SLOVENSKI STANDARD
SIST EN ISO 14155:2012

01-januar-2012

Nadomešča:
SIST EN ISO 14155:2011
SIST EN ISO 14155:2011/AC:2011

Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse (ISO 14155:2011)

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2011)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonnes pratiques cliniques (ISO 14155:2011)

Ta slovenski standard je istoveten z: **EN ISO 14155:2011**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14155:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155

October 2011

ICS 11.100.20

Supersedes EN ISO 14155:2011

English Version

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonnes pratiques cliniques (ISO 14155:2011)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2011)

This European Standard was approved by CEN on 20 September 2011.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 14155:2011) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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 14155:2011.

This new edition contains revised Annexes ZA and ZB.

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 Directive(s).

For relationship with EU Directives, see informative Annexes 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, Croatia, 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 14155:2011 has been approved by CEN as EN ISO 14155:2011 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 Union 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.1 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.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

For all requirements related to clinical investigations contained in the directive and referred to in the following chart: Obligations attributed to the "sponsor" under ISO 14155 shall be incumbent, under the MDD to the manufacturer, if located in the EU/EEA/Turkey/Switzerland, and incumbent to the Authorized Representative otherwise. Both may refer to external service providers in order to fulfil their obligations.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Entire standard	Annex I. 6a	Partial fulfilment of the ER, as regards 1) the documentation of clinical investigations of medical devices used in the clinical evaluation process as referred to in Annex X.1.1[1] and 2) parts of Annex X.2 listed below.
4.1, 5.2 and 5.3	Annex X: 2.2.	ISO 14155 does not refer to a particular version of the declaration of Helsinki. The latest available version of the declaration of Helsinki must be taken into account. National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.
5,3, 5.4, A.7	Annex X: 2.3.1	
5.3, A.3 and A.6	Annex X 2.3.2.	

[1] See MEDDEV 2.7/1, Section 6.3.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.3, A.3 and A.6	Annex X: 2.3.3.	
5.3, A.5 and 8.2.5	Annex X: 2.3.4.	
6.4.1, 8.2.5 d) and 9.8	Annex X: 2.3.5.	Partial compliance: covers internal procedures of sponsor to address SAE[2]-reporting requirements of the Directive.
5.5, 5.8, 6, 9.2, 9.3 and Annex B	Annex X: 2.3.6.	
7.3	Annex X: 2.3.7.	
5.4, Annex A; 5.5, Annex B; 4.7	Annex VIII, 2.2., structure/content of the documents required in the 2nd, 3rd and 5th indent.	National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.

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

[2] SAE = Serious Adverse Event.

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 Union 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.1 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.1 — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices

For all requirements related to clinical investigations contained in the directive and referred to in the following chart: Obligations attributed to the "sponsor" under ISO 14155 shall be incumbent, under the MDD to the manufacturer, if located in the EU/EEA/Turkey/Switzerland, and incumbent to the Authorized Representative otherwise. Both may refer to external service providers in order to fulfil their obligations.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
Entire standard	6a	Partial fulfilment of the ER, as regards 1) the documentation of clinical investigations of medical devices used in the clinical evaluation process as referred to in Annex VII.1.1[3] and 2) parts of Annex VII.2 listed below.
4.1, 5.2 and 5.3	Annex 7: 2.2.	ISO 14155 does not refer to a particular version of the declaration of Helsinki. The latest available version of the declaration of Helsinki must be taken into account. National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.
5,3, 5.4, A.7	Annex 7: 2.3.1.	

[3] See MEDDEV 2.7/1, Section 6.3.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
5.3, A.3 and A.6	Annex 7: 2.3.2.	
5.3, A.3 and A.6	Annex 7: 2.3.3.	
5.3, A.5 and 8.2.5	Annex 7: 2.3.4.	
6.4.1, 8.2.5 d) and 9.8	Annex 7: 2.3.5.	Partial compliance: covers internal procedures of sponsor to address SAE[4]-reporting requirements of the Directive.
5.5, 5.8, 6, 9.2, 9.3 and Annex B	Annex 7: 2.3.6.	
7.3	Annex 7: 2.3.7.	
5.4, Annex A; 5.5, Annex B; 4.7	Annex 7, 2.2., structure/content of the documents required in the 2nd, 3rd and 5th indent.	National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.

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

[4] SAE = Serious Adverse Event.

INTERNATIONAL STANDARD

ISO 14155

Second edition
2011-02-01

Clinical investigation of medical devices for human subjects — Good clinical practice

Investigation clinique des dispositifs médicaux pour sujets humains — Bonnes pratiques cliniques

Reference number
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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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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 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition of ISO 14155-1:2003 and the first edition of ISO 14155-2:2003, which have been technically revised.