SmartSuite

Framework / Software Security / ISO Industry Standards

IEC 62304:2006 + A1:2015

IEC 62304 specifies lifecycle process requirements for developing and maintaining safe, effective medical device software.

What it is

IEC 62304 is an international standard for medical device software lifecycle processes that helps organizations ensure the safety, reliability, and effectiveness of software used in medical devices. The framework establishes requirements for managing the development, maintenance, risk management, and validation of medical software throughout its lifecycle.

Published by the International Electrotechnical Commission (IEC), IEC 62304 applies to medical device manufacturers, developers, and quality assurance teams responsible for software components or standalone medical software. The standard covers software risk management, change control, documentation, verification, and compliance oversight in regulated healthcare environments.

At a glance

PUBLISHER
International Electrotechnical Commission (IEC)

TYPE
Standard

VERSION
IEC 62304:2006 + Amendment 1:2015

EFFECTIVE
2006

DOMAIN
Software Security

FAMILY
ISO Industry Standards

REGION
International (IEC)

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Regulatory Compliance

IMPLEMENTATION COMPLEXITY
High

Source: https://webstore.iec.ch/publication/3842

Why it matters

- **Strengthen software risk management** Enable systematic identification, analysis, and control of software-related risks throughout the product lifecycle to protect patient safety.
- **Enhance regulatory alignment** Support adherence to international medical device regulations, easing global market access and regulatory submissions.
- **Increase audit readiness** Facilitate preparation for external audits by promoting complete, accurate, and up-to-date technical documentation and software process records.
- **Improve product quality assurance** Promote disciplined development, verification, and maintenance practices that reduce software defects and support long-term device reliability.

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How SmartSuite supports IEC 62304

Software Lifecycle Process Structure

Manage lifecycle plans, roles, and required activities by software safety class.

Requirements-to-Test Traceability

Connect requirements, risks, tests, and releases with end-to-end traceability.

Verification and Validation Evidence

Centralize test plans, results, reviews, and approvals aligned to lifecycle steps.

Configuration and Change Management

Track versions, change approvals, and release evidence to maintain control.

Defect and Problem Resolution Workflow

Manage defects, investigations, corrective actions, and closure verification.

Audit-Ready Traceability Reporting

Report coverage, gaps, and traceability status across the software lifecycle.

Common framework mappings

ISO 13485:2016 | ISO 14971:2019 | ISO 27001:2022 | ISO 27018 | NIST CSF 2.0

Official resources

IEC 62304 Standard

Defines requirements for medical device software lifecycle processes, ensuring software safety and reliability.

webstore.iec.ch/publication/3842

Frequently asked questions

What is IEC 62304 used for?

IEC 62304 is used as a standard for the development and maintenance of medical device software, providing a framework that ensures safety, reliability, and regulatory compliance throughout the software lifecycle. It establishes process requirements and documentation needed to demonstrate effective management of software risks within medical products.

Is IEC 62304 compliance mandatory or certifiable?

IEC 62304 compliance is not directly certifiable, but adherence is often required by regulatory authorities in many jurisdictions as part of overall medical device approval. Manufacturers may need to demonstrate conformance with IEC 62304 during audits or when submitting technical files to bodies such as the FDA or notified bodies in the EU.

Who does IEC 62304 apply to?

IEC 62304 applies to organizations involved in the development, maintenance, and lifecycle management of medical device software, including both embedded software within medical hardware and standalone software as a medical device (SaMD). It is relevant for manufacturers, developers, and quality/regulatory professionals.

What are the key concepts and artifacts required by IEC 62304?

Key concepts in IEC 62304 include software risk management, safety classification (Class A, B, C), configuration management, and problem resolution processes. Required artifacts include software development plans, risk analysis reports, verification and validation evidence, and detailed documentation of changes and maintenance.

How should organizations implement IEC 62304?

Organizations should integrate IEC 62304 processes into their existing software development life cycle, ensuring alignment between risk management, quality assurance, and regulatory requirements. Implementation typically involves establishing documented procedures, structured review processes, and traceability between requirements, design, testing, and maintenance.

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How does IEC 62304 relate to other regulatory frameworks like ISO 13485?

IEC 62304 complements standards such as ISO 13485, which sets requirements for quality management systems in medical device manufacturing. While ISO 13485 covers the broader quality framework, IEC 62304 specifically addresses software development lifecycle processes and is often referenced as a harmonized standard for regulatory compliance.

What ongoing compliance requirements are associated with IEC 62304?

Maintaining compliance with IEC 62304 requires organizations to continuously manage software risks, rigorously control changes, keep documentation up to date, and routinely verify and validate software. Annual reviews, regular audits, and updated risk assessments are essential to demonstrate sustained conformance.

How would SmartSuite support IEC 62304?

SmartSuite can streamline IEC 62304 compliance by enabling organizations to document and track all phases of the software lifecycle, perform and record risk assessments, manage changes and configuration items, collect verification and validation evidence, and generate comprehensive reports for audit readiness and regulatory submissions.

License included / downloadable: No IEC 62304 is published by the International Electrotechnical Commission. Access to the full standard typically requires purchasing official documentation through authorized standards organizations. License not included with platform

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

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