SLOVENSKI STANDARD
SIST EN ISO 14155-2:2009

01-november-2009

Nadomeġ ļa:
SIST EN ISO 14155-2:2003

Kliniļ ne raziskave medicinskih pripomoļ kov za ljudi - 2. del: Naļ rti kliniļ nih raziskav (ISO 14155-2:2003)

Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)

Klinische Prüfung von Medizinprodukten an Menschen - Teil 2: Klinische Prüfpläne (ISO 14155-2:2003)

Investigation clinique des dispositifs médicaux sur les sujets humains - Partie 2: Plan d'investigation clinique (ISO 14155-2:2003)

Ta slovenski standard je istoveten z: **EN ISO 14155-2:2009**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14155-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155-2

July 2009

ICS 11.100.20

Supersedes EN ISO 14155-2:2003

English Version

Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)

Investigation clinique des dispositifs médicaux pour sujets humains - Partie 2: Plans d'investigation clinique (ISO 14155-2:2003)

Klinische Prüfung von Medizinprodukten an Menschen - Teil 2: Klinische Prüfpläne (ISO 14155-2:2003)

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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 14155-2:2009: E

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Foreword

The text of ISO 14155-2:2003 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 14155-2:2009 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 14155-2:2003.

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 14155-2:2003 has been approved by CEN as a EN ISO 14155-2:2009 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
4.5.1	Annex X: 1.1.1	This requirement is also addressed in A.2.5 of EN 14155-1:2003
4.5.3	Annex X: 1.1.2	This requirement is also addressed in 11 of EN 14155-1:2003
4.5.4	Annex X: 2.3.4	
	Annex X: 1.1.a)	This requirement is not addressed in this standard
	Annex X: 1.1 b)	This requirement is partly addressed in Clause 7 of EN 14155-1:2003
	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
	Annex X: 2.2	This requirement is addressed in Clause 5 of EN 14155-1:2003
Entire document	Annex X: 2.3.1	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.7	Annex X: 2.3.2	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.7	Annex X: 2.3.3	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.11	Annex X: 2.3.5	This requirement is also addressed in 8.2 i) of EN 14155-1:2003
	Annex X: 2.3.6	This requirement is addressed in 10.2 a) of EN 14155-1:2003
	Annex X: 2.3.7	This requirement is addressed in 11.2 of EN 14155-1:2003

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
4.5.1	Annex 7: 1.1.1	This requirement is also addressed in A.2.5 of EN 14155-1:2003
4.5.3	Annex 7: 1.1.2	This requirement is also addressed in Clause 11 of EN 14155-1:2003
4.5.4	Annex 7: 2.3.4	
	Annex 7: 1.2	This requirement is addressed in A.2.5 of EN 14155-1:2003
	Annex 7: 1.3	This requirement is addressed in Clause 7 of EN 14155-1:2003
	Annex 7: 1.4	This requirement is not addressed in this standard
	Annex 7: 1.5	This requirement is not addressed in this standard
	Annex 7: 1.6	This requirement is addressed in 6.5 of EN 14155-1:2003
Entire document	Annex 7: 2.3.1	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.7	Annex 7: 2.3.2	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.7	Annex 7: 2.3.3	This requirement is also addressed in 6.3 of EN 14155-1:2003
4.11	Annex 7: 2.3.5	This requirement is also addressed in 8.2 i) of EN 14155-1:2003
	Annex 7: 2.3.6	This requirement is addressed in 10.2 a) of EN 14155-1:2003
	Annex 7: 2.3.7	This requirement is addressed in 11.2 of EN 14155-1:2003

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

INTERNATIONAL STANDARD

ISO 14155-2

First edition
2003-05-15

Clinical investigation of medical devices for human subjects —

Part 2: Clinical investigation plans

Investigation clinique des dispositifs médicaux pour sujets humains — Partie 2: Plans d'investigation clinique

Reference number
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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.

ISO 14155-2 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 194, *Biological evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

This first edition, together with the first edition of ISO 14155-1, cancels and replaces ISO 14155:1996, which has been technically revised.

ISO 14155 consists of the following parts, under the general title *Clinical investigation of medical devices for human subjects*:

— *Part 1: General requirements*

— *Part 2: Clinical investigation plans*

For the purposes of this part of ISO 14155, the CEN annex regarding fulfilment of European Council Directives has been removed.