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STN	**Zdravotnícke pomôcky Aplikácia manažérstva rizika pri zdravotníckych pomôckach (ISO 14971: 2019) Zmena A11**	**STN EN ISO 14971/A11 85 5231**

Medical devices. Application of risk management to medical devices

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. 04/22

Obsahuje: EN ISO 14971:2019/A11:2021

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English version

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)

This amendment A11 modifies the European Standard EN ISO 14971:2019; it was approved by CEN on 27 October 2021.

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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 and CENELEC 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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EN ISO 14971:2019/A11:2021

Contents

Page

European foreword

This document (EN ISO 14971:2019/A11:2021) has been prepared by Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 14971:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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

This Amendment to the European Standard EN ISO 14971:2019 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports requirements of EU Regulation(s).

For relationship with EU Regulation(s), see informative Annex ZA, and ZB, which are 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 websites.

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