

**Meditstiiniseadmete 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 14155:2011 sisaldab Euroopa standardi EN ISO 14155:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 28.02.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.02.2011.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 14155:2011 consists of the English text of the European standard EN ISO 14155:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 01.02.2011.

The standard is available from Estonian standardisation organisation.

ICS 11.100.20

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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 10 December 2010.

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

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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of an identical text or by endorsement, at the latest by August 2011, and conflicting national standards shall be withdrawn at the latest by August 2011.

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 14155-1:2009 and EN ISO 14155-2:2009.

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.

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Endorsement notice

The text of ISO 14155:2011 has been approved by CEN as a 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 normative clauses of this standard 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.

NOTE This standard is specifically intended to provide a means for getting presumption of conformity to the part of Essential Requirement 6a that refers to clinical investigations, as developed in Annex X, 2nd part (2.1 to 2.3.7) of the above-mentioned directive.

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 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 normative clauses of this standard 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.

NOTE This standard is specifically intended to provide a means for getting presumption of conformity to the part of Essential Requirement 5. that refers to clinical investigations, as developed in Annex 7, 2nd part (2.1 to 2.3.7) of the above mentioned directive.

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

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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*