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STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · INTERNATIONAL STANDARD

IEC 62366-1

Medical devices — Part 1: Application of usability engineering to medical devices

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ISSUED BY	IEC/SC 62A with ISO/TC 210	PREPARED BY	Conner Davidson
EDITION	Edition 1.1 (2015 + Amendment 1:2020)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-iec-62366-1.html

CURRENT EDITION Edition 1.1 (2015 with Amendment 1:2020) is current. FDA's 2016 human factors guidance covers similar ground for US submissions.

What It Covers

A usability engineering process that treats use error as a design input: who uses the device, where, for what, and which use scenarios could lead to harm.

Who It Applies To

All medical device manufacturers, for the user interface of every device, including labeling and training materials.

Key Requirements

- A use specification: intended users, use environments, and the user interface.
- Known use problems and hazard-related use scenarios identified and linked to risk management.
- A user interface specification, with formative evaluations during design.
- A summative evaluation showing the final design is safe to use, and a usability engineering file.

What an Auditor Asks to See

- The use specification and the hazard-related use scenarios.
- Formative and summative evaluation protocols, participants, and results.
- Traceability from use errors observed to design or labeling changes.

Where Systems Fall Short

- A summative test run on a prototype that differs from what shipped.
- Use errors from complaints never fed back into the scenarios.

How QES helps. Usability files tied into the risk file and the complaint system, so field use errors reach the design. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. IEC Webstore — IEC 62366-1 — webstore.iec.ch; Greenlight Guru — ISO standards for medical devices (2026) — www.greenlight.guru/blog/iso-standards.

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