Compliance 2025 Checklist

✅ Integrated Quality and Risk Management

The AIA complements—not replaces—MDR/IVDR. That means your **Quality Management System (QMS)** must also handle **AI-specific risks**, including data drift, real-world behaviour, and unpredictable model outputs. The best approach? Fold AIA requirements directly into your existing MDR/IVDR QMS to avoid duplication.

✅ AI Data Governance Requirements

AIA Article 10 mandates **clean, representative, and bias-controlled training, validation, and testing data**. That includes demographic diversity, appropriate sampling sizes, and mitigation strategies for bias. You'll need to log system behaviour, audit AI decisions, and prove compliance in your **technical documentation**.

✅ Explainability and Human Oversight in AI Medical Devices

Medical professionals must be able to understand and challenge AI decisions—especially when they affect diagnosis or treatment. That's not just best practice—it's **EU law**. You must provide training for deployers (like radiologists or clinicians), create clear instructions for use, and design for **human-in-the-loop control**.

✅ Adaptive AI? You'll Need a Change Control Plan

AI that learns post-deployment (adaptive or continuously learning models) must have a **Pre-Determined Change Control Plan** built into the conformity assessment. Otherwise, any substantial modification will trigger a full reassessment under both MDR/IVDR and AIA—especially after **2 August 2027**.

✅ Cybersecurity in AI Medical Software

AI systems are now required to be secure **by design**. That includes securing the model itself, training data pipelines, system interfaces, and real-time monitoring tools. The AIA adds **AI-specific cybersecurity standards** that go beyond MDR/IVDR—covering threats like adversarial attacks, model manipulation, and data poisoning.

✅ Post-Market Monitoring with AI in Mind

You'll need a **post-market surveillance system** that actively tracks AI performance, bias emergence, and interaction with other AI systems. The EU will publish an official template for AIA-compliant PMS by **February 2026**—but smart manufacturers are aligning now.