SVENSK STANDARD
SS-EN ISO 14971:2020

Medicintekniska produkter – Tillämpning av ett system för riskhantering för medicintekniska produkter (ISO 14971:2019)

Medical devices – Application of risk management to medical devices (ISO 14971:2019)

Svenska Institutet för Standarder

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Svenska Institutet för Standarder

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Europastandarden EN ISO 14971:2019 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14971:2019.

Denna standard ersätter SS-EN ISO 14971:2012, utgåva 4

The European Standard EN ISO 14971:2019 has the status of a Swedish Standard. This document contains the official version of EN ISO 14971:2019.

This standard supersedes the SS-EN ISO 14971:2012, edition 4

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)

This European Standard was approved by CEN on 5 August 2019.

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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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Contents

Page

European foreword ..... **vii**

Introduction ..... **viii**

1 Scope **10**

2 Normative references **10**

3 Terms and definitions **10**

4 General requirements for *risk management* system **16**
4.1 *Risk management process* 16
4.2 Management responsibilities 17
4.3 Competence of personnel 18
4.4 *Risk management* plan 18
4.5 *Risk management file* 19

5 *Risk analysis* **19**
5.1 *Risk analysis process* 19
5.2 *Intended use* and *reasonably foreseeable misuse* 19
5.3 Identification of characteristics related to *safety* 20
5.4 Identification of *hazards* and *hazardous situations* 20
5.5 *Risk estimation* 21

6 *Risk evaluation* **21**

7 *Risk control* **22**
7.1 *Risk control* option analysis 22
7.2 Implementation of *risk control* measures 22
7.3 *Residual risk* evaluation 23
7.4 *Benefit-risk* analysis 23
7.5 *Risks* arising from *risk control* measures 23
7.6 Completeness of *risk control* 23

8 Evaluation of overall *residual risk* **23**

9 *Risk management* review **24**

10 Production and *post-production* activities **24**
10.1 General 24
10.2 Information collection 25
10.3 Information review 25
10.4 Actions 25

Annex A (informative) **Rationale for requirements** **27**

Annex B (informative) ***Risk management process* for *medical devices*** **36**

Annex C (informative) **Fundamental *risk* concepts** **40**

Bibliography **47**

European foreword

This document (EN ISO 14971:2019) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/JTC 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 June 2020, and conflicting national standards shall be withdrawn at the latest by June 2020.

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

This document supersedes EN ISO 14971:2012.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14971:2019 has been approved by CEN as EN ISO 14971:2019 without any modification.

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* 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 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, not only to the patient, but also to the user and other persons. *Risks* can also be related to damage to property (for example objects, data, other equipment) or the environment.

Risk management is a complex subject because each stakeholder can place a different value on the acceptability of *risks* in relation to the anticipated *benefits*. 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* involves an inherent degree of *risk*, even after the *risks* have been reduced to an acceptable level. It is well known that in the context of a clinical *procedure* 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* and the *benefit*. Each stakeholder's perception 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 decisions are beyond the scope of this document and 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 decisions 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.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— “may” is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— “can” is used to express possibility and capability; and

— “must” is used to express an external constraint that is not a requirement of the document.

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 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 phases of the *life cycle* of a *medical device*. The *process* described in this document applies to *risks* associated with a *medical device*, such as *risks* related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

The *process* described in this document can also be applied to products that are not necessarily *medical devices* in some jurisdictions and can also be used by others involved in the *medical device life cycle*.

This document does not apply to:

— decisions on the use of a *medical device* in the context of any particular clinical *procedure*; or

— business *risk management*.

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

Risk management can be an integral part of a quality management system. However, this document does not require the *manufacturer* to have a quality management system in place.

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:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accompanying documentation
materials accompanying a *medical device* (3.10) and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the *medical device* (3.10), 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.

3.2
benefit
positive impact or desirable outcome of the use of a *medical device* (3.10) 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 positive impact on public health.

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

[SOURCE: ISO/IEC Guide 63:2019, 3.1]

3.4
hazard
potential source of *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.5
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.4)

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

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified — Note 1 to entry added.]

3.6
intended use
intended purpose
use for which a product, *process* (3.14) or service is intended according to the specifications, instructions and information provided by the *manufacturer* (3.9)

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 63:2019, 3.4]

3.7
in vitro diagnostic medical device
IVD medical device
device, whether used alone or in combination, intended by the *manufacturer* (3.9) 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
series of all phases in the life of a *medical device* (3.10), from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019, 3.5]