
Irish Standard
I.S. EN ISO 14971:2012

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

# I.S. EN ISO 14971:2012

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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**I.S. EN ISO 14971:2012**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 14971

July 2012

ICS 11.040.01

Supersedes EN ISO 14971:2009

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 16 May 2012.

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

# 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 14971:2012 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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

This document supersedes EN ISO 14971:2009.

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 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.

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

**Endorsement notice**

The text of ISO 14971:2007, Corrected version 2007-10-01, has been approved by CEN as an EN ISO 14971:2012 without any modification.

I.S. EN ISO 14971:2012

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*

Reference number
ISO 14971:2007(E)

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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.

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 date[1)] 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.

# 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

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”.