SLOVENSKI STANDARD
SIST EN ISO 14155:2026

01-junij-2026

Nadomešča:
SIST EN ISO 14155:2020
SIST EN ISO 14155:2020/A11:2025

Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse (ISO 14155:2026)

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2026)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2026)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique clinique (ISO 14155:2026)

Ta slovenski standard je istoveten z: **EN ISO 14155:2026**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14155:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155

April 2026

ICS 11.100.20

Supersedes EN ISO 14155:2020

English Version

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2026)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique clinique (ISO 14155:2026)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2026)

This European Standard was approved by CEN on 13 January 2026.

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

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

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European foreword

This document (EN ISO 14155:2026) 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 October 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.

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 14155:2020.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 14155:2026 has been approved by CEN as EN ISO 14155:2026 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to Annex XV of Regulation (EU) 2017/745 of 5 April 2017 concerning clinical investigations of medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA Regulations.

This Annex ZA covers the relationship of this European standard with Annex XV of Regulation (EU) 2017/745 (Table ZA.1). Where requirements laid down in that Annex XV refer to Article 62 of this Regulation, the related requirements laid down in the section of Article 62 cited have also been considered when establishing the relationship of the clauses of this European standard with Annex XV in Table ZA.1.

Where a definition in this harmonized standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

For all requirements related to clinical investigations contained in Regulation (EU) 2017/745 and referred to in the following table, obligations attributed to the "sponsor" under ISO 14155 shall be incumbent under the Regulation to the Sponsor if located in the Union; When established, the Legal Representative is responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745.

Table ZA.1 — Correspondence between this European Standard and Annex XV of Regulation (EU) 2017/745 [OJ L 117]

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter I, 1	4 a)	Covered by a general reference to the Declaration of Helsinki; however, the latest edition of the Declaration should be used. National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.
Annex XV, Chapter I, 2.1	6.2, 6.3, 6.4, 7.4.4, 7.4.5 and Annex A	6.2 of this document covers risk management considerations for risks related to the use of the investigational device and their disclosure, risks related to clinical procedures required by the clinical investigation plan that are outside routine clinical practice, as well as risks related to the clinical investigation process. 6.3 of this document refers to the literature review of the standard of care, as a basis to define the appropriate study design as well as the requirement to take into consideration and relevant pre-clinical data. 6.4 of this document combined with Annex A provides a detailed outline on the study design and statistical considerations required to obtain scientific valid data on safety, performance and clinical benefits. Note: This document covers the risk assessment process for potentially unacceptable risks. Aspect relating to benefit-risk of devices as referred to in Article 62(1) of Regulation (EU) 2017/745 are covered in this standard by referring to ISO 14971.
Annex XV, Chapter I, 2.2	6.3, 6.4, A.2 i), A.3, A.4, A.5, A.6 and A.7	

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter I, 2.3	6.3, 6.4, A.3, A.4, A.5, A.6 and A.7	
Annex XV, Chapter I, 2.4	6.3, 6.4, 6.8, 9.2.1 b) to e), 10.2, 10.3, A.2 h), A.3, A.6 and A.7	Partially covered - this document does not cover the requirements of the clinical evaluation plan as this is not part of the clinical investigation. However, 6.3 does refer to the appropriate literature review required prior to designing a clinical investigation.
Annex XV, Chapter I, 2.5	6.2, 6.3, A.2 e), f) and g), A.3, A.4, A.6, A.7 and B.2	
Annex XV, Chapter I, 2.6	6.3, A.6 and A.7	
Annex XV, Chapter I, 2.7	6.5, 9.2.1 g), 9.2.2, 10.2, A.2 h) and Annex B	
Annex XV, Chapter I, 2.8	8.4, 9.2.6, 10.6 r) and Annex D	
Annex XV, Chapter II, 2.1	B.2, B.4 a)	
Annex XV, Chapter II, 2.2	B.2 f) to h)	
Annex XV, Chapter II, 2.3	B.3	
Annex XV, Chapter II, 2.4, first indent	6.3, B.2 a), B.4	Partially covered – this document requires a prior assessment of relevant scientific literature but does not specifically require its incorporation into the Investigator's Brochure except for what is mentioned in B.2 a). Also, this document requires a prior assessment of relevant scientific literature and available data on the same or similar devices but is not specific on safety, performance and clinical benefits.
Annex XV, Chapter II, 2.4, second indent	6.3, B.2 a), B.4 a) and b)	Partially covered – this document requires a prior assessment of relevant scientific literature and available data on the same or similar devices but is not specific on safety, performance and clinical benefits.
Annex XV, Chapter II, 2.5	B.5	
Annex XV, Chapter II, 2.6	B.2 c)	Partially covered – this document does not specifically refer to a particular regulatory system. The

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
		document does not include the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.
Annex XV, Chapter II, 2.7	B.6	Partially covered-this document does not specifically refer to a particular regulatory system.
Annex XV, Chapter II, 3.1.1	A.1.2 b)	
Annex XV, Chapter II, 3.1.2	9.2.1 b), A.1.3	Covered - the document outlines that a local representative shall be selected if the sponsor is not resident in the country (countries) in which the clinical investigation is to be carried out. Article 62(2) of the Regulation specifies that when the sponsor is not established in the Union, its legal representative is responsible for ensuring conformance with the sponsor's obligations pursuant to the Regulation and shall be the addressee for all communications with the sponsor provided for in the Regulation.
Annex XV, Chapter II, 3.1.3	A.1.4	
Annex XV, Chapter II, 3.1.4	A.12 f)	
Annex XV, Chapter II, 3.1.5	A.1.5	Partially covered – in the document, the language used for the synopsis is not specified as this is considered as a country specific regulatory requirement.
Annex XV, Chapter II, 3.2	6.3, A.2, A.3 a) and b), A.4 a)	Background literature review and current state of the art are not covered as part of the identification of the device but as part of the justification of the design which is derived from literature review as outlined in 6.3 of the document.
Annex XV, Chapter II, 3.3	A.4	
Annex XV, Chapter II, 3.5	A.5	
Annex XV, Chapter II, 3.6	6.3, A.6.1 a) to e), A.7	

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter II, 3.6.1	A.6.1 a), A.6.1 c)	
Annex XV, Chapter II, 3.6.2	A.2 a), A.6.2 a) and b)	
Annex XV, Chapter II, 3.6.3	A.5, A.6.3 j), A.15	To fully cover requirement 3.6.3, the information provided should also include immuno-compromised and elderly subjects, if applicable. However, Clause A.5 of this document does require the study design to be relevant for the target population as well as A.6.3 j) requiring clarification of the relationship of the investigation population to the target population.
Annex XV, Chapter II, 3.6.4	A.6.1 b), A.7 j), A.7 k) and A.7 l)	
Annex XV, Chapter II, 3.6.5	A.6.4	
Annex XV, Chapter II, 3.6.6	A.6.5	
Annex XV, Chapter II, 3.7	A.7	
Annex XV, Chapter II, 3.8	A.8	
Annex XV, Chapter II, 3.9	A.9	
Annex XV, Chapter II, 3.10	A.10	
Annex XV, Chapter II, 3.11	A.11	
Annex XV, Chapter II, 3.12	A.12	
Annex XV, Chapter II, 3.13	A.13	
Annex XV, Chapter II, 3.14	A.14	
Annex XV, Chapter II, 3.15	A.16, A.7 f) 6), A.7 n)	Traceability for implantable devices is not covered.
Annex XV, Chapter II, 3.16	A.6.4 h) to j), A.16 c)	To fully cover requirement 3.16, information should be provided on the additional care required that differs from that normally expected for the medical condition in question.
Annex XV, Chapter II, 3.17	A.17	
Annex XV, Chapter II, 3.18	A.2, A.5	
Annex XV, Chapter II, 3.19	A.18	
Annex XV, Chapter II, 4.2	7.1, 9.2.2 i) and j), A.12 c)	
Annex XV, Chapter II, 4.3	5.3, 9.2.2 f) and h), A.12 e)	

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter II, 4.4	5.8	
Annex XV, Chapter II, 4.5	5.8.4 e), 7.7	
Annex XV, Chapter II, 4.5, first indent	5.8.4 e), 5.8.5 f) and g), 7.7	
Annex XV, Chapter II, 4.5, second indent	5.8.4 e), 5.8.5 f) and g), 7.7, 7.8.2 c), 7.8.3 g)	
Annex XV, Chapter III, 2	6.9, 9.2.1 a), 10.8	
Annex XV, Chapter III, 4	9.2.1 g), 9.2.3, 9.2.4	
Annex XV, Chapter III, 5	8.1, 9.2.3 f), 9.2.4.5	
Annex XV, Chapter III, 6	7.11, 9.1 c)	
Annex XV, Chapter III, 7, first indent	8.4, D.2, D.4, D.12	To fully conform to this requirement, the signature page must be part of the clinical investigation report. Note 1 of 8.4 does refer to national requirements regarding the clinical report which may be different worldwide.
Annex XV, Chapter III, 7, second indent	8.4, D.2 i) and j)	
Annex XV, Chapter III, 7, third indent	8.4, D.4	
Annex XV, Chapter III, 7, fourth indent	D.6.1	
Annex XV, Chapter III, 7, fifth indent	D.6.2, D.13	This document in addition to the clinical investigation plan summary of D.6.2 does also require the full plan to be in the Annex of the report.
Annex XV, Chapter III, 7, sixth indent	D.7 e), D.7 f), D.7 g) 1), D.7 g) 4), D.7 g) 5)	Justification and rationale for the analysis is required in Clause D.7 g) of the document.
Annex XV, Chapter III, 7, seventh indent	D.7 g) 2) and 3)	
Annex XV, Chapter III, 7, eighth indent	D.8	The discussion includes the clinical relevance and importance of the results in light of other existing data which should be understood including standard of care.

Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

Table ZA.3 — Prevailing terms of Regulation (EU) 2017/745 for the use of this European standard under that Regulation

Term used in this EN	Clause(s)/subclause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
adverse event AE	3.2	Article 2(57)	Both definitions are substantially equivalent. The definition in this document specifies that an adverse event may be whether anticipated or unanticipated. A note specifies that the definition includes events related to the investigational medical device or the comparator. A note specifies that the definition includes events related to the use of the investigational medical device and the clinical procedure(s) required by the CIP that are outside to routine clinical practice but not related to the use of the device.
clinical investigation	3.9	Article 2(45)	Both definitions are substantially equivalent. The definition in this document specifies an investigation undertaken to assess the clinical performance, effectiveness or safety of a medical device. In the Regulation, the definition is an investigation undertaken to assess the safety or performance of a device. Effectiveness is defined in this document and introduced as the term is used in regulations outside Europe.
clinical	3.10	Article 2(47)	Both definitions are substantially

Term used in this EN	Clause(s)/subclause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
investigation plan CIP			equivalent. In the Regulation, the definition includes statistical considerations. However, per Clause A.7 of Annex A of this document, a statistical design and analysis is expected in the content of the CIP. In this document, the definition includes "record-keeping".
clinical performance	3.12	Article 2(52)	Both definitions are substantially equivalent. In this document, a note specifies that not all clinical investigations have clinical benefits to subjects e.g; healthy volunteers, clinical investigations only gathering data etc..
device deficiency	3.19	Article 2(59)	Both definitions are substantially equivalent. The definition in this document includes the inadequacy of a medical device with respect to its usability. A note also specifies that the definition includes device deficiencies related to the investigational medical device or the comparator.
ethics committee EC	3.25	Article 2(56)	Both definitions are substantially equivalent. In the Regulation, the definition specifies that the EC is empowered to give opinions taking into account the views of laypersons.
informed consent	3.28	Article 2(55)	Both definitions are substantially equivalent. Per section 5.8.1 of this document informed consent is obtained in writing from the subject or where applicable, the subject's legally designated representative. In the Regulation, the definition specifies an authorization or agreement from the legally designated representative in the case of minors and of incapacitated subjects.
investigational medical device	3.30	Article 2(46)	Both definitions are substantially equivalent. The definition in this document specifies that the device

Term used in this EN	Clause(s)/subclause (s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
			is assessed in a clinical investigation for safety, clinical performance or effectiveness. It also includes notes specifying that this includes medical devices already on the market.
investigator	3.31	Article 2(54)	The definition in this document distinguishes between the terms *principal investigator* and *investigator*, whereas the Regulation only defines the role of the investigator which corresponds to the definition of *principal investigator* in this document.
medical device	3.35	Article 2(1)	Both definitions are substantially equivalent. In the Regulation, the definition also specifies: A medical device can be used for one or more medical purposes where the standard does not specify medical Under medical purposes, the Regulation adds in the first bullet point prediction and prognosis, The Regulation second bullet point also adds disability in addition to injury, The third bullet point ads pathological process or state, The fourth bullet has additional specification including organ, blood and tissue donations The Regulation however does not include devices supporting or sustaining life as medical purpose.
serious adverse event SAE	3.46	Article 2(58)	Both definitions are substantially equivalent. The criterion v) chronic disease in the definition of the Regulation is part of the permanent impairment criterion in the definition of this document.
serious health threat	3.47	Article 2(66)	Both definitions are similar but used in a different target population. The definition in the Regulation includes the full target population of a

Term used in this EN	Clause(s)/subclause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
			market released product 'public' health threat, where the definition in this document has been adapted to target the clinical investigation population and is considered as a signal amongst reported serious adverse events rather than a different definition of adverse event.
sponsor	3.50	Article 2(49)	Both definitions are substantially equivalent. The definition in this document specifies that the sponsor assumes liability. A note indicates that when an investigator initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator.
subject	3.51	Article 2(50)	Both definitions are substantially equivalent. In this document, the definition specifies that a subject is a participant in a clinical investigation either as a recipient of the investigational medical device or a comparator. A note indicates that the definition includes healthy volunteers.

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 product(s) falling within the scope of this standard.