



SLOVENSKI STANDARD
SIST EN ISO 14971:2001/AC:2003

01-september-2003

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Medical devices - Application of risk management to medical devices (ISO 14971:2000)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2000)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2000)

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ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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English version

Medical devices - Application of risk management to medical
devices (ISO 14971:2000)

Dispositifs médicaux - Application de la gestion des risques
aux dispositifs médicaux (ISO 14971:2000)

Medizinprodukte - Anwendung des Risikomanagements
auf Medizinprodukte (ISO 14971:2000)

This European Standard was approved by CEN on 3 December 2000, and by CENELEC on 2 May 2001.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN/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/CENELEC member into its own language and notified to the Management Centre has the same status as the official versions.

CEN/CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

The text of the International Standard ISO 14971:2000 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with IEC/SC 62A, CEN Management Centre (CMC) and CENELEC.

This European Standard supersedes EN 1441:1997, for which the date of withdrawal is extended. National implementations of EN 1441:1997 shall be withdrawn at the latest by March 2004.

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 2001, and conflicting national standards shall be withdrawn at the latest by March 2004.

This European Standard 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 Directive(s).

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

Annexes A to G are informative.

Endorsement notice

The text of the International Standard ISO 14971:2000 was approved by CEN/CENELEC as a European Standard without any modification.