



SLOVENSKI STANDARD
SIST EN ISO 14155:2020/A11:2025

01-februar-2025

**Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse -
Dopolnilo A11**

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

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique
clinique

Ta slovenski standard je istoveten z: EN ISO 14155:2020/A11:2024

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ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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SIST EN ISO 14155:2020/A11:2025 **en,fr,de**

EUROPEAN STANDARD

EN ISO 14155:2020/A11

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2024

ICS 11.100.20

English Version

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

Investigation clinique des dispositifs médicaux pour
sujets humains - Bonne pratique clinique

Klinische Prüfung von Medizinprodukten an Menschen
- Gute klinische Praxis

This amendment A11 modifies the European Standard EN ISO 14155:2020; it was approved by CEN on 27 November 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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.

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

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

EN ISO 14155:2020/A11:2024 (E)

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European foreword

This document (EN ISO 14155:2020/A11:2024) has been prepared by Technical Committee CEN/TC 206 “Biological and clinical evaluation of medical devices”, the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 14155:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.

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 amends EN ISO 14155:2020 with a revised European Foreword and the European Annex ZA.

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.

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 [O] 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) 2017/747 (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 harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the difference is indicated in Table ZA.3. 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) 2017/47 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.