ICS 11.100.20 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2025

STN	**Klinické skúšanie zdravotníckych pomôcok na humánne použitie Správna klinická prax (ISO 14155: 2020) Zmena A11**	**STN EN ISO 14155/A11** 85 4001

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/25

Obsahuje: EN ISO 14155:2020/A11:2024

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155:2020/A11

December 2024

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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.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.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.

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