SLOVENSKI STANDARD
oSIST prEN ISO 14971:2018

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Medicinski pripomočki - Uporaba obvladovanja tveganja pri medicinskih pripomočkih (ISO/DIS 14971:2018)

Medical devices - Application of risk management to medical devices (ISO/DIS 14971:2018)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO/DIS 14971:2018)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO/DIS 14971:2018)

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Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

ICS: 11.040.01

Member bodies are requested to consult relevant national interests in IEC/SC 62A before casting their ballot to the e-Balloting application.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

This third edition cancels and replaces the second edition, which has been technically revised. The main changes compared to the previous edition are as follows:

— A clause on normative references is included, following the requirements of ISO-IEC Directives, Part 2.

— The defined terms are updated and many are derived from ISO/IEC Guide 63:20xx. A definition of benefit is introduced.

— More attention is given to the benefits that are expected from the use of the medical device. The term benefit-risk analysis is aligned with terminology used in some regulations.

— It is explained that the process described in ISO 14971 can be used for managing all types of risks associated with medical devices, including those related to data and systems security.

— The method for the evaluation of the overall residual risk and the criteria for its acceptability must be defined in the risk management plan. The method can include gathering and reviewing data and literature for the medical device and similar devices on the market. The criteria for the acceptability of the overall residual risk can be different from the criteria for acceptability of individual risks.

— The requirements to disclose residual risks are merged into one requirement, after the overall residual risk has been evaluated and judged acceptable.

— The review before commercial distribution of the medical device concerns the execution of the risk management plan. The results of the review are documented as the risk management report. The manufacturer must determine when subsequent reviews and updates of the risk management report are needed.

93 — The clause on production and post-production information is clarified and restructured. More detail is given
94 on the information to be collected and the actions to take when the information is determined to be relevant
95 to safety.

96 — Several informative annexes are moved to the guidance in ISO/TR 24971, which has been revised in parallel.
97 More information and a rationale for the requirements in this third edition of ISO 14971 is provided in
98 Annex A. The correspondence between the clauses of the second edition and those of this third edition is
99 given in Annex B.

100 For purposes of future IEC maintenance, Subcommittee 62A has decided that the contents of this publication will
101 remain unchanged until the maintenance result date[1)] indicated on the IEC web site under http://webstore.iec.ch
102 in the data related to the specific publication. At this date, the publication will be

103 — reconfirmed,

104 — withdrawn,

105 — replaced by a revised edition, or

106 — amended.

1) IEC National Committees are requested to note that for this publication the maintenance result date is 2024.

Introduction

The requirements contained in this document provide manufacturers with a framework within which experience, insight and judgment are applied systematically to manage the risks associated with the use of medical devices.

This document was developed specifically for manufacturers of medical devices or medical systems on the basis of established principles of risk management that have evolved over many years. This document could be used as guidance in developing and maintaining a risk management process for manufacturers of other products that are not necessarily medical devices in some jurisdictions and for suppliers and other parties involved in the medical device life-cycle.

This document deals with processes for managing risks associated with medical devices. Risks can be related to injury or damage, primarily to the patient, but also to the operator, other persons, data, property, other equipment and the environment.

As a general concept, activities in which an individual or an organization is involved can expose those or other stakeholders to hazards which can lead to a harm, i.e., injury or cause loss of or damage to something they value. Risk management is a complex subject because each stakeholder can place a different value on the probability of harm occurring and its severity.

The concepts of risk management are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

It is generally accepted that the concept of risk has two key components:

— the probability of occurrence of harm; and

— the consequences of that harm, that is, how severe it might be.

All stakeholders need to understand that the use of a medical device entails an inherent degree of risk, even after the risks have been reduced. It must be accepted in the context of the clinical procedure that some residual risks remain. The acceptability of a risk to a stakeholder is influenced by the key components listed above and by the stakeholder's perception of the risk. Each stakeholder's perception of the risk can vary depending upon their cultural background, the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a risk is perceived also takes into account other factors, for example, whether exposure to the hazard or hazardous situation seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society.

As one of the stakeholders, the manufacturer reduces risks and makes judgments relating to the safety of a medical device, including the acceptability of residual risks. The manufacturer takes into account the generally acknowledged state of the art, in order to determine the suitability of a medical device to be placed on the market for its intended use. This document specifies a process through which the manufacturer of a medical device can identify hazards associated with the medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of the controls throughout the life-cycle of the medical device.

The decision to use a medical device in the context of a particular clinical procedure requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgments are beyond the scope of this document and should take into account the intended use, the circumstances of use, the performance and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure. Some of these judgments can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.

For any particular medical device, other standards or regulations could require the application of specific methods for managing risk. In those cases, it is necessary to also follow the requirements outlined in those documents.

Medical devices — Application of risk management to medical devices

1 Scope

This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and *in vitro* diagnostic (IVD) medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this document are applicable to all stages of the life-cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as for example those related to biocompatibility, data and systems security, electricity, moving parts, radiation, usability, and other risks.

This document does not apply to decisions on the use of a medical device in the context of any particular clinical procedure. This document does also not apply to business risk management.

This document does not specify acceptable risk levels, but requires manufacturers to establish objective criteria for risk acceptability.

This document does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.

NOTE Guidance on the application of this document can be found in ISO/TR 24971 [9].

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
accompanying documentation
materials accompanying a medical device and containing information for the operator, the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the medical device, particularly regarding safe use

Note 1 to entry: The accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: Accompanying documentation is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

[SOURCE: IEC 62366-1:2015, 3.2, modified — Inserted “the operator” and “decommissioning and disposal”, Note 3 to entry deleted.]

3.2
benefit
positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health

Note 1 to entry: Benefits can include positive impact on clinical outcome, the patient’s quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or public health impact.

3.3
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:20XX, 2.1]

3.4
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 63:20XX, 2.2]

3.5
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more hazards

Note 1 to entry: See Annex C for an explanation of the relationship between “hazard” and “hazardous situation”.

[SOURCE: ISO/IEC Guide 63:20XX, 2.3, modified — Note 1 to entry added.]

3.6
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

[SOURCE: ISO/IEC Guide 63:20XX, 2.4]

3.7
***in vitro* diagnostic medical device**
IVD medical device
device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1:2009, 3.27, modified — NOTE deleted.]

3.8
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:20XX, 2.5]

3.9

manufacturer

natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: ISO/IEC Guide 63:20XX, 2.6]

3.10

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of *in vitro* examination of specimens derived from the human body,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Note 1 to entry: Products which could be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO/IEC Guide 63:20XX, 2.7]

3.11
objective evidence
data supporting the existence or verity of something

Note 1 to entry: Objective evidence can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 9000:2015, 3.8.3, modified — Note 2 to entry deleted.]

3.12
post-production
part of the life-cycle of the medical device after the design has been completed and the medical device has been manufactured

EXAMPLES Transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.

3.13
procedure
specified way to carry out an activity or a process

Note 1 to entry: Procedures can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

3.14
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the “intended result” of a process is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 are deleted.]

3.15
reasonably foreseeable misuse
use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 63:20XX, 2.8.]

3.16
record
document stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action.

Note 2 to entry: Generally records need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

3.17
residual risk
risk remaining after risk control measures have been implemented

[SOURCE: ISO/IEC Guide 63:20XX, 2.9]

3.18
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63:20XX, 2.10, modified – Note 1 to entry deleted]

3.19
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 63:20XX, 2.11]

3.20
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.21
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:20XX, 2.12]

3.22
risk estimation
process used to assign values to the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63:20XX, 2.13]

3.23
risk evaluation
process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

[SOURCE: ISO/IEC Guide 63:20XX, 2.14]

3.24
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[SOURCE: ISO/IEC Guide 63:20XX, 2.15]

3.25
risk management file
set of records and other documents that are produced by risk management

3.26
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 63:20XX, 2.16]

3.27
severity
measure of the possible consequences of a hazard

[SOURCE: ISO/IEC Guide 63:20XX, 2.17]

3.28
state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the “generally acknowledged state of the art”.

[SOURCE: ISO/IEC Guide 63:20XX, 2.18]

3.29
top management
person or group of people who directs and controls a manufacturer at the highest level

[SOURCE: ISO 9000:2015, 3.1.1, modified — “An organization” replaced by “a manufacturer”, Notes to entry deleted.]

3.30
use error
user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user

Note 1 to entry: Use error includes the inability of the user to complete a task.

Note 2 to entry: Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment.

Note 3 to entry: Users might be aware or unaware that a use error has occurred.

Note 4 to entry: An unexpected physiological response of the patient is not by itself considered use error.

Note 5 to entry: A malfunction of a medical device that causes an unexpected result is not considered a use error.

[SOURCE: IEC 62366-1:2015, 3.21, modified — Note 6 to entry deleted.]

3.31
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process

390 Note 3 to entry: The word “verified” is used to designate the corresponding status.

391 [SOURCE: ISO/IEC Guide 63:20XX, 2.19]

392 4 General requirements for risk management

393 4.1 Risk management process

394 The manufacturer shall establish, implement, document and maintain throughout the life-cycle of the medical
395 device being considered: an ongoing process for identifying hazards associated with a medical device,
396 estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the
397 risk control measures.

398 This process shall include the following elements:

399 — risk analysis;

400 — risk evaluation;

401 — risk control; and

402 — production and post-production activities.

403 Where a documented product realization process exists, it shall incorporate the appropriate parts of the risk
404 management process.

405 NOTE 1 Product realization processes are described in for example ISO 13485:2016 [5].

406 NOTE 2 A documented quality management system process can be used to address safety in a systematic manner, in
407 particular to enable the early identification of hazards and hazardous situations in complex medical devices and systems.

408 NOTE 3 A schematic representation of the risk management process is shown in Figure 1. Depending on the specific life-
409 cycle phase, individual elements of risk management can have varying emphasis. Also, risk management activities can be
410 performed iteratively or in multiple steps as appropriate to the medical device. Annex B contains a more detailed overview
411 of the steps in the risk management process.

412 Compliance is checked by inspection of the appropriate documents.

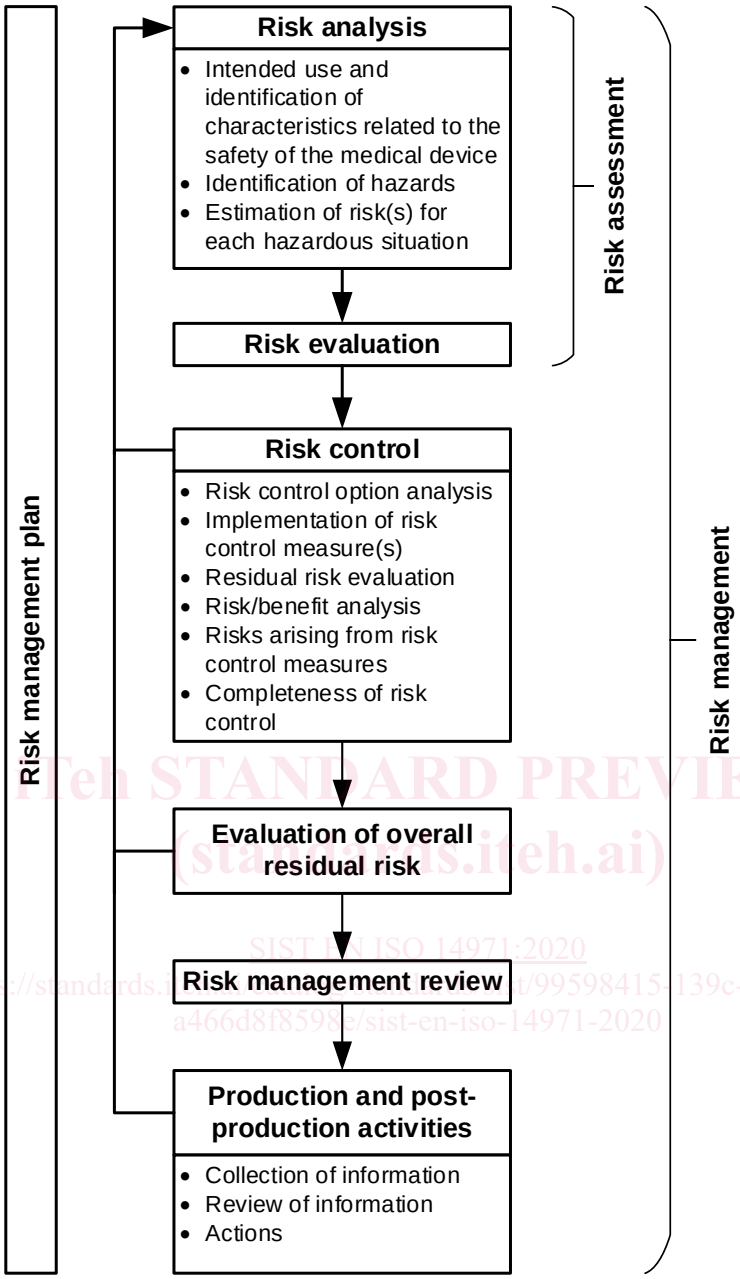

Figure 1 — A schematic representation of the risk management process

4.2 Management responsibilities

Top management shall provide evidence of its commitment to the risk management process by ensuring:

— the provision of adequate resources; and

— the assignment of qualified personnel (see 4.3) for risk management.

Top management shall define and document a policy for establishing and reviewing criteria for risk acceptability. The policy shall provide a framework that ensures that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally acknowledged state of the art and known stakeholder concerns.