



# SLOVENSKI STANDARD SIST EN ISO 14155:2020

01-oktober-2020

Nadomešča:

SIST EN ISO 14155:2011/AC:2011

SIST EN ISO 14155:2012

---

**Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse (ISO 14155:2020)**

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

**iTeh STANDARD PREVIEW**  
(standards.iteh.ai)

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

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

**Ta slovenski standard je istoveten z: EN ISO 14155:2020**

---

**ICS:**

11.040.01	Medicinska oprema na splošno	Medical equipment in general
-----------	------------------------------	------------------------------

**SIST EN ISO 14155:2020**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 14155:2020

<https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020>

EUROPEAN STANDARD

EN ISO 14155

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2020

ICS 11.100.20

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.

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, Turkey and United Kingdom.



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

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

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>
<b>Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered .....</b>	<b>5</b>
<b>Annex ZB (informative) Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered.....</b>	<b>7</b>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 14155:2020](https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020)  
<https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020>

## 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 14971:2020	ISO 14971:2019

**EN ISO 14155:2020 (E)**

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.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 14155:2020](https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020)

<https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020>

## 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 <sup>a</sup> and parts of Annex X.2 listed below.

## EN ISO 14155:2020 (E)

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, 10.3 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 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	
<sup>a</sup> 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 <sup>a</sup> and parts of Annex VII.2 listed below.

## EN ISO 14155:2020 (E)

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	
<sup>a</sup> 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.

INTERNATIONAL  
STANDARD

ISO  
14155

Third edition  
2020-07

---

---

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

*Investigation clinique des dispositifs médicaux pour sujets humains —  
Bonne pratique clinique*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 14155:2020](https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020)

[https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-  
e8255d9fb758/sist-en-iso-14155-2020](https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020)



Reference number  
ISO 14155:2020(E)

© ISO 2020

## iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 14155:2020

<https://standards.iteh.ai/catalog/standards/sist/e948d5ad-2764-42b0-b6b0-e8255d9fb758/sist-en-iso-14155-2020>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Summary of good clinical practice (GCP) principles</b> .....	<b>9</b>
<b>5 Ethical considerations</b> .....	<b>10</b>
5.1 General.....	10
5.2 Improper influence or inducement.....	10
5.3 Compensation and additional health care.....	10
5.4 Registration in publicly accessible database.....	11
5.5 Responsibilities.....	11
5.6 Communication with the ethics committee (EC).....	11
5.6.1 General.....	11
5.6.2 Initial EC submission.....	11
5.6.3 Information to be obtained from the EC.....	12
5.6.4 Continuing communication with the EC.....	12
5.6.5 Continuing information to be obtained from the EC.....	12
5.7 Vulnerable populations.....	12
5.8 Informed consent.....	13
5.8.1 General.....	13
5.8.2 Process of obtaining informed consent.....	13
5.8.3 Special circumstances for informed consent.....	14
5.8.4 Information to be provided to the subject.....	15
5.8.5 Informed consent signature.....	17
5.8.6 New information.....	17
<b>6 Clinical investigation planning</b> .....	<b>17</b>
6.1 General.....	17
6.2 Risk management.....	18
6.2.1 General.....	18
6.2.2 Investigational device including clinical procedure risks and their disclosure.....	18
6.2.3 Clinical investigation process.....	18
6.3 Justification for the design of the clinical investigation.....	19
6.4 Clinical investigation plan (CIP).....	19
6.5 Investigator's brochure (IB).....	19
6.6 Case report forms (CRFs).....	20
6.7 Monitoring plan.....	20
6.8 Investigation site selection.....	21
6.9 Agreement(s).....	21
6.10 Labelling.....	21
6.11 Data monitoring committee (DMC).....	21
<b>7 Clinical investigation conduct</b> .....	<b>22</b>
7.1 General.....	22
7.2 Investigation site initiation.....	22
7.3 Investigation site monitoring.....	22
7.4 Adverse events and device deficiencies.....	22
7.4.1 Signals requiring immediate action.....	22
7.4.2 Adverse events.....	23
7.4.3 Device deficiencies.....	23
7.4.4 Risk assessment process for potentially unacceptable risks.....	23
7.5 Clinical investigation documents and documentation.....	24
7.5.1 Amendments.....	24
7.5.2 Subject identification log.....	24

## ISO 14155:2020(E)

7.5.3	Source documents	25
7.6	Additional members of the investigation site team	25
7.7	Subject privacy and confidentiality of data	25
7.8	Document and data control	25
7.8.1	Traceability of documents and data	25
7.8.2	Recording of data	25
7.8.3	Electronic clinical data systems	26
7.9	Investigational device accountability	27
7.10	Accounting for subjects	27
7.11	Auditing	27
<b>8</b>	<b>Suspension, termination, and close-out of the clinical investigation</b>	<b>28</b>
8.1	Completion of the clinical investigation	28
8.2	Suspension or premature termination of the clinical investigation	28
8.2.1	Procedure for suspension or premature termination	28
8.2.2	Procedure for resuming the clinical investigation after temporary suspension	29
8.3	Routine close-out	29
8.4	Clinical investigation report	30
8.5	Risk assessment and conclusions	30
8.6	Document retention	31
<b>9</b>	<b>Responsibilities of the sponsor</b>	<b>31</b>
9.1	Clinical quality management	31
9.2	Clinical investigation planning and conduct	31
9.2.1	Selection and training of clinical personnel	31
9.2.2	Preparation of documents and materials	32
9.2.3	Conduct of clinical investigation	33
9.2.4	Monitoring	33
9.2.5	Safety evaluation and reporting	36
9.2.6	Clinical investigation close-out	37
9.3	Outsourcing of duties and functions	37
9.4	Communication with regulatory authorities	37
<b>10</b>	<b>Responsibilities of the principal investigator</b>	<b>38</b>
10.1	General	38
10.2	Qualification of the principal investigator	38
10.3	Qualification of investigation site	38
10.4	Communication with the EC	38
10.5	Informed consent process	39
10.6	Compliance with the CIP	39
10.7	Medical care of subjects	40
10.8	Safety reporting	41
	<b>Annex A (normative) Clinical investigation plan (CIP)</b>	<b>42</b>
	<b>Annex B (normative) Investigator's brochure (IB)</b>	<b>51</b>
	<b>Annex C (informative) Case report forms (CRFs)</b>	<b>54</b>
	<b>Annex D (normative) Clinical investigation report</b>	<b>56</b>
	<b>Annex E (informative) Essential clinical investigation documents</b>	<b>61</b>
	<b>Annex F (informative) Adverse event categorization</b>	<b>68</b>
	<b>Annex G (informative) EC responsibilities</b>	<b>70</b>
	<b>Annex H (informative) Application of ISO 14971 to clinical investigations</b>	<b>74</b>
	<b>Annex I (informative) Clinical development stages</b>	<b>75</b>
	<b>Annex J (informative) Clinical investigation audits</b>	<b>80</b>
	<b>Bibliography</b>	<b>83</b>

## 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 14155:2011), which has been technically revised. The main changes to the previous edition are as follows:

- inclusion of a summary section of GCP principles (see [Clause 4](#));
- reference to registration of the clinical investigation in a publicly accessible database (see [5.4](#));
- inclusion of clinical quality management (see [9.1](#));
- inclusion of risk-based monitoring (see [6.7](#));
- inclusion of statistical considerations in [Annex A](#);
- inclusion of guidance for ethics committees in [Annex G](#);
- reinforcement of risk management throughout the process of a clinical investigation (planning to consideration of results) including [Annex H](#);
- clarification of applicability of the requirements of this document to the different clinical development stages (see [Annex I](#));
- inclusion of guidance on clinical investigation audits (see [Annex J](#)).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).