SmartSuite

Framework / Quality & Safety / ISO Industry Standards

IEC 62304:2006 + A1:2015

IEC 62304 defines life cycle processes, software safety classes A, B and C, and risk, change and problem controls for medical device software.



What it is

IEC 62304 is the international standard for the life cycle processes of medical device software, both software that is itself a medical device and software embedded in a device. The current text is IEC 62304:2006+AMD1:2015 (Edition 1.1), which manufacturers apply to the development and maintenance of that software; Edition 1.0 was published on 9 May 2006 and Amendment 1 on 26 June 2015.

At a glance

PUBLISHER
International Electrotechnical Commission (IEC), with ISO as a dual logo standard

TYPE
Standard

VERSION
IEC 62304:2006+AMD1:2015, Edition 1.1 (consolidated version)

EFFECTIVE
June 26, 2015 (Edition 1.1, with Amendment 1)

DOMAIN
Quality & Safety

FAMILY
ISO Industry Standards

REGION
International

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Voluntary

IMPLEMENTATION COMPLEXITY
High

Source: webstore.iec.ch/en/publication/22794

Why it matters

- **Effort scaled to risk** Clause 4.3 assigns each software system a safety class, and compliance is defined by class (1.4), so a low-risk component carries a lighter documentation load than a high-risk one.
- **One risk process** ISO 14971 is the normative reference for risk management, and clause 7 adds the software-specific steps inside the device risk management process.
- **Maintenance held to the same standard** Clause 6 requires a maintenance plan (6.1), problem and modification analysis (6.2) and controlled modification (6.3).
- **Controlled change and problem handling** Clause 8 covers configuration identification, change control and status accounting, and clause 9 sets eight steps for software problem resolution.

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How SmartSuite supports IEC 62304

Safety Class Register

Record each software system's class (A, B or C), the hazard analysis behind it and the approver (clause 4.3).

Development Plan and Activities

Track the clause 5 activities for each release: planning, requirements, design, unit verification, integration, system testing and release (5.1 to 5.8).

Requirements-to-Test Traceability

Connect software requirements, risk control measures and test results so each hazard has a verified control (5.2, 7.2, 7.3).

Software Item and SOUP Inventory

List software items and software of unknown provenance with versions and known anomalies (8.1).

Change and Release Control

Route each change request through analysis, approval, risk review and release (6.2, 7.4, 8.2).

Problem Report Workflow

Manage problem reports from entry to verified resolution, with trend review (9.1 to 9.7).

Common framework mappings

ISO 13485:2016 | ISO 14971:2019 | ISO 27001 | ISO 27018 | NIST CSF 2.0

Official resources

IEC 62304:2006+AMD1:2015 on the IEC Webstore

Consolidated Edition 1.1 of Medical device software - Software life cycle processes, with scope and edition history.

webstore.iec.ch/en/publication/22794

IEC 62304:2006/AMD1:2015 on the IEC Webstore

Amendment 1 to IEC 62304, published 26 June 2015, adding legacy software and the risk-based safety classification.

webstore.iec.ch/en/publication/22790

Frequently asked questions

Which edition of IEC 62304 is current?

The current text is IEC 62304:2006+AMD1:2015, Edition 1.1, a consolidated version of the 2006 first edition and its 2015 Amendment 1, published on 26 June 2015. The IEC webstore shows a stability date of 2028 and lists an Edition 2.0 project in preparation, so the 2015 text remains the one to cite today.

What are the software safety classes in IEC 62304?

Under clause 4.3 the manufacturer assigns each software system class A, B or C according to the possible effects on the patient, operator or other people of a hazard to which the software contributes. Class A means no injury or damage to health is possible, class B means non-serious injury is possible, and class C means death or serious injury is possible. Compliance is defined per class (1.4), and Table A.1 summarizes the requirements for each.

Is IEC 62304 mandatory or certifiable?

It is a standard, not a certification scheme. Under clause 1.4 compliance means implementing all the processes, activities and tasks required for the software safety class, and it is assessed by inspecting documentation including the risk management file, by internal or external audit. Regulators use it as an accepted route: the FDA accepts a declaration of conformity to named clauses of the recognized version.

How does IEC 62304 relate to ISO 14971 and ISO 13485?

ISO 14971 is the normative reference for risk management (clause 2), and clause 7 adds software-specific steps inside that process. The standard assumes development inside a quality management system (4.1), and Annex C relates it to ISO 13485. For standalone software, the system-level activities that it does not cover are found in standards such as IEC 82304-1.

How does IEC 62304 treat legacy software and off-the-shelf software?

Amendment 1 added clause 4.4 for legacy software, meaning software whose design predates the current version of the standard. Software of unknown provenance is addressed in clause 8.1.2, within the configuration management process, and the scope notes (1.2) confirm that the requirements for it apply to embedded software.

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Full framework page and mappings: smartsuite.com/frameworks/iec-62304-medical-device-software-lifecycle-processes