MEDITSIINISEADME KLIINILINE UURING INIMESEL. HEA KLIINILINE TAVA

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14155:2020 sisaldab Euroopa standardi EN ISO 14155:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14155:2020 consists of the English text of the European standard EN ISO 14155:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.08.2020.	Date of Availability of the European standard is 19.08.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.100.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155

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Supersedes EN ISO 14155:2011

English Version

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique clinique (ISO 14155:2020)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2020)

This European Standard was approved by CEN on 2 May 2020.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 18 November 2020.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 14155:2020 E

European foreword

This document (EN ISO 14155:2020) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological and clinical evaluation 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 February 2021, and conflicting national standards shall be withdrawn at the latest by February 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14155:2011.

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 the relationship with EU Directive(s) see informative Annex ZA and ZB, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this document ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	**Equivalent dated standard**	
	EN	ISO or IEC
ISO 14971	EN ISO 14971:2019	ISO 14971:2019

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14155:2020 has been approved by CEN as EN ISO 14155:2020 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/295 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

For all requirements related to clinical investigations contained in the regulation and referred to in the following table: obligations attributed to the "sponsor" under ISO 14155 shall be incumbent under the Directive 93/42/EEC 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.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Annex I, 6a	Entire standard	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[a] and parts of Annex X.2 listed below.

Annex X, 2.2	4, 5, 6.2, 6.3 and 8.4	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.
Annex X, 2.3.1	6.2, 6,3, 6.4, A.4, A.5, A.6 and A.7	
Annex X, 2.3.2	6.3, 6.4, A.2 i), A.3, A.4, A.5 and A.6	
Annex X, 2.3.3	6.3, 6.8, 7.3, 10.2, 10.3and A.6	Covered provided that the investigation site's facilities are similar to the facilities required for the intended use of the investigational device.
Annex X, 2.3.4	6.2, 6.3, 7.4, 9.2.5, 10.8, A.3, A.4, A.5, A.6 and A.7	
Annex X, 2.3.5	7.4, 9.2.5 and 10.8	
Annex X, 2.3.6	6.5, 6.8, 9.2.1, 10.2, 10.3 and Annex B	
Annex X, 2.3.7	8.4, 9.2.6, 10.6 r) and Annex D	
[a] See MEDDEV 2.7/1, Section 6.3.		

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/295 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 90/385/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

For all requirements related to clinical investigations contained in the regulation and referred to in the following table: obligations attributed to the "sponsor" under ISO 14155 shall be incumbent under the Directive 90/385/EEC 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.

Table ZB.1 — Correspondence between this European Standard and Annex I of Directive 90/385/EEC [OJ L 189]

Essential Requirements of Directive 90/385/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
5 a	Entire standard	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[a] and parts of Annex VII.2 listed below.

Annex 7, 2.2	4, 5, 6.2, 6.3 and 8.4	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.
Annex 7, 2.3.1	6.2, 6,3, 6.4 and Annex A	
Annex 7, 2.3.2	6.3, 6.4, A.2 i)and A.3 to A.6	
Annex 7, 2.3.3	6.3, 6.8, 7.3, 10.2, 10.3 and A.6	Covered provided that the investigation site's facilities are similar to the facilities required for the intended use of the investigational device.
Annex 7, 2.3.4	6.2, 6.3, 7.4, 9.2.5, 10.8 and A.3 to A.7	
Annex 7, 2.3.5	7.4, 9.2.5 and 10.8	
Annex 7, 2.3.6	6.5, 6.8, 9.2.1, 10.2, 10.3 and Annex B	
Annex 7, 2.3.7	8.4, 9.2.6, 10.6 r) and Annex D	
[a] See MEDDEV 2.7/1, Section 6.3.		

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WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.