



SLOVENSKI STANDARD SIST EN ISO 14971:2009

01-november-2009

BUXca Yý U
SIST EN ISO 14971:2007

A YX]V]bg_]df]dca c _]!'I dcfUVUcVj`UXcj Ub'U'hj Y[Ub'Udf]'a YX]V]bg_]df]dca c _] 'fGC`%- +%&\$\$+ždcdfUj`YbUj Yfn]U&\$\$+!%\$!\$%&

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2007, Version corrigé 2007-10-01)

ITEH STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: EN ISO 14971:2009

ICS:

11.040.01 Medicinska oprema na splošno Medical equipment in general

SIST EN ISO 14971:2009 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 14971:2009

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14971

July 2009

ICS 11.040.01

Supersedes EN ISO 14971:2007

English version

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2007, Version corrigée de 2007-10-01)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01)

This European Standard was approved by CEN on 13 June 2009.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN or CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN or CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

[SIST EN ISO 14971:2009](https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009)

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>



CEN Management Centre:
Avenue Marnix 17, B-1000 Brussels

CENELEC Central Secretariat:
Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	4
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices	5
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on In Vitro Diagnostic Devices	6

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 14971:2009](https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009)

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>

Foreword

The text of ISO 14971:2007, Corrected version 2007-10-01 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14971:2009 by Technical Committee CEN/CLC TC 3 "Quality management and corresponding general aspects for medical devices" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14971:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives 93/42/EEC on Medical Devices, 90/385/EEC on Active Implantable Medical Devices and 98/79/EC on In Vitro Diagnostic Devices.

For relationship with EU Directives, see informative Annexes ZA, ZB and ZC, which are an integral part of this document.

The present standard can also be used to support some parts of the conformity assessment procedures described in annexes of the European medical devices directives (90/385/EEC, 93/42/EEC and (98/79/EC):

- an adequate description of: results of the risk analysis
- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action

NOTE: Other requirements may be applicable to this aspect

In establishing the policy for determining risk acceptability criteria, this standard allows manufacturers to choose from a range of options within those permitted by regulations (see clause 3.2). European medical devices directives require that, in selecting the most appropriate solutions for the design and construction of the devices, these solutions must conform to safety principles, taking account of the generally acknowledged state of the art, and the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

In this context, 'eliminating' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety; (see also Annex D.8).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14971:2007, Corrected version 2007-10-01 has been approved by CEN as a EN ISO 14971:2009 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

Annex ZB (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 90/385/EEC on active implantable medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

Annex ZC (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on In Vitro Diagnostic Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on in vitro diagnostic devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 98/79/EC on in vitro diagnostic devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 14971

Second edition
2007-03-01

Corrected version
2007-10-01

Medical devices — Application of risk management to medical devices

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 14971:2009](https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009)

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>



Reference number
ISO 14971:2007(E)

© ISO 2007

ISO 14971:2007(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 14971:2009](https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009)

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Terms and definitions.....	1
3 General requirements for risk management	5
3.1 Risk management process	5
3.2 Management responsibilities	7
3.3 Qualification of personnel	7
3.4 Risk management plan.....	7
3.5 Risk management file	8
4 Risk analysis	8
4.1 Risk analysis process	8
4.2 Intended use and identification of characteristics related to the safety of the medical device	9
4.3 Identification of hazards	9
4.4 Estimation of the risk(s) for each hazardous situation.....	9
5 Risk evaluation.....	10
6 Risk control	11
6.1 Risk reduction	11
6.2 Risk control option analysis	11
6.3 Implementation of risk control measure(s).....	11
6.4 Residual risk evaluation.....	12
6.5 Risk/benefit analysis	12
6.6 Risks arising from risk control measures.....	12
6.7 Completeness of risk control	12
7 Evaluation of overall residual risk acceptability	13
8 Risk management report.....	13
9 Production and post-production information.....	13
Annex A (informative) Rationale for requirements	15
Annex B (informative) Overview of the risk management process for medical devices	23
Annex C (informative) Questions that can be used to identify medical device characteristics that could impact on safety	25
Annex D (informative) Risk concepts applied to medical devices	32
Annex E (informative) Examples of hazards, foreseeable sequences of events and hazardous situations	49
Annex F (informative) Risk management plan	54
Annex G (informative) Information on risk management techniques.....	56
Annex H (informative) Guidance on risk management for <i>in vitro</i> diagnostic medical devices.....	60
Annex I (informative) Guidance on risk analysis process for biological hazards.....	76
Annex J (informative) Information for safety and information about residual risk	78
Bibliography	80

ISO 14971:2007(E)

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

International Standard ISO 14971 was prepared by 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*. Annex H, "Guidance on risk management for *in vitro* diagnostic medical devices", was prepared by ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 14971:2000) as well as the amendment ISO 14971:2000/Amd.1:2003.

For purposes of future IEC maintenance, Subcommittee 62A has decided that the contents of this publication will remain unchanged until the maintenance result date¹⁾ indicated on the IEC web site under <http://webstore.iec.ch> in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition or
- amended.

This corrected version of ISO 14971:2007 incorporates the following correction:

- a corrected version of Figure 1 on page 6.

1) IEC National Committees are requested to note that for this publication the maintenance result date is 2014.

Introduction

The requirements contained in this International Standard 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 International Standard was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in other healthcare industries, this International Standard could be used as informative guidance in developing and maintaining a risk management system and process.

This International Standard deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment.

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

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

- a) the probability of occurrence of harm;
- b) the consequences of that harm, that is, how severe it might be.

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.

All stakeholders need to understand that the use of a medical device entails some degree of risk. The acceptability of a risk to a stakeholder is influenced by the components listed above and by the stakeholder's perception of the risk. Each stakeholder's perception of the risk can vary greatly depending upon their cultural background, the socio-economic and educational background of the society concerned, the actual and perceived state of health of the patient, and many other factors. The way a risk is perceived also takes into account, for example, whether exposure to the hazard 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. 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 should take into account the intended use, performance and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use. 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.

As one of the stakeholders, the manufacturer makes judgments relating to safety of a medical device, including the acceptability of risks, taking into account the generally accepted 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 International Standard specifies a process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.

For any particular medical device, other International Standards could require the application of specific methods for managing risk.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 14971:2009

<https://standards.iteh.ai/catalog/standards/sist/a30213f8-f77b-49ee-ad08-13a8038c096f/sist-en-iso-14971-2009>

Medical devices — Application of risk management to medical devices

1 Scope

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.

This International Standard does not apply to clinical decision making.

This International Standard does not specify acceptable risk levels.

This International Standard 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.

2 Terms and definitions

SIST EN ISO 14971:2009

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

2.1

accompanying document

document accompanying a medical device and containing information for those accountable for the installation, use and maintenance of the medical device, the operator or the user, particularly regarding safety

NOTE Adapted from IEC 60601-1:2005, definition 3.4.

2.2

harm

physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

2.3

hazard

potential source of harm

[ISO/IEC Guide 51:1999, definition 3.5]

2.4

hazardous situation

circumstance in which people, property, or the environment are exposed to one or more hazard(s)

[ISO/IEC Guide 51:1999, definition 3.6]

NOTE See Annex E for an explanation of the relationship between “hazard” and “hazardous situation”.