SmartSuite

Framework / Risk Management / ISO Industry Standards

ISO 14971:2019

ISO 14971 is a medical device risk management standard for identifying, evaluating, and controlling device risks to protect patients.

What it is

ISO 14971 is an international risk management standard that helps organizations in the medical device industry identify, evaluate, and control risks associated with medical devices throughout their lifecycle. Its primary objective is to enhance patient safety and ensure regulatory compliance by providing a systematic framework for risk analysis and mitigation.

Published by the International Organization for Standardization (ISO), ISO 14971 is widely adopted by medical device manufacturers, suppliers, and regulators. The standard addresses areas such as hazard identification, risk evaluation, risk control measures, and ongoing risk monitoring, aligning with the regulatory requirements imposed by global health authorities.

At a glance

PUBLISHER International Organization for Standardization (ISO)	TYPE Standard	VERSION ISO 14971:2019
EFFECTIVE 2019	DOMAIN Risk Management	FAMILY ISO Industry Standards
REGION International	INDUSTRY Healthcare & Life Sciences	ADOPTION MODEL Risk Management
IMPLEMENTATION COMPLEXITY High		

Source: https://www.iso.org/standard/72704.html

Why it matters

- **Support regulatory compliance** Enable organizations to meet stringent international and regional medical device regulations, reducing barriers to market entry and approval.
- **Strengthen patient safety practices** Improve identification, evaluation, and mitigation of potential device hazards, directly supporting enhanced protection of patient health.
- **Enhance audit readiness** Maintain well-documented risk management files, facilitating smoother regulatory audits and demonstrating comprehensive oversight and control.
- **Align with quality management systems** Integrate seamlessly with standards like ISO 13485 to ensure cohesive and proactive risk mitigation throughout the device lifecycle.

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How SmartSuite supports ISO 14971:2019

Hazard Identification and Harm Analysis

Identify hazards, hazardous situations, and potential harms across device lifecycles.

Risk Severity and Acceptance Decisions

Assess risk severity and probability and document acceptance decisions.

Risk Control Implementation and Traceability

Track mitigation measures and link controls to specific risks and product components.

Verification of Risk Controls

Capture testing, validation, and evidence demonstrating effectiveness of risk controls.

Post-Market Surveillance and Feedback

Monitor real-world performance, incidents, and feedback to update risk assessments.

Risk Management Reporting and Compliance

Provide dashboards showing risk status, residual risks, and regulatory readiness.

Common framework mappings

IEC 62304 | ISO 13485:2016 | ISO 31000:2018 | ISO 27001:2022 | NIST CSF 2.0

Official resources

ISO 14971:2019 Standard

Defines the process for risk management applicable to medical devices.

iso.org/standard/72704.html

Frequently asked questions

What is ISO 14971 used for?

ISO 14971 is used to systematically identify, assess, and manage risks associated with medical devices throughout their lifecycle. The standard ensures that manufacturers prioritize patient safety and comply with global regulatory requirements by implementing effective risk management processes.

Is ISO 14971 mandatory or certifiable?

ISO 14971 itself is not certifiable, but implementation is often mandatory or strongly recommended by regulatory authorities such as the EU Medical Device Regulation (MDR) and U.S. FDA. Compliance with ISO 14971 is typically assessed during regulatory audits and as part of ISO 13485 certification.

Who does ISO 14971 apply to?

ISO 14971 applies to organizations involved in the design, development, production, post-production monitoring, and support of medical devices, including manufacturers, suppliers, and contract organizations. It is relevant for all classes of medical devices, from low-risk to high-risk products.

What are the key concepts and artifacts of ISO 14971?

Key artifacts include the Risk Management Plan, Risk Management File, hazard identification documentation, risk analyses, risk evaluations, records of implemented controls, and documented benefit-risk decisions. The process requires comprehensive documentation and traceability of all risk management activities.

How does the ISO 14971 risk management process work?

Organizations following ISO 14971 establish risk management plans, identify hazards, analyze and evaluate risks, implement control measures, and document residual risk and ongoing monitoring efforts. The process is iterative and lifecycle-oriented, requiring continual reassessment based on new data or post-market information.

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How does ISO 14971 relate to other frameworks like ISO 13485 or MDR?

ISO 14971 is closely linked to ISO 13485, which sets broader quality management system requirements for medical devices. It also aligns with regional regulatory frameworks, including the EU MDR and FDA's Quality System Regulation (QSR), serving as a recognized benchmark for risk management practices.

What are ongoing compliance requirements for ISO 14971?

Ongoing requirements include continuous post-market surveillance, regular review of risk assessments, documentation of any changes affecting risk, and periodic updates to the Risk Management File. Organizations must ensure effective communication of new risks and controls to stakeholders and maintain readiness for audits.

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Full framework page and mappings: smartsuite.com/frameworks/iso-14971-medical-device-risk-management-2019