

STN	Sterilizácia zdravotníckych pomôcok nízkoteplotnou parou a formaldehydom Požiadavky na vývoj, validáciu a rutinnú kontrolu sterilizačného procesu zdravotníckych pomôcok (ISO 25424: 2018/Amd 1: 2022) Zmena A1	STN EN ISO 25424/A1 85 5016
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Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)

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. 07/22

Obsahuje: EN ISO 25424:2019/A1:2022, ISO 25424:2018/Amd 1:2022

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EUROPEAN STANDARD

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NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1 (ISO 25424:2018/Amd 1:2022)

Stérilisation des produits de santé - Formaldéhyde et vapeur à faible température - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation pour dispositifs médicaux - Amendement 1 (ISO 25424:2018/Amd 1:2022)

Sterilisation von Produkten für die Gesundheitsfürsorge - Niedertemperatur-Dampf-Formaldehyd - Anforderungen an die Entwicklung, Validierung und Routineüberwachung von Sterilisationsverfahren für Medizinprodukte - Änderung 1 (ISO 25424:2018/Amd 1:2022)

This amendment A1 modifies the European Standard EN ISO 25424:2019; it was approved by CEN on 28 December 2021.

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.

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

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EN ISO 25424:2019/A1:2022 (E)

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European foreword

This document (EN ISO 25424:2019/A1:2022) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 25424:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

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 has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

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

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA and ZB 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 should 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 in table ZA.2.

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 25424:2018/Amd 1:2022 has been approved by CEN as EN ISO 25424:2019/A1:2022 without any modification.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN