

COMPLIANCE YOU CAN TRUST. INNOVATION YOU CAN SCALE.

AI Act & ISO 42001:2023 compliance, made seamless.

Translate AI regulatory obligations into effective governance, controlled risk and auditable evidence.

YOUR CHALLENGES

-  **UNCLEAR REQUIREMENTS** Which AI systems, risks classes and regulatory mandates actually apply to your devices ?
-  **OPERATIONALIZATION GAPS** How do complex AI requirements translate into day-to-day governance, technical controls, and evidence?
-  **AUDIT & REGULATOR SCRUTINY** How to build a defensible, audit-ready framework that withstands strict Notified Body inspection?

OUR APPROACH

01 ASSESS

- Current organization & device readiness assessment
- Regulatory gap analysis (EU MDR 2017/745, EU IVDR 2017/746, AI Act)
- Prioritized compliance roadmap & action plan



02 IMPLEMENT

- Ready-to-use ISO/IEC 42001:2023 Quality Management System toolkit
- Documentation and evidence framework
- Hands-on technical support



03 ASSURE

- Dedicated training on ISO/IEC 42001:2023
- On-demand AI regulatory hotline
- Continuous post-market & lifecycle guidance
- Audit & Notified Body support

YOUR BENEFITS



CLARIFIED SCOPE

Eliminate regulatory ambiguity and accelerate your AI device roadmap with a clearly defined compliance perimeter.



TURNKEY OPERATIONAL TOOLKIT

Operationalize AI governance instantly without reinventing procedures.



NOTIFIED BODY CONFIDENCE

Deliver fully defensible, standard-compliant documentation built for smooth auditor approval.

**READY TO ASSESS YOUR
AI COMPLIANCE?**

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