



# SLOVENSKI STANDARD

## kSIST FprEN ISO 14971:2009

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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)

**Ta slovenski standard je istoveten z: FprEN ISO 14971**

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**ICS:**

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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<b>kSIST FprEN ISO 14971:2009</b>	<b>en</b>
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**FprEN ISO 14971**

February 2009

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ICS 11.040.01

Will supersede 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 corrigé 2007-10-01)

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

This draft European Standard is submitted to CEN/CENELEC members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/CLC/TC 3.

If this draft becomes a European Standard, CEN/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.

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

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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 FprEN 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 document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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).

### Endorsement notice

The text of ISO 14971:2007, Corrected version 2007-10-01 has been approved by CEN as a FprEN 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.