ILNAS

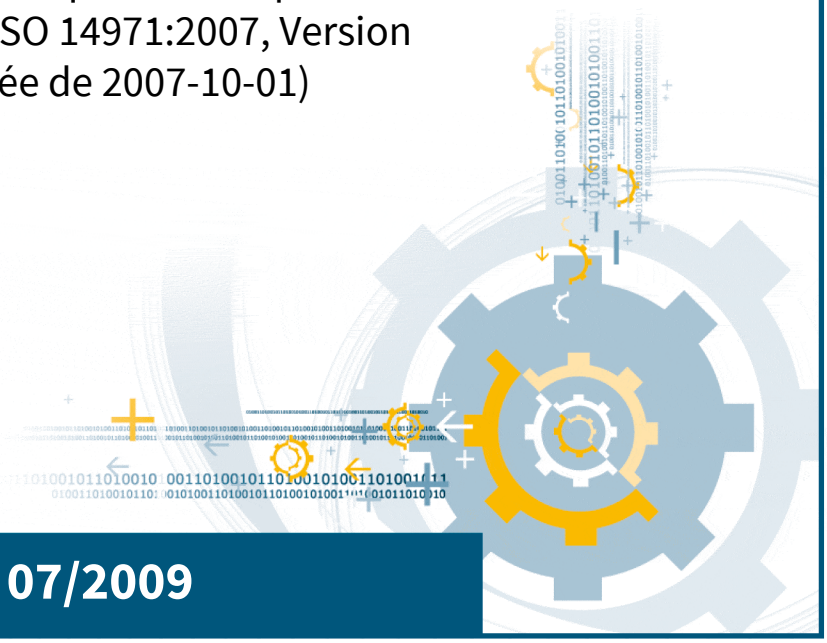
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 14971:2009

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, korrigierte Fassung 2007-10-01)

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



07/2009

National Foreword

This European Standard EN ISO 14971:2009 was adopted as Luxembourgish Standard ILNAS-EN ISO 14971:2009.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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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.

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Ref. No. EN ISO 14971:2009 E

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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

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Medical devices — Application of risk management to medical devices

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

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