SLOVENSKI STANDARD
SIST EN 14180:2003/kprA2:2009

01-april-2009

Sterilizatorji za uporabo v medicini - Sterilizatorji s paro nizke temperature in s formaldehidom - Zahteve in preskušanje

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren - Anforderungen und Prüfung

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

Ta slovenski standard je istoveten z: **EN 14180:2003/prA2**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN 14180:2003/kprA2:2009 **en,fr,de**

EUROPEAN STANDARD

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FINAL DRAFT
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ICS

English Version

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

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This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

This draft amendment A2, if approved, will modify the European Standard EN 14180:2003. If this draft becomes an amendment, 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.

This draft amendment was established by CEN 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 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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Foreword

This document (EN 14180:2003/prA2:2009) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

1 Modification to the Introduction

Replace the 5th and 6th paragraphs with the following:

"Validation and routine control of sterilization processes are essential to ensure their efficacy. This standard does not cover validation and routine control of a LTSF process. Criteria for validation and routine control of LTSF sterilization processes are given in EN 15424.

At the present state of knowledge, LTSF sterilizers should not be assumed to deliver processes effectively inactivating the causative agents of spongiform encephalopathies such as scrapie, Bovine Spongiform Encephalophaty and Creutzfeld-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. (See also EN 15424:2007 1.2.1)."

Replace "EN 61010–2–042" *in last paragraph with* "EN 61010–2–040".

2 Modification to Clause 2

Delete the following references:

"EN 866-1, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements"*

(including associated footnote.)

"EN 866–5, *Biological systems for testing sterilizers and sterilization processes — Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers"*

(including associated footnote.)

Add the following references:

*"*EN ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2006)*"

"EN ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2006)*"

Replace:

"EN 61010–2–042:1997, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2–042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes (IEC 61010–2–042:1997)"*

with:

"EN 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005)*"

3 Modification to Clause 3

Replace definition 3.5 with the following:

“**3.5**
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[ISO/TS 11139:2006, definition 2.3]”

4 Modification to 4.2.4.1

Replace reference to "EN 61010–2–042" *with* "EN 61010–2–040".

5 Modification to 4.2.4.2

Replace the existing 4.2.4.2 with the following:

"**4.2.4.2** Sterilizers shall comply with EN 61326 regarding electromagnetic compatibility (EMC).

Sterilizers operating either in areas in which medical electrical equipment is intended to be used or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified in EN 61326.

For immunity, the requirements of EN 61326:2006, Table 2 shall apply.

The selected immunity performance criteria shall ensure that the sterilizer performance as specified in 5.2 will be met during normal operation, when exposed to disturbance phenomena given in EN 61326:2006, Table 2."

6 Modification to 4.2.6.2

Replace the existing note with the following:

"NOTE The access for maintenance should be positioned so that it will not compromise the safety of either the product or persons. Requirements for access are specified in EN 61010–2–040."

7 Modification to 4.3.8.1

Replace the existing note 2 with the following:

"NOTE 2 Except if required in EN 61010–2–040 the items a), b), e), f), g) and h) may be incorporated into a system whereby the user may select the display of any measurement."

8 Modification to 5.2.5

Replace the reference to "EN 61010–2–042" *with* "EN 61010–2–040".

9 Modification to 5.3.1

Replace the existing note with the following:

"NOTE Additional requirements regarding intervention safety and environmental aspects are specified in EN 61010–2–040."

10 Modification to 5.4.2

Replace the existing note with the following:

"NOTE EN 61010–2–040 may require both in some cases."

11 Modification of 5.4.3

Replace the existing note with the following:

"NOTE Additional safety requirements regarding faults are given in EN 61010–2–040."

12 Modification to 5.4.5

Replace the reference to "EN 61010–2–042" *with* "EN 61010–2–040".

13 Modification to 6.2

Replace "

When tested in accordance with A.3.5, the desorption stage of the sterilization cycle shall be able to reduce the value of formaldehyde residues in/on processed items as follows:

— The mean value calculated for test pieces of the same test load shall not exceed 200 µg.

— The peak value for any single test piece shall not exceed 250 µg."

with "

When tested in accordance with A.3.5, the desorption stage of the sterilization cycle shall be able to reduce the value of formaldehyde residues in/on processed items as follows:

— The mean value calculated for test pieces of the same test load shall not exceed 200 µg

— The value for any single test piece shall not exceed 400 µg.

NOTE 3 Test results from practice have shown a rather large variance of the formaldehyde residue values up to 30% (standard deviation). It is assumed that this is caused by stochastic distribution of condensate accumulations inside the chamber and at the load (test pieces) during the process. "

14 Modification to 8.3

Replace the existing 8.3 with the following:

"8.3 Markings regarding safety and environmental aspects are specified in EN 61010–2–040."

15 Modification to Clause 9.1 m)

Replace the text of 9.1 m) with the following:

"further details of equipment installation for safety as required by EN 61010–2–040;"

16 Modification to 9.2 a) list item 10)

Replace the text of list item 10 with the following:

"further details of equipment operation for safety as required by EN 61010–2–040;"

17 Modification to 9.2 i)

Replace the text of 9.2 i) with the following:

"further details of equipment maintenance for safety as required by EN 61010–2–040"

18 Modification to 10.7

In note 2, replace the reference to "EN 61010-2-042" *with* "EN 61010-2-040".

19 Modification to 10.8

Replace the final paragraph with the following:

"Installation site ventilation facilities shall be installed as required by safety or environmental aspects in EN 61010-2-040."

20 Modification to A.3.3.6

Replace

"**A.3.3.6** Culture both the exposed and the untreated biological indicators in accordance to with EN 866–1.

NOTE EN 866–1 is currently under revision by ISO/TC 198/WG 4 (Vienna Agreement)."

with

"**A.3.3.6** Culture both the exposed and the untreated biological indicators in accordance with EN 11138–1."

21 Modification to B.3.3

Replace the existing B.3.3 with the following:

"The production test is used to demonstrate compliance of each sterilizer with its type test performance. The series of tests listed in Table B.1 and specified in A.3 are reference tests recommended for use in demonstrating conformity with the performance requirements specified in this Standard."

22 Modification to B.3.4

Replace the first paragraph with the following:

"Requirements and guidance for IQ are given in EN 15424 and are not a normative part of this Standard. For sterilizers submitted to IQ which are covered by this Standard it should be confirmed that:"