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STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · INTERNATIONAL STANDARD

IEC 62304

Medical device software — Software life cycle processes

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ISSUED BY	IEC/SC 62A with ISO/TC 210	PREPARED BY	Conner Davidson
EDITION	Edition 1.1 (2006 + Amendment 1:2015)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-iec-62304.html

CURRENT EDITION Edition 1.1 is current. A second edition is at committee-draft stage; a final draft is not expected before 2028, and the draft cannot be used for a conformity claim. **Next:** Edition 2 would widen the scope to health software and simplify safety classes; plan for it, but build to 1.1.

What It Covers

The life cycle processes for software that is part of a medical device or is itself a device: development, maintenance, risk management, configuration management, and problem resolution.

Who It Applies To

Manufacturers of devices containing software and of software as a medical device, and their software suppliers.

Key Requirements

- A software safety class (A, B, or C) assigned from risk, which sets how much rigor each activity needs.
- A software development plan, requirements, architecture, and for higher classes detailed design and unit verification.
- Software of unknown provenance (SOUP) identified, with its requirements and known anomalies evaluated.
- A maintenance plan, problem resolution, and configuration management after release.

What an Auditor Asks to See

- The software development plan and the safety classification rationale.
- The SOUP list with versions and evaluated anomalies.
- Traceability from requirements to tests, and the problem reports since release.

Where Systems Fall Short

- SOUP lists missing operating systems, libraries, or their versions.
- No defined process for evaluating problem reports after release.

How QES helps. Software files aligned to the device risk file, with SOUP and problem resolution brought under document control. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. IntuitionLabs — IEC 62304 Edition 2 status (updated October 2026) — intuitionlabs.ai/articles/iec-62304-edition-2-medical-software-changes; IEC Webstore — IEC 62304 — webstore.iec.ch.

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