

# AI-Enabled Medical Devices Need One Regulatory Home

One Device. One Regulatory System. One National Authority.



**~1,600**

AI-enabled medical devices authorised in the US by mid 2026.<sup>1</sup>



**74%**

of EU countries already use AI assisted diagnostics – but adoption is slowed by regulatory uncertainty.<sup>2</sup>



**400,000**

lives/year could be saved and €200bn in annual savings unlocked by AI in European health systems.<sup>3</sup>

**Policy Ask:** AI Act requirements should be embedded in MDR/IVDR – one lifecycle, one set of regulations, one national authority, from design to vigilance.

## Patients & Governance



### One national authority, full picture

The national authority already handles withdrawals, warnings, and software updates. Splitting off AI compliance fragments patient-safety oversight.



### Fragmented today:

Two parallel national authority tracks – one for the device, one for its AI – risk conflicting decisions and slower safety action.

## Innovation & Access



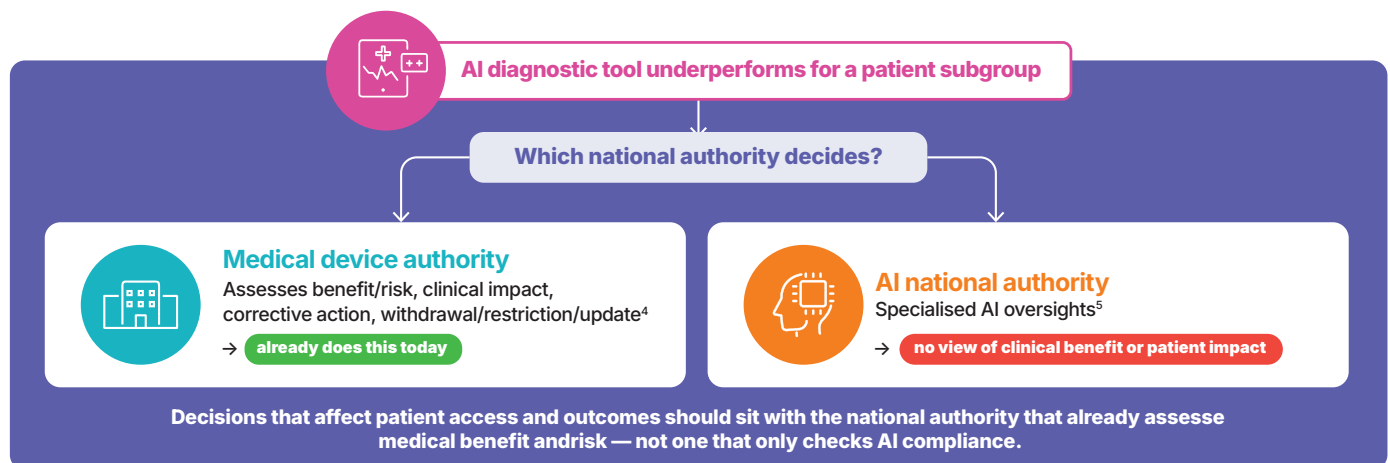
### One clear rulebook

Integrated rules mean no duplicate procedures, lower cost for developers (especially SMEs), and faster patient access.



### Fragmented today:

Two rulebooks, two assessment tracks across 27 Member States, more uncertainty – and slower access to innovation for patients and health systems.



## Other Safety-Critical Sectors Are Moving The Same Direction



### Aviation

- ✓ AI requirements folded into the existing aviation safety framework
- ✓ One safety authority, one lifecycle, no parallel AI-only layer



### Machinery & Industrial

- ✓ AI requirements folded into existing product safety legislation
- ✓ Same sectoral home, no duplicate AI rulebook<sup>6</sup>

**One national authority. One rulebook. Better patient safety, faster innovation.**

#### Sources:

1. FDA / Nyquist AI, "AI/ML Medtech at Mid-Year 2026" – ~1,606 cumulative FDA-authorised AI/ML devices, H1 2026.
2. WHO/Europe, "First-ever snapshot of AI in health care across EU Member States," April 2026 – 74% diagnostics, 63% chatbots.
3. MedTech Europe / Deloitte impact study – potential 400,000 lives saved/year, €200bn annual savings, 1.8bn working hours freed across European health systems (potential impact, not current use).
4. MDCG 2025-6 guidance; AI Act Article 43(3) – current single conformity-assessment pathway for high-risk medical device AI.
5. European Journal of Risk Regulation (2025) – unresolved inconsistencies between AI Act and MDR in practice.
6. EASA AI Roadmap 2.0 (2023); European Commission Machinery Regulation delegated act process (2026) – sectoral integration in progress.