

DIGITAL HEALTH COMPLIANCE.

BUILT FOR CONFIDENCE.

End-to-end digital health compliance from software design to cybersecurity governance.

Build digital health products on a foundation of secure design, regulatory compliance and defensible evidence.

YOUR CHALLENGES



REGULATORY AMBIGUITY Which exact software qualification (MDR, IVDR, SaMD) and standards (IEC 62304, AI Act) apply?



DOCUMENTATION OVERLOAD How to ensure software architecture, development processes, risk controls and technical documentation remain consistent and defensible throughout the lifecycle?



CONVERGING GOVERNANCE How to embed cybersecurity, AI and post-market governance across the QMS and product lifecycle?

OUR APPROACH

01 ASSESS

- Comprehensive software audit and lifecycle process evaluation
- Regulatory gap analysis across EU MDR 2017/745, EU IVDR 2017/746, IEC 62304, and the EU AI Act
- Software qualification report and prioritized execution roadmap



02 IMPLEMENT

- Technical documentation, core templates, and compliant frameworks
- Aligned IEC 62304, IEC 81001-5-1, ISO 27001 and applicable AI requirements;
- Risk management, traceability, secure development practices and technical evidence.



03 ASSURE

- Dedicated team training on digital health standards and regulations
- On-demand technical and regulatory hotline for queries
- Audit and regulatory review support
- Continuous post-market surveillance and software maintenance guidance

YOUR BENEFITS



REGULATORY CLARITY & TRACEABILITY

Clear interpretation of applicable requirements, enabling robust controls, end-to-end traceability and defensible evidence to support compliance.



AUDIT-READY SOFTWARE COMPLIANCE

Consistent software lifecycle, risk and technical documentation designed to support regulatory, notified-body and customer review.



COMPREHENSIVE CYBERSECURITY & AI GOVERNANCE

Security and AI governance embedded into development, quality and post-market processes, supporting sustainable compliance.

READY TO ASSESS YOUR DIGITAL HEALTH COMPLIANCE?

WWW.EFOR-GROUP.COM



Committed to **Excellence**