MedTech Europe
from diagnosis to cure

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.[1]

74%
of EU countries already use AI assisted diagnostics – but adoption is slowed by regulatory uncertainty.[2]

400,000
lives/year could be saved and €200bn in annual savings unlocked by AI in European health systems.[3]

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.

AI diagnostic tool underperforms for a patient subgroup

Which national authority decides?

Medical device authority
Assesses benefit/risk, clinical impact, corrective action, withdrawal/restriction/update[4]
→ already does this today

AI national authority
Specialised AI oversights[5]
→ no view of clinical benefit or patient impact

Decisions that affect patient access and outcomes should sit with the national authority that already assesse medical benefit andrisk — not one that only checks AI compliance.

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[6]

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.