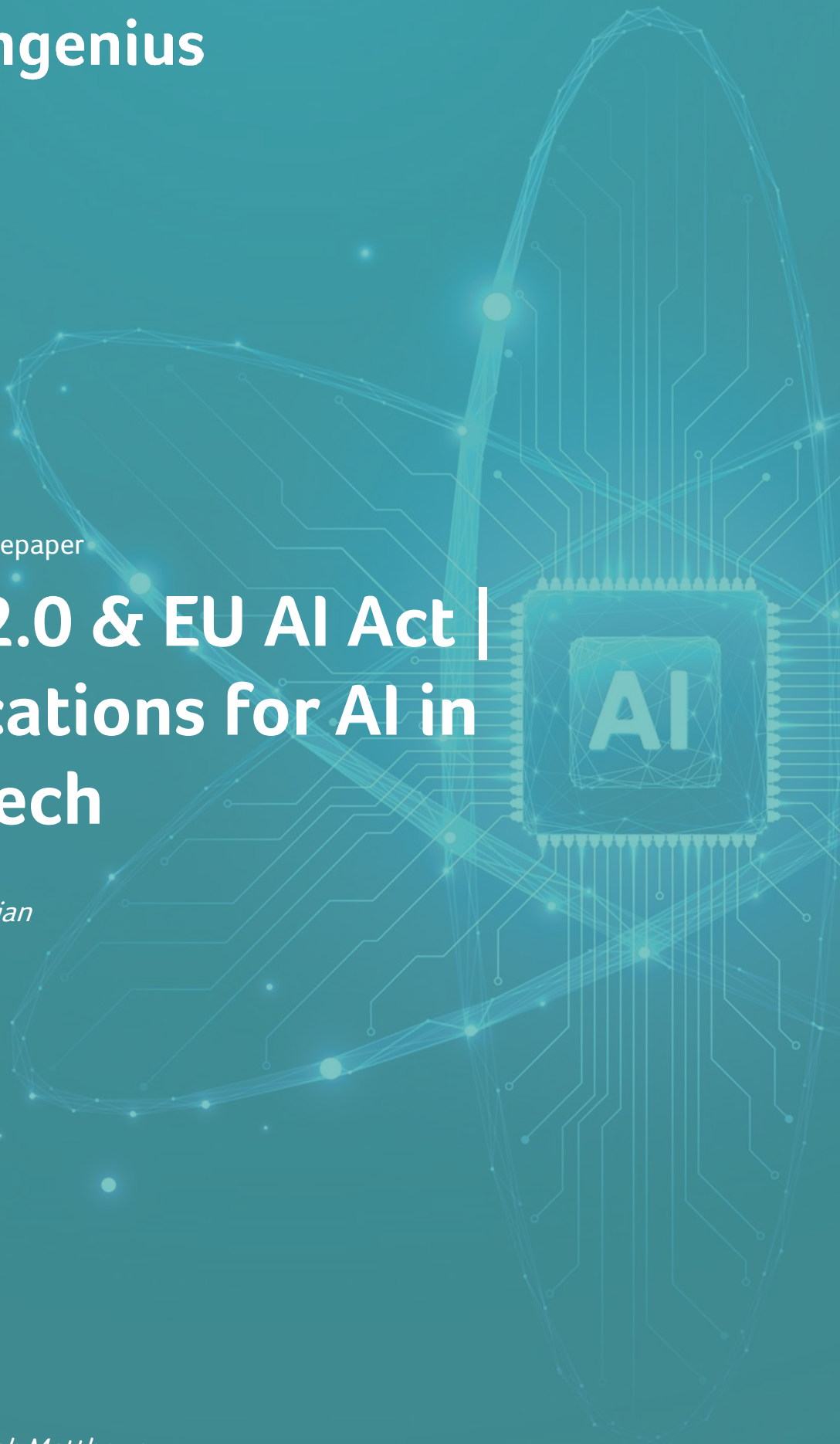
Congenius

Congenius Whitepaper

MDR 2.0 & EU AI Act | Implications for AI in MedTech

August 2026

By Richie Christian



Edited by Hannah Matthews

In this whitepaper...

The Commission's proposal COM (2025) 1023 final (widely known as MDR 2.0) aims to simplify and streamline the MDR by removing duplicative procedures and adopting a more risk-based approach.

Published on 16 December 2025 and now before Parliament and the Council under the ordinary legislative procedure, it responds to nearly a decade of practical experience with the original regulations.

Beyond simplification, one objective of MDR 2.0 involves seeking a single conformity assessment process that properly integrates AI and cybersecurity requirements rather than preserving overlapping regimes.

In this whitepaper, our Head of Regulatory Richie Christian recaps the **interconnection between the MDR and EU AI Act**, discusses the potential impact of **the proposed changes in MDR 2.0 related to AI in MedTech**, and offers **practical preparation advice** for manufacturers of AI-enabled medical devices.

MDR & EU AI Act | Limitations & Overlap

MDR shortcomings | Interpretation, cooperation, burden, delays

Implementation of MDR and IVDR has exposed **structural shortcomings** that undermine the original goals.

Conformity assessment timelines are slow and unpredictable, **delaying market entry**. About 60% of manufacturers cite administrative burden as the top barrier to innovation, whilst over 70% have added resources just to stay compliant. Furthermore, **interpretation varies** across Member States, and fixed five-year recertification cycles create bottlenecks regardless of a device's actual risk profile.

International cooperation is limited (Brazil and Australia have both scaled back CE mark recognition), and dedicated pathways for breakthrough or orphan devices never materialised. Low-risk activities often face high-risk scrutiny, for example, routine blood draws for IVD studies are treated like biopsies, and low-risk software is routinely over-classified.

This has resulted in **device availability issues** and an **increase in burden** for small and medium-sized enterprises, impacting the EU's ability to accelerate innovation.

MDR & EU AI Act | Limitations & Overlap

Introduction of EU AI Act

Passed on 12 July 2024 and entering into force on 1 August 2024, the EU AI Act (2024/1689) became the **world's first AI regulation** - establishing a **horizontal, risk-based framework for AI** across all sectors.

The EU Commission's stated aim was to capture AI's opportunities while addressing its risks, explicitly citing healthcare as a focus area, and to **prevent fragmentation of the single market** through EU-wide rules rather than a patchwork of national approaches.

Implementation has followed a staggered timeline: prohibited practices became enforceable on 2 February 2025; obligations for general-purpose AI models took effect on 2 August 2025; and the Act began to apply broadly, including many high-risk products, on 2 August 2026. For medical devices and IVDs specifically, the critical date is 2 August 2027, when devices and safety components falling under Article 6(1) become high-risk products under the Act.

MDR & EU AI Act | Limitations & Overlap

AI Act shortcomings | Complexity, overregulation, dual compliance

The introduction of the AI Act has introduced **uncertainty and complexity** across multiple sectors, leading to broader structural critiques from a wide range of stakeholders. The challenges have focused on foundational aspects such as the definition of AI systems and infrastructural issues from unavailability of harmonised standards to designation of Notified Bodies.

The AI Act has tipped the field into **overregulation** with over 1,000 recitals, articles, and annexes; guidelines; codes of practice; and technical standards layered on top. This has undermined the legal certainty it was meant to provide.

The MedTech industry has questioned layering the AI Act onto existing device regulation as it risks "**double regulation**", requiring manufacturers to navigate two complex legal frameworks at once.

High-Risk AI systems (HRAI)

Under the AI Act, High-Risk AI (HRAI) systems are those deemed to pose significant risk to health, safety, or fundamental rights. In MedTech, this primarily captures AI already regulated under the MDR/IVDR: under Article 6(1), any device incorporating AI or qualifying as AI-based software that requires third-party conformity assessment is automatically classified high-risk.

This triggers dual compliance in that manufacturers must satisfy both MDR/IVDR's sector-specific safety and clinical performance requirements and the AI Act's new horizontal requirements covering data governance, risk and quality management, transparency, and human oversight.

Because these systems are high-risk, independent Notified Bodies remain in the loop for market assessment.

MDR & EU AI Act | Limitations & Overlap

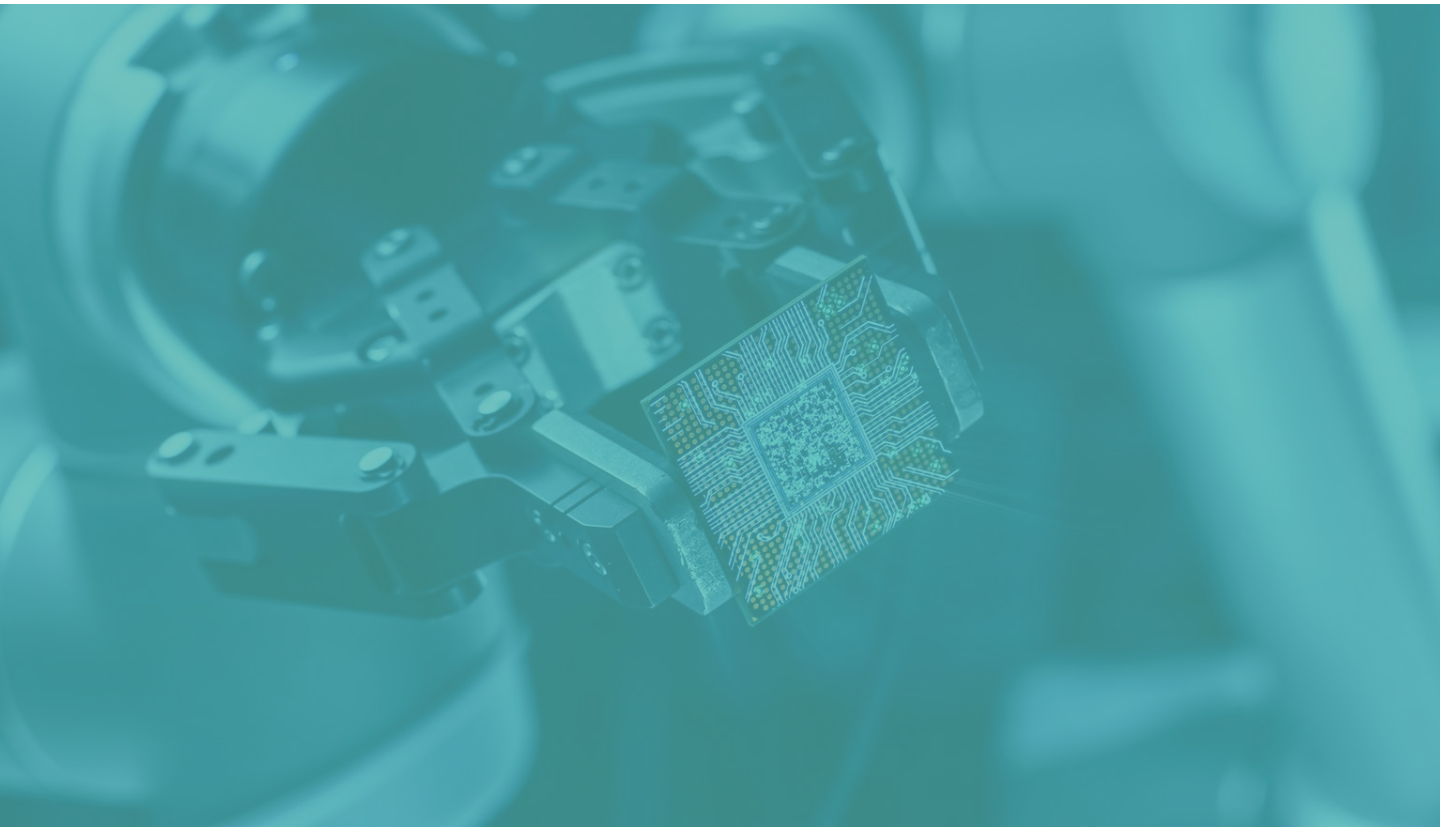
AI Act shortcomings | Complexity, overregulation, dual compliance

New horizontal AI standards also collide with established vertical medical standards, particularly on **risk management**, threatening heavier documentation burdens and bottlenecks if the role of Notified Bodies stays undefined.

Under the AI Act, **investigational devices** could be forced to obtain an AI Act CE mark before they've even completed the testing needed to prove safety.

Furthermore, the concept of **"substantial modification"** carries different meanings under MDR/IVDR and the AI Act, and it remains unclear whether MDR/IVDR compliance will be legally recognised as satisfying AI Act requirements.

Therefore, the industry's preferred path forward is to integrate AI-specific requirements directly into the MDR/IVDR's existing General Safety and Performance Requirements (GSPR), producing one conformity assessment process instead of two in parallel.



Addressing the limitations | MDR 2.0 & Digital Omnibus for EU AI Act

MDR 2.0 | Removing dual compliance

MDR 2.0 proposes moving the reference to MDR from Annex I, Section A to Section B of the EU AI Act. This will establish the MDR as the primary sectoral framework for AI medical devices rather than running a parallel horizontal track. Relevant AI-specific requirements would then be incorporated into Annex I of the MDR itself via delegated or implementing acts. This would allow gaps to be closed without duplicating obligations already covered.

Momentum for this sector-first approach is building across all three institutions: the Commission through the MDR revision, the Parliament's LIBE/IMCO committees through corresponding AI Omnibus amendments, and several Member States through the "Friends of Industry" initiative calling for clearer interplay between the AI Act and sectoral legislation.

Digital Omnibus for EU AI Act

The Digital Omnibus is a broader legislative initiative aimed at improving regulatory coherence across EU digital law, including the AI Act. It aims to address overlaps between the AI Act and sectoral frameworks such as the MDR/IVDR. For MDR/IVDR specifically, the package brings the following notable changes:

- A **"stop the clock"** mechanism delays high-risk AI obligations until the Commission formally confirms the system is ready, including harmonised standards and sufficient Notified Body capacity
- Notified Bodies gain a **streamlined path to dual designation** under both the AI Act and MDR/IVDR through a single application and unified assessment, cutting duplicative procedures
- An **alignment in terminology to close a key legal uncertainty**: the AI Act's "substantial modification" is brought in line with MDR/IVDR's "substantial change," and investigational or performance study devices are clarified as not "placed on the market" under the AI Act
- Established risk-management frameworks like **ISO 14971 would be recognised** as satisfying corresponding AI Act obligations, avoiding parallel safety assessments

Addressing the limitations | MDR 2.0 & Digital Omnibus for EU AI Act

Two frameworks, two approaches

The Digital Omnibus and MDR 2.0 take different routes to the same destination. The Digital Omnibus keeps medical AI within the AI Act's high-risk framework but delays deadlines and streamlines the interplay with sectoral legislation, making dual compliance efficient and giving Notified Bodies a clearer path to assess AI Act and MDR/IVDR requirements in one process.

MDR 2.0 goes further by shifting medical devices to Section B of Annex III in the AI Act, effectively removing the HRAI overlay for AI medical devices altogether, leaving MDR/IVDR as the sole governing regime.

Timeline of developments

	MDR 2.0	EU AI Act Amendments
Nov 2025		• EU Commission publishes Digital Omnibus on AI proposal
Dec 2025	• EU Commission publishes proposal COM(2025) 1023 final, amending MDR (2017/745) & IVDR (2017/746)	
Jan 2026	• Proposal formally enters legislative process • Stakeholders submit feedback during public consultation period	
Mar 2026		• Council adopts its negotiating mandate (General Approach) • European Parliament adopts its negotiating position
Apr 2026		• First trilogue negotiations fail to reach agreement due to disagreements over scope of simplification & treatment of sectoral legislation
May 2026		• Parliament & Council reach provisional political agreement during resumed trilogue negotiations • Member State representatives endorse provisional agreement
Jun 2026	• Council publishes progress report (ST 9801/26) • European Parliament publishes draft report (Schenk, PE787.987)	• Parliament formally approves the agreed text • Council gives its final approval, completing legislative procedure
Jul 2026		• Published in the OJEU • Regulation enters into force
Q4 2026	• Trilogue negotiations between Commission, Parliament, & Council to agree on common legislative text	
Q1-Q2 2027	• Expected provisional political agreement & formal adoption by Parliament & Council • Publication in the OJEU • Regulation enters into force	

Current outlook for MDR 2.0 & EU AI Act

MDR 2.0 | What's next?

With respect to MDR 2.0, article-by-article examination in the Council Working Party began in March 2026, with four full-day meetings held, nearly completing a full read-through. In the Council's 5 June 2026 progress report (ST 9801/26), delegations broadly supported the proposal's objectives in incentivising innovation, simplification, reducing disproportionate burden, and fostering more uniform Notified Body practices.

Importantly, delegations supported reducing overlaps with the AI Act and cybersecurity legislation, moving towards a single regulatory framework (under the MDR and IVDR) through implementing delegated acts.

Delegations noted further refinement is needed for MDCG/EMA roles and responsibilities, classification coordination, expert panels, well-established technology devices, Notified Body oversight, post-market surveillance, SME fee reductions, delegated powers, and international cooperation.

At the end of June 2026, a draft report from Parliament (Schenk, PE787.987) proposed further amendments to the initial December 2025 proposal. Many of these align with the initial proposal; however, long-standing fundamental issues with respect to medical device software classification per Rule 11 persist with Class I being a logical impossibility due to the wording of this rule in the latest proposal. As noted above, these amendments are subject to further dialogue and refinement during the legislative process in the remainder of 2026 and early 2027.

Current outlook for MDR 2.0 & EU AI Act

EU AI Act | What's next?

Compared to MDR 2.0, the AI Act amendments have been on an expedited timeline due to the 2 August 2026 deadline when HRAI system requirements would have taken effect. The amended text was published in the Official Journal of the European Union (OJEU) on 24 July 2026 and entered into force on 27 July 2026. The approved text confirms the following significant changes:

- **Stop-the-clock:** Standalone high-risk AI (Annex III) deferred to 2 December 2027; AI embedded in products under existing safety law (Annex I for medical devices, machinery, and toys) deferred to 2 August 2028 from 2 August 2027
- **Transparency grace period:** Content-marking rules for pre-existing systems get a 3-month grace period to 2 December 2026; other transparency duties still apply from 2 August 2026
- **New prohibition:** Ban on nudifier apps/AI-generated child sexual abuse material; safeguards required by 2 December 2026
- **AI Office powers expanded:** Oversight now covers AI systems built on GPAI models
- **Bias-detection data processing:** Extended to all AI providers/deployers (not just high-risk)
- **Machinery carve-out:** Machinery regulation products excluded from high-risk AI rules; medical devices and toys remain in scope
- **Sandboxes:** National sandbox deadline pushed to 2 August 2027
- **Registration:** Self-assessed non-high-risk systems must still register (lighter footprint)

Despite the push from the MedTech industry to transfer MDR/IVDR from Section A to B of Annex III of the AI Act, the approved text did not implement this change. This "failed Annex B move" is now certain and means that full conformance to HRAI system requirements per the AI Act still apply.

Preparing for regulatory change

Continue preparation, despite longer lead times

For manufacturers of AI-enabled medical devices or IVDs, the AI Act amendments give more time to prepare for AI Act HRAI obligations. Regardless of how the AI Act interplay will be handled via MDR 2.0, manufacturers should continue to prepare to meet HRAI obligations within existing QMS and technical documentation.

Consider that medical devices will still be within the AI Act's scope

It's important to note that the Section B move in Annex III of the AI Act, were it to happen, does not remove medical devices out of the AI Act's scope completely, as certain provisions must still be met (such as Article 6(1) and Articles 102-109).

Familiarise with harmonised standards

Harmonised standards development for the AI Act is currently underway, and many foundational standards (AI QMS, risk management, etc.) are expected to be published in the next 6-12 months. Manufacturers should familiarise themselves with these standards and their requirements for potential implementation in the next 12-24 months.

Build robust documentation on AI lifecycle

Notified Bodies already expect comprehensive information for AI-enabled medical devices and IVDs, with detailed information on model development, data management, mode validation, and post-market surveillance. Manufacturers should continue to build robust documentation on all aspects of AI lifecycle to meet existing MDR and IVDR requirements.

Monitor MDR 2.0 developments

With respect to MDR 2.0, the proposed amendments are still being discussed, and many details will likely change during the legislative process. It's entirely possible that there are still HRAI obligations per the AI Act to meet under the new MDR and IVDR frameworks. Manufacturers should continue to monitor MDR 2.0 developments for the remainder of 2026.

Congenius

Should you have a challenge related to AI in MedTech, please get in touch – our team is ready and happy to help.

Congenius AG
Riedstrasse 1
CH - 8953 Dietikon

E: info@congenius.ch
T: +41 44 741 04 04

congenius.ch

Revision 1 – August 2026