

ISO 14971 Medical Device Risk Management

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ISO 14971 Frame

ISO 14971 (Medical devices — Application of risk management to medical devices) is the dominant international medical-device risk-management standard, integrated with FDA QSR, EU MDR, and similar regulatory frameworks globally.

Architecture Implications

Risk management requirements increasingly require structural support for autonomous medical devices. Hazard analysis, risk control measure verification, and post-market surveillance all benefit from architectural substrate.

Architectural Mapping

Reversibility classification supports hazard analysis. Stage-gated commitment supports risk-control-measure decomposition. Composite admissibility supports multi-authority medical-device operation.

Standard Evolution

ISO 14971 ongoing revision and emerging integration with FDA PCCP framework
push toward structurally-supported architecture.