SLOVENSKI STANDARD
kSIST FprEN ISO 14155-2:2009

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: **FprEN ISO 14155-2**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

kSIST FprEN ISO 14155-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
FprEN ISO 14155-2

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English Version

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

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

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

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 258.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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 FprEN ISO 14155-2:2009 by Technical Committee CEN/TC 258 “Clinical investigation of medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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.

Endorsement notice

The text of ISO 14155-2:2003 has been approved by CEN as a FprEN 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.