The AI Act × MDR/IVDR Integration Checklist

A practical guide for MedTech and diagnostics leaders: check in five questions whether your device counts as a high-risk AI system, map every AI Act duty into the technical file you already maintain, and build the outcome evidence your buyers will ask for next.

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Edition: August 2026, updated September 2026

Inside: 5-question scope check · Article 8(2) integration map · Real-world evidence roadmap · 90-day plan

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Why this guide, why now

Two things happened in one week of August 2026 that change how AI-enabled medical devices will be bought and sold. On August 18, the FDA opened a discussion paper on generative AI-enabled devices, its clearest signal yet that tighter US rules are coming. On August 19, a peer-reviewed study in *PLOS Digital Health* quantified something the industry preferred not to discuss:

What the study measured	Devices
AI/ML-enabled medical devices authorized by the FDA (as of Dec 5, 2025)	**1,357**
Linked to a registered clinical trial	34 (2.5%)
With posted trial results	12 (0.9%)
With peer-reviewed publications	12 (0.9%)
Evaluated against patient-centered outcomes (mortality, morbidity, readmissions)	**3 (0.2%)**

Regulatory clearance tells your buyer that your device is safe and substantially equivalent. It does not tell them that it improves care. Until now, almost nobody checked. That is ending: health systems, payers and investors increasingly ask **governance questions before clinical questions**, and journalists now have a peer-reviewed benchmark to hold claims against.

Meanwhile the EU has already legislated the answer. Under the AI Act (Regulation (EU) 2024/1689), most AI-enabled medical devices are **high-risk AI systems** with binding obligations. The good news, confirmed by the joint AI Board and MDCG guidance of June 2025: you do not need a second compliance universe. You need one integrated workstream, and this guide shows you how to set it up.

> **The strategic reframe:** treating evidence and governance as a commercial asset, not a compliance tax, is becoming the differentiator in front of notified bodies, payers and enterprise health system buyers.

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Part 1: Are you in scope? The five-question check

Work through these five questions for each product and pipeline candidate. You will need your software architecture documentation and your current MDR/IVDR classification.

#	Question	Your answer
1	**Does your software qualify as an AI system under Article 3(1)?** A machine-based system that operates with some autonomy and infers from inputs how to generate outputs (predictions, recommendations, decisions). Machine learning and deep learning components typically qualify. Simple deterministic rule-based calculations usually do not. The MDCG 2025-6 guidance helps with edge cases.	Yes ☐ No ☐
2	**Is the AI a product, or a safety component of a product, covered by MDR or IVDR?** This covers software embedded in a device as well as software that is itself the device (SaMD).	Yes ☐ No ☐
3	**Does your conformity assessment involve a notified body?** MDR: Class IIa, IIb and III, plus Class I devices that are sterile, have a measuring function or are reusable surgical instruments. IVDR: everything except non-sterile Class A, so Class A sterile, B, C and D.	Yes ☐ No ☐
4	**Are you the provider or a deployer?** As the manufacturer placing the system on the EU market you are the provider and carry the full obligations. If you also operate the system for customers, deployer duties can apply on top.	Provider ☐ Deployer ☐
5	**Have you mapped the timeline against your certification cycle?** Obligations for high-risk AI systems under Annex I (which covers MDR/IVDR devices) apply from August 2, 2028, after the Digital Omnibus (Regulation (EU) 2026/1744) moved the date by one year. Notified body queues and technical file updates take 12 to 18 months. If your next certification touchpoint falls after mid-2028, the AI Act work has to be finished before it, so start planning now.	Yes ☐ No ☐

> **Verdict:** if you answered yes to questions 1 to 3, your device is a high-risk AI system under Article 6(1) of the AI Act. That is not a catastrophe, it is a project, and Part 2 shows why it is smaller than it looks.

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Part 2: The Article 8(2) integration map

In June 2025 the AI Board and the Medical Device Coordination Group jointly published AIB 2025-1 / MDCG 2025-6 ("Interplay between the MDR/IVDR and the AI Act"). Its most valuable message: manufacturers **do not need a parallel compliance pathway**. Under Article 8(2), AI Act testing, reporting and documentation can be integrated into the MDR/IVDR technical documentation you already maintain. Here is where each AI Act duty lands:

AI Act requirement	Where it lands in your existing system	Integration tip
Risk management (Art. 9)	ISO 14971 risk management file	Extend your existing hazard analysis with AI-specific risks: bias, data drift, automation bias. One risk file, not two.
Data and data governance (Art. 10)	Design and development records, V&V documentation	Document training, validation and test data provenance, representativeness and bias controls where your V&V evidence already lives.
Technical documentation (Art. 11, Annex IV)	MDR Annex II/III technical file	Add one AI annex to your existing file structure. Article 8(2) explicitly allows a single set of documentation.
Record-keeping and logging (Art. 12)	IEC 62304 lifecycle documentation	Specify automatic event logging in the software architecture, then reuse the logs for post-market surveillance and vigilance.
Transparency and instructions (Art. 13)	Instructions for use, SSCP	State AI capabilities, limitations and performance metrics in the IFU your users already read.
Human oversight (Art. 14)	Usability engineering file (IEC 62366)	Design and validate override and confirmation steps as part of your usability validation.
Accuracy, robustness, cybersecurity (Art. 15)	GSPR 17, cybersecurity documentation (IEC 81001-5-1, MDCG 2019-16)	Add AI performance metrics plus robustness and drift testing to existing software verification.
Quality management system (Art. 17)	ISO 13485 QMS	Extend existing SOPs (design control, change control, CAPA) with AI lifecycle elements. No second QMS.
Conformity assessment (Art. 43)	Your notified body procedure under MDR/IVDR	Ask your notified body early whether it is, or will be, designated under the AI Act so one combined assessment is possible.

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AI Act requirement	Where it lands in your existing system	Integration tip
Post-market monitoring (Art. 72)	PMS plan, PMCF/PMPF, PSUR	Fold model performance monitoring and drift detection into the PMS plan. PMCF is your real-world evidence engine (see Part 3).
Serious incident reporting (Art. 73)	Vigilance (MDR Art. 87-89)	Align incident definitions and reporting timelines in one SOP so one event triggers one coordinated report.

> **The one decision that saves months:** give AI Act and MDR/IVDR compliance to one integrated team with one plan. Companies that run them as two projects pay twice, once in cost, once in delay.

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Part 3: From “cleared” to evidence-backed, the RWE roadmap

Clearance is a floor, not a proof of value. With the evidence gap now public and quantified, the companies that voluntarily build and publish outcome evidence will own the trust conversation. Five steps:

Step 1: Audit the gap between your claims and your evidence

Take the top three claims in your sales decks and investor material. For each, write down the strongest evidence behind it: technical performance (sensitivity, AUC), workflow effect (reading time, triage speed), or patient outcome (mortality, readmission). Most companies discover that every claim rests on the first tier.

Step 2: Choose outcome endpoints your buyers actually buy

Death, stroke, readmission, time to diagnosis or treatment, avoided procedures, staff hours saved, cost per case. Pick one or two per product and align them with the business case of the person who signs the purchase order.

Step 3: Use the machinery you already own

Your PMCF/PMPF plan under MDR/IVDR is a legitimate real-world evidence engine: registries, structured EHR collaborations, pragmatic prospective studies. Register studies on ClinicalTrials.gov, it is inexpensive credibility and it puts you in the small group that can be verified.

Step 4: Publish, including neutral results

Peer-reviewed where possible, preprints where speed matters. A published neutral result signals more integrity than an unpublished success claim, and integrity is exactly what the market is about to start paying for.

Step 5: Make evidence a sales asset

Build one evidence dossier per claim and train your commercial teams to answer governance questions. In enterprise health system deals, those questions now come before the clinical ones.

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Part 4: Your first 90 days

Phase	What to do
Weeks 1-2 Inventory	List every product and pipeline item with an AI component. Run the Part 1 check for each. Name one owner for the combined AI Act plus MDR/IVDR workstream.
Weeks 3-6 Gap assessment	Walk the Part 2 map line by line against your technical file and QMS. Contact your notified body: is it designated (or applying) under the AI Act, and what will a combined assessment look like?
Weeks 7-12 Plan and commit	Update QMS SOPs, draft your RWE roadmap (Part 3), brief the board using the six questions below. Optional but smart: submit a comment to the FDA docket by October 19, 2026 and help shape the rules you will live under.

Six questions every board should be able to answer

1. Which of our products are high-risk AI systems under Article 6(1), and who owns that list?
2. Can the evidence we hold today support every claim our sales team makes?
3. Do we run AI Act and MDR/IVDR compliance as one workstream or as two?
4. Is our notified body preparing for combined assessments, and are we in its queue?
5. What is our real-world evidence plan for our highest-revenue AI product?
6. What happens to our pipeline if a competitor publishes patient outcome data first?

Key dates to put in your calendar

Date	What happens
June 2025	AIB 2025-1 / MDCG 2025-6 joint guidance published. If you read one section, read the part on Article 8(2) integration.
July 27, 2026	Digital Omnibus, Regulation (EU) 2026/1744, in force. It rewrites Article 4 (AI literacy) and moves the high-risk dates: Annex III to December 2, 2027, Annex I to August 2, 2028.
August 18, 2026	FDA discussion paper on generative AI-enabled devices opened for comment.
October 19, 2026	FDA comment deadline, Docket FDA-2026-N-7874 on regulations.gov. A rare window to shape US rules before they are drafted.
August 2, 2028	AI Act obligations apply to high-risk AI systems in devices under Annex I (MDR/IVDR). Moved from August 2, 2027 by the Digital Omnibus.

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Sources

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This guide is provided for general information. It is not legal or regulatory advice and does not replace consultation with your notified body or qualified counsel.

Work through this with your own portfolio?

I am **Selina Gaertner**, AI strategy consultant for Life Sciences and MedTech. Before founding my consulting practice I spent many years in sales and marketing leadership roles in international MedTech companies, which is why I look at AI regulation the way your customers do: as a buying decision.

“AI is a business model question, not an IT ticket.”

I help leadership teams turn exactly the topics in this guide into an executable plan: scope assessment across the portfolio, the integrated AI Act plus MDR/IVDR workstream, and an evidence strategy your commercial team can sell with.

> **Book a 30-minute strategy call:** calendly.com/gaertner-selina/30min-with-selina-gaertner
>
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