SLOVENSKI STANDARD
SIST EN ISO 14155-1:2009

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Kliniļ ne raziskave medicinskih pripomoļ kov za ljudi - 1. del: Sploġne zahteve (ISO 14155-1:2003)

Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

Klinische Prüfung von Medizinprodukten an Menschen - Teil 1: Allgemeine Anforderungen (ISO 14155-1:2003)

Investigation clinique des dispositifs médicaux pour sujets humains - Partie 1: Exigences générales (ISO 14155-1:2003)

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Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

Investigation clinique des dispositifs médicaux pour sujets humains - Partie 1: Exigences générales (ISO 14155-1:2003)

Klinische Prüfung von Medizinprodukten an Menschen - Teil 1: Allgemeine Anforderungen (ISO 14155-1:2003)

This European Standard was approved by CEN on 27 June 2009.

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

CEN members are the national standards bodies 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 14155-1:2003 has been prepared by Technical Committee ISO/TC 194 “Biological evaluation of medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14155-1:2009 by Technical Committee CEN/TC 258 “Clinical investigation of medical devices” the secretariat of which is held by DIN.

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 14155-1:2003.

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 EC Directives.

For relationship with EC Directives, see informative Annex ZA and ZB, which are an integral part of this document.

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 14155-1:2003 has been approved by CEN as a EN ISO 14155-1:2009 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 given in table ZA 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.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
A.2.5	Annex X: 1.1.1	This requirement is also addressed in 4.5.1 of EN 14155-2:2003
11	Annex X: 1.1.2	This requirement is also addressed in 4.5.3 of EN 14155-2:2003
	Annex X: 1.1.a)	This requirement is not addressed in this standard
7	Annex X: 1.1.b)	This requirement is partly addressed in this standard
	Annex X: 1.1.c)	This requirement is not addressed in this standard
	Annex X: 1.1.d)	This requirement is not addressed in this standard
5	Annex X: 2.2	
6.3	Annex X: 2.3.1	Entire EN 14155-2
6.4	Annex X: 2.3.2	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.4	Annex X: 2.3.3	This requirement is also addressed in 4.7 of EN 14155-2:2003
	Annex X: 2.3.4	This requirement is not addressed in this standard This requirement is addressed in 4.5.4 of EN 14155-2:2003
8.2 i)	Annex X: 2.3.5	This requirement is also addressed in 4.11 of EN 14155-2:2003
10.2 a)	Annex X: 2.3.6	
11.2	Annex X: 2.3.7	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) 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 given in table ZB 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.

Table ZB — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
A.2.5	Annex 7: 1.1.1	This requirement is also addressed in 4.5.1 of EN 14155-2:2003
11	Annex 7: 1.1.2	This requirement is also addressed in 4.5.3 of EN 14155-2:2003
A.2.5	Annex 7: 1.2	
7	Annex 7: 1.3	
	Annex 7: 1.4	This requirement is not addressed in this standard
	Annex 7: 1.5	This requirement is not addressed in this standard
6.3	Annex 7: 2.3.1	Entire EN 14155
6.4	Annex 7: 2.3.2	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.4	Annex 7: 2.3.3	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.5	Annex 7: 1.6	
	Annex 7: 2.3.4	This requirement is not addressed in this standard This requirement is addressed in 4.5.4 of EN 14155-2:2003
8.2 i)	Annex 7: 2.3.5	This requirement is also addressed in 4.11 of EN 14155-2:2003
10.2 a)	Annex 7: 2.3.6	
11.2	Annex 7: 2.3.7	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

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Clinical investigation of medical devices for human subjects —

Part 1: General requirements

Investigation clinique des dispositifs médicaux pour sujets humains — Partie 1: Exigences générales

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