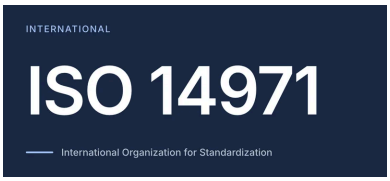
SmartSuite

Framework / Risk Management / ISO Industry Standards

ISO 14971:2019

ISO 14971:2019 specifies the risk management process for medical devices: hazards, risk evaluation, risk control, overall residual risk and post-production monitoring.



What it is

ISO 14971:2019 is the international standard that specifies terminology, principles and a process for managing the risks of medical devices, including software as a medical device and in vitro diagnostic devices, across the whole device life cycle. Prepared by ISO/TC 210 and IEC/SC 62A, it was published in December 2019 as the third edition, replacing ISO 14971:2007.

It is written for manufacturers, who identify hazards, estimate and evaluate the associated risks, control them and monitor the controls (clause 1). The standard requires objective criteria for risk acceptability but does not set acceptable levels, and it does not require a quality management system. It does not cover decisions on using a device in a clinical procedure or business risk management (clause 1).

At a glance

PUBLISHER
International Organization for Standardization (ISO)

TYPE
Standard

VERSION
ISO 14971:2019 (third edition)

EFFECTIVE
December 2019 (third edition published; ISO sets no separate effective date)

DOMAIN
Risk Management

FAMILY
ISO Industry Standards

REGION
International

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Voluntary

IMPLEMENTATION COMPLEXITY
High

Source: iso.org/standard/72704.html

Why it matters

- **Benefit is a defined term** The 2019 edition defines benefit, reasonably foreseeable misuse and state of the art, and aligns benefit-risk analysis (clause 7.4) with the terminology used in some regulations.
- **Overall residual risk has criteria** The method for evaluating overall residual risk and the criteria for its acceptability are defined in the risk management plan, and can differ from the criteria for individual risks (clauses 4.4 and 8).
- **Security risks are in scope** Risks related to data and systems security are named in the scope, and the foreword says the process can manage them.
- **A documented review before release** The review before commercial distribution checks execution of the risk management plan, and its results are documented as the risk management report (clause 9).

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How SmartSuite supports ISO 14971:2019

Risk Management Plan and File

Record the plan, the acceptability criteria and the method for overall residual risk, with links to the contents of the risk management file (clauses 4.4 and 4.5).

Intended Use and Misuse

Capture intended use and reasonably foreseeable misuse for each device (clause 5.2).

Hazards and Hazardous Situations

Register hazards, hazardous situations, estimated risk and the evaluation against the criteria (clauses 5.4 to 6).

Risk Control Measures

Track control options, implementation and residual risk per hazard, including risks arising from the controls (clauses 7.1 to 7.6).

Overall Residual Risk and Review

Hold the overall residual risk evaluation and the review record made before commercial distribution (clauses 8 and 9).

Post-Production Information

Log collected information, review outcomes and actions taken when information is relevant to safety (clauses 10.2 to 10.4).

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 does ISO 14971:2019 cover?

It specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic devices. The process helps manufacturers identify hazards, estimate and evaluate risks, control them and monitor the controls, in all phases of the device life cycle (clause 1).

Is ISO 14971 mandatory or certifiable?

ISO 14971 is a process standard, not a management system standard, and it does not require a quality management system (clause 1). Use is voluntary, although EN ISO 14971:2019 and its A11:2021 amendment are listed as harmonized standards under Regulation (EU) 2017/745. Manufacturers show conformity through their risk management file and report.

What records does the standard expect?

The risk management plan (clause 4.4) and the risk management file (4.5) are the core records. The review before commercial distribution checks execution of the plan and is documented as the risk management report (clause 9). The overall residual risk evaluation (clause 8) and production and post-production information (clause 10) feed the same file.

What changed in the 2019 edition?

The third edition added a normative references clause and defined benefit, reasonably foreseeable misuse and state of the art. It aligned the term benefit-risk analysis with regulations, said the process can manage data and systems security risks, and required the method and criteria for overall residual risk to be set in the plan. Production and post-production requirements were restructured, and several informative annexes moved to ISO/TR 24971.

How does ISO 14971 relate to ISO 13485?

Risk management can be part of a quality management system, such as one built on ISO 13485, but ISO 14971 does not require one (clause 1). ISO 13485:2016 sets the system requirements; the FDA states that its QMSR, which incorporates ISO 13485:2016, now specifically requires risk management. ISO/TR 24971:2020 gives guidance on applying ISO 14971.

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