

An on-device model that produces a clinical inference is regulated twice — as medical device software and as high-risk AI. **The regimes stack**; they do not substitute.

The device-embedded high-risk date is fixed at 2 August 2028, but the evidence the AI Act assesses — data governance, technical documentation, human-oversight design — is generated during development and cannot be reconstructed. **Decide the AI question in the RIA before model lock; build the artifacts now.**

THE PICTURE Three regimes stack on one model — MDR / IVDR, AI Act, FDA lifecycle

BASE

EU MDR / IVDR (MDSW)

Is the software a device, and what class?
Conformity assessment, technical file,
clinical evaluation.

OVERLAY

EU AI Act — high-risk

Once Art. 6(1) is met: risk management,
data governance, tech file, logging,
oversight (Arts. 9–15, 17, 72)

PARALLEL

FDA lifecycle track

Total-product-lifecycle approach (draft, Jan
2025) and Predetermined Change Control
Plans (final, Aug 2025).

AI Act requirements are assessed inside the MDR / IVDR conformity assessment (Art. 43(3)) in one set of technical documentation (Art. 11(2)).
Coordination is not exemption.

QOINTA'S POSITION Four positions that turn "not yet" into "now"

High-risk AI when the device needs a notified body

Article 6(1) has two cumulative conditions: the AI is, or is a safety component of, an MDR / IVDR device, and that device needs third-party conformity assessment. Class IIa and up qualify.

A trial model is inside the AI Act's frame

The research exclusions (Art. 2(6), 2(8)) do not cover testing in real-world conditions, and MDCG 2025-6 treats a clinical investigation of medical-device AI as exactly that.

The 2028 date is the trap, not the reprieve

Regulation (EU) 2026/1744 fixed 2 August 2028 for device-embedded AI. The artifacts it assesses are produced two to three years earlier; a model built without them cannot acquire them.

Change is intrinsic to ML — control it in the specification

A substantial modification needs new conformity assessment unless pre-determined in the technical documentation (Art. 43(4)); in the US, a PCCP. An unplanned retrain breaks validation.

FIVE DEPLOYMENT FACTS, EACH ANSWERED BY EVIDENCE BUILT PRE-LOCK

- 1 Run the RIA to fix device status and class**; apply the Article 6(1) test and scope the high-risk duties early.
- 2 Build the AI Act technical documentation and data-governance records** alongside the MDR technical file — one set (Art. 11(2)).
- 3 Agree a PCCP up front** — modifications, modification protocol, impact assessment — and pre-determine changes in the EU file.
- 4 Document training, validation and test data governance** (Art. 10) and test transfer to the enrolled population (QPP-01).
- 5 Design human oversight in** where output is acted on without clinician review; record the oversight measures and decision pathway.

2 Aug 2028

device-embedded high-risk
AI obligations apply
(Regulation (EU) 2026/1744)

2 Dec 2027

stand-alone Annex III high-risk obligations apply

27 Jul 2026

Digital Omnibus on AI in force — the dates are law, not a proposal

3

PCCP components: modifications, modification protocol, impact assessment

Read with care. FDA's lifecycle-management guidance for AI-enabled device software functions remains a draft. Unrecoverability of late evidence and further national AI regimes are qointa's assessments. COM(2025) 1023 is still open.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-07 Change Control · QPP-16 PCCP



Summary of QPP-04 1.0 — the full paper, with sources and figures, is published at qointa.com.

EU MDR / IVDR · EU AI Act, Reg. (EU) 2024/1689 as amended by Reg. (EU) 2026/1744, Arts. 2, 6(1), 8–15, 17, 43, 72 · MDCG 2025-6 · FDA AI lifecycle draft (Jan 2025) · FDA PCCP guidance (Aug 2025) · COM(2025) 1023

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