Meditsiiniseadmete inimmõju kliiniline uuring. Hea kliiniline tava (ISO 14155:2011)

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14155 V2:2011 sisaldab Euroopa standardi EN ISO 14155:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14155 V2:2011 consists of the English text of the European standard EN ISO 14155:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.10.2011.	Date of Availability of the European standard text 19.10.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EN ISO 14155

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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

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Ref. No. EN ISO 14155:2011: E

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.	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.

Contents

Page

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

1 Scope

This International Standard addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

The principles set forth in this International Standard also apply to all other clinical investigations and should be followed as far as possible, considering the nature of the clinical investigation and the requirements of national regulations.

This International Standard specifies general requirements intended to

— protect the rights, safety and well-being of human subjects,

— ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,

— define the responsibilities of the sponsor and principal investigator, and

— assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

It does not apply to *in vitro* diagnostic medical devices.

NOTE Standards developed by ISO/TC 194 are intended to be applied to medical devices. Users of this International Standard will need to consider whether other standards and/or requirements also apply to the investigational device(s) under consideration.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*