

IEC 62304 Medical Device Software Lifecycle

by [Nick Clark](#) | Published April 25, 2026

IEC 62304 Frame

IEC 62304 (Medical device software — Software lifecycle processes) establishes safety-class structure (A/B/C) with C the most stringent for software where failure could cause death or serious injury.

Architecture Implications

Class-C medical software increasingly faces emerging continuously-improving AI-software requirements that traditional waterfall lifecycle handling does not support effectively.

Architectural Mapping

Runtime-signed adaptation artifacts map to medical-software update authority. Sandbox pre-activation maps to safety-class-appropriate verification. Cascade-deactivation maps to medical-software incident response.

Standard Evolution

IEC 62304 emerging revision integrating AI/ML capabilities and emerging FDA PCCP framework integration both push toward structurally-supported architecture.