SLOVENSKI STANDARD
SIST EN ISO 10993-7:2009/oprA1:2018

01-oktober-2018

Biološko ovrednotenje medicinskih pripomočkov - 7. del: Ostanki po sterilizaciji z etilenoksidom - Dopolnilo A1 (ISO 10993-7/DAM 1:2018)

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1 (ISO 10993-7/DAM 1:2018)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände - Änderung 1 (ISO 10993-7:2008/DAM 1:2018)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène - Amendement 1 (ISO 10993-7:2008/DAM 1:2018)

Ta slovenski standard je istoveten z: **EN ISO 10993-7:2008/prA1**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-7:2009/oprA1:2018 **en,fr,de**

DRAFT AMENDMENT

ISO 10993-7:2008/DAM 1

ISO/TC **194**

Secretariat: **DIN**

Voting begins on:
2018-08-09

Voting terminates on:
2018-11-01

Biological evaluation of medical devices —

Part 7:
Ethylene oxide sterilization residuals

AMENDMENT 1

Évaluation biologique des dispositifs médicaux —

Partie 7: Résidus de stérilisation à l'oxyde d'éthylène

AMENDEMENT 1

ICS: 11.100.20

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO 10993-7:2008/DAM 1:2018(E)

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Published in Switzerland

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

A list of all parts in the ISO 10993- series can be found on the ISO website.

Biological evaluation of medical devices —

Part 7:
Ethylene oxide sterilization residuals

AMENDMENT 1

Normative references

Replace the reference to ISO 10993-1:— (including the footnote) with the following:

> ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Renumber subsequent footnotes.

Delete ISO 10993-12 and move to Bibliography

Renumber subsequent biblio entries.

4.1, first paragraph to third paragraph

> Delete all except the NOTE.

4.2, second paragraph

Replace the reference "ISO 10993-1:—, 5.3;" with "ISO 10993-1:2018, 5.3;"

4.2, a) to c)

Relace the text by the following:

> a) Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h.
>
> b) Prolonged exposure (B) – medical devices whose cumulative sum of single, multiple or repeated contact time is likely to exceed 24 h but not exceed 30 d.
>
> c) Long-term exposure (C) – medical devices whose cumulative sum of single, multiple or repeated contact time exceeds 30 d.

4.3.1, first paragraph

Replace the paragraph with the following:

> The use of materials that can be sterilized by methods other than EO and the sterilization process shall be considered during product design and development, so that EO sterilization shall be used only when justified. Therefore, when EO is used for sterilization, elements leading to this choice shall be documented. The allowable limits, presented below, shall be regarded as maximum allowable amount on the device and an additional goal of the manufacturer applying this standard should be to reduce the residues levels of EO sterilization by e.g. other method(s), improved process(es), other material(s), design. As far as possible, given the generally recognized state of the art and given that the risk-benefit ratio is not adversely affected.

4.3.1, third paragraph

Replace the paragraph with the following:

The limits for permanent contact and prolonged exposure devices are expressed as maximum average daily doses. These limits carry additional constraints for the first 24 h of the exposure period and, in the case of the permanent contact devices, for the first 30 days, whichever extraction method is used. These constraints place limitations on the amount of EO and ECH that can be delivered to the patient during these early time periods.

4.3.1, fourth paragraph

Replace the paragraph with the following:

If data are available, consideration should be given for proportioning the limits downward if multiple devices with the residue of concern are used at one time, or proportioning the limits upward when device use is only for a part of the exposure period of concern. These concomitant exposure factors (CEF) and proportional exposure factors (PEF) are given in ISO 10993-17. A default value of 0,2 for CEF have been given for 5 medical devices used and contributing to the patient residues daily exposure. When the device risk analysis shows that more than five medical devices sterilized by EO can contribute to the total daily exposure, then the allowable limits shall be adjusted accordingly.

4.3.2, first paragraph

Replace the paragraph with the following:

In the case of a device used in an adult of body mass $_{m}$b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 0,1 mg/d. In addition, the maximum EO dose shall not exceed:

4.3.2, last paragraph

Replace the paragraph with the following:

When the risk analysis indicates that the device may be used in special populations, the appropriate patient body mass shall be used for the derivation of the allowable limits. For example, if the device is intended to be used in premature neonates, neonates or children, the allowable limits shall be derived using the abovementioned limits and diminished by the pro rata of the appropriate body mass. The appropriate default body mass used for each category of special patient population should be justified and documented.

4.3.3, first paragraph

Replace the paragraph with the following:

In the case of a device used in an adult of body mass $_{m}$b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 0,2 mg/d. In addition, the maximum EO dose shall not exceed:

4.3.3, last paragraph

Replace the paragraph with the following:

When the risk analysis indicates that the device may be used in special populations, the appropriate patient body mass shall be used for the derivation of the allowable limits. For example, if the device is intended to be used in premature neonates, neonates or children, the allowable limits shall be derived using the abovementioned limits and diminished by the pro rata of the appropriate body mass. The appropriate default body mass used for each category of special patient population should be justified and documented.

4.3.4

Replace the text with the following:

In the case of a device used in an adult of body mass m_b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 4 mg. The average daily dose of ECH to patient shall not exceed 9 mg.

When the risk analysis indicates that the device may be used in special populations, the appropriate patient body mass shall be used for the derivation of the allowable limits. For example, if the device is intended to be used in premature neonates, neonates or children, the allowable limits shall be derived using the abovementioned limits and diminished by the pro rata of the appropriate body mass.

4.4.2, last paragraph

Delete the last sentence.

4.4.6.2

Add a new paragraph after the NOTE:

The extraction solvent used for extractions proceeded by simulation should be representative of the medical device environment during its use. Depending on the medical device use, the more relevant extraction solvent should be chose in order to simulate the real use. I.e. for feeding tubes, a mixture water/ethanol (1/1) could be used to simulate "fat liquids"[1] and acid water can simulate gastric liquids in which the device is immerged in (external environment). Except otherwise specified the default solvent option can be water.

4.4.6.3.1

Add the following at the end of the subclause:

The simulation should be the preferred exhaustive extraction procedure for permanent exposition medical devices. If another procedure is used this shall be justified and documented.

B.2.1, second paragraph

Add the following sentence to the end of the paragraph:

The way to determine these validation data is reported in numerous validation guidelines including ICH Q2 (R2). See [A] to [I].

B.2.1, second paragraph

Add the following NOTE after the paragraph:

NOTE For EO, it is extremely difficult to carry out the determination of the accuracy using spiked preparation because of the volatility of this compound. As an alternative, the use of commercially available certified standards is recommended.

B.2.1, third paragraph

Delete the second sentence of this paragraph.

B.2.2 to B.2.6

Delete all subclauses

C.1, second paragraph

Replace the text of the second sentence with the following:

Maximum allowable limits for ethylene chlorohydrin residues where ECH has been found to be present in medical devices sterilized with EO are also specified in the case of a device used in an adult of body mass m_b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors).

C.1, sixth paragraph