AI compliance and standards

If you use AI, we record every AI system you run, set its risk tier and confirm whether you are a provider or a deployer. You get a ranked plan against the EU Artificial Intelligence Act (AI Act).

If you build high-risk AI, we build the quality management system that Article 17 of the AI Act requires, to EN 18286. It fits into your existing ISO 13485 or ISO/IEC 27001 system, so you run one system, one risk file and one technical file.

WHAT IT COVERS

EU AI Act

Gap analysis, AI register and risk tiers, with your role confirmed.

ISO/IEC 42001

An AI management system taken to certification, or added to ISO/IEC 27001.

EN 18286

The Article 17 quality system for high-risk AI, built into ISO 13485.

HOW IT WORKS

01 Readiness check — 4 TO 6 DAYS
Which standard you need, which systems are high-risk, how far you are.

02 Build — 3 TO 6 MONTHS
The system written into your business, with records and trained owners.

03 Prepare for certification — BEFORE AUDIT
Everything checked before certification or your notified body.

04 Keep it current — 12 MONTHS
New AI systems assessed, rule changes tracked, quarterly reviews.

ACROSS EUROPE AND BEYOND

The AI Act applies to any AI system placed on the EU market, wherever its provider is based. We work with Irish and European providers, and with UK and United States companies selling AI into the EU. Providers outside the EU also need an authorised representative in the Union for high-risk systems. ISO/IEC 42001 is recognised worldwide.

WHO IT IS FOR
Medtech and software as a medical device, HR, education, credit and insurance AI

WHY NOW
Annex III from 2 December 2027; Annex I from 2 August 2028

LED BY
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Start with a 30-minute briefing, at no charge.

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