SLOVENSKI STANDARD
SIST EN ISO 25424:2020/oprA1:2021

01-junij-2021

Sterilizacija izdelkov za zdravstveno nego - Para z nizko temperaturo in s formaldehidom - Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke - Dopolnilo A1 (ISO 25424:2018/DAM 1:2021)

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/DAM 1:2021)

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/DAM 1:2021)

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/DAM 1:2021)

Ta slovenski standard je istoveten z: **EN ISO 25424:2019/prA1**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 25424:2020/oprA1:2021 **en,fr,de**

DRAFT AMENDMENT

ISO 25424:2018/DAM 1

ISO/TC **198**

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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

AMENDMENT 1

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

ICS: 11.080.01

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Foreword

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Amendment 1 to ISO 25424:2018 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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.

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

Terms and definitions

Delete all cross-references within the definitions to other terms defined in ISO 25424.

3.18

Replace the sentence after the list ("and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means") with the following:

"and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means".

3.41

Replace term and definition with the correct definition from ISO 11139:2018, 3.137 as follows:

3.41

inactivation curve

graphical representation of decrease in viability of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions

11.1 b) and c)

Replace 11.1 b) and c) with the following text:

b) if chemical indicators are used as part of the product release, the complete colour change of these (see 8.4 and 10.3);

c) if biological indicators or PCDs containing BIs are used as part of the product release, acceptable results after cultivation of these (see 8.3 and 10.2); and

Table D.1

Replace wrong cross-reference in line "3 emission to air"/column "used, Stage C, last line from C.9.3.4 to C.9.4.4:

Environmental aspects (inputs and outputs)	Product life-cycle			
	Production and reproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
	Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
3 Emission to air	**Introduction** 5.1 5.5 6.3.3 8.6 9.3.1 9.3.3 9.4.2.2 C.9.3.4 C.9.4.4	—	**Introduction** 5.1 5.5 6.3.3 8.6 9.3.1 9.3.3 9.4.2.2 C.9.3.4 C.9.4.4	—

Annex ZA
(informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ 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 ZD.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, 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 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.

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 a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using low temperature steam and formaldehyde for medical devices, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This General Safety and Performance Requirement is addressed only with regard to devices for which treatment by low temperature steam and formaldehyde is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of a specific microbial state by low temperature steam and formaldehyde are not covered.
11.4 first sentence only	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using low temperature steam and formaldehyde for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by low temperature steam and formaldehyde is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility by low temperature steam and formaldehyde are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.