SLOVENSKI STANDARD
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Nebiologġki sistemi za uporabo v sterilizatorjih ï 5. del: Specifikacija za sisteme indikatorjev in razvoj izloļ evalnih naļ rtov za preskuġanje delovanja majhnih sterilizatorjev tipov B in S

Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 5: Festlegungen von Indikatorsystemen und Prüfkörpern für die Leistungsprüfung von Klein-Sterilisatoren vom Typ B und vom Typ S

Systemes non biologiques destinés a etre utilisés dans des stérilisateurs - Partie 5: Spécifications des systemes indicateurs et dispositifs d'épreuve de procédé destinés a etre utilisés pour les essais de performances relatifs aux petits stérilisateurs de Type B et de Type S

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Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S

Systèmes non biologiques destinés à être utilisés dans des stérilisateurs - Partie 5: Spécifications des systèmes indicateurs et dispositifs d'épreuve de procédé destinés à être utilisés pour les essais de performances relatifs aux petits stérilisateurs de Type B et de Type S

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This European Standard was approved by CEN on 25 July 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2002, and conflicting national standards shall be withdrawn at the latest by February 2002.

This European Standard has been considered by CEN/TC 102 as one of a series of European Standards concerned with non-biological indicators used in the testing, monitoring and routine operation of sterilizers. These standards are:

EN 867-1	*Non-biological systems for use in sterilizers – Part 1: General requirements*
EN 867-2	*Non-biological systems for use in sterilizers – Part 2: Process indicators (Class A)*
EN 867-3	*Non-biological systems for use in sterilizers – Part 3: Specification for Class B indicators for use in the Bowie and Dick test*
EN 867-4	*Non-biological systems for use in sterilizers – Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration*
prEN 867-5	*Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

In addition CEN/TC 102 Working Group 7 has prepared a series of European Standards describing biological indicators for use in sterilizers. These European Standards are:

EN 866-1	*Biological systems for testing sterilizers and sterilization processes – Part 1: General requirements*
EN 866-2	*Biological systems for testing sterilizers and sterilization processes – Part 2: Particular systems for use in ethylene oxide sterilizers*
EN 866-3	*Biological systems for testing sterilizers and sterilization processes – Part 3: Particular systems for use in moist heat sterilizers*
EN 866-4	*Biological systems for testing sterilizers and sterilization processes – Part 4: Particular systems for use in irradiation sterilizers*
EN 866-5	*Biological systems for testing sterilizers and sterilization processes – Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers*
EN 866-6	*Biological systems for testing sterilizers and sterilization processes – Part 6: Particular systems for use in dry heat sterilizers*
EN 866-7	*Biological systems for testing sterilizers and sterilization processes – Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers*
EN 866-8	*Biological systems for testing sterilizers and sterilization processes – Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers*

The annexes A, B, C and D are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

The indicators and process challenge devices described in this European Standard are intended specifically for use in carrying out tests on small steam sterilizers, Type B or Type S.

prEN 13060 Parts 2 and 4 specify requirements and tests for small steam sterilizers Type B which are intended to process solid products, hollow products, and porous products any of which may be wrapped in one or more layers of sterilization grade packaging materials (see EN 868) and for small steam sterilizers Type S which may also be specified by the manufacturer of the small steam sterilizer as intended to process hollow products and/or porous products.

Small sterilizers unable to accommodate a sterilization module (600 mm x 300 mm x 300 mm) cannot be tested using the tests described in EN 285:1996 for large sterilizers for wrapped goods and porous loads either because the chamber size is unable to accommodate the standard test packs or because the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume.

The indicator systems described in this European Standard are intended to be used, in conjunction with the appropriate process challenge device, to demonstrate the rapid and complete penetration of steam into the process challenge device. The construction of the process challenge device and the performance of the indicator are designed to ensure that penetration of steam in the load within the sterilizer will provide adequate assurance that steam penetration will occur in routine loads.

1 Scope

This European Standard specifies the performance requirements and test methods for non-biological indicator systems, including the process challenge devices within which they are intended to function, to be used for testing the steam penetration performance of small steam sterilizers, Type B or Type S where appropriate. The test systems specified are intended for use only in small steam sterilizers Type B conforming to prEN 13060-2 and having a usable chamber space greater than 10 l and for small steam sterilizers Type S conforming to prEN 13060-4 also having a usable chamber space greater than 5 l.

Non-biological indicator systems and the associate process challenge devices are specified for various types of load. The possible loads are considered in two classes: Porous loads, which can be wrapped or unwrapped, or hollow instrument loads, which also can be wrapped or unwrapped.

The relevant section of this European Standard on porous loads specifies the requirements for:

– a standard process challenge device to be used in the small load test for porous loads in small steam sterilizers;

– an indicator system for use in the porous load process challenge device. An indicator for this purpose is a Class B indicator as described in EN 867-1.

– an indicator employing an alternative process challenge device equivalent to the porous load process challenge device.

The relevant section of this European Standard on hollow instruments specifies the requirements for:

– hollow load process challenge devices to be used to simulate hollow instrument loads as defined in prEN 13060-4;

– an indicator system, for use in one of the hollow load process challenge device, for assessing steam penetration in a wrapped load of hollow instruments. An indicator for this purpose is a Class B indicator as described in EN 867-1.

The process challenge devices described in this standard are intended for use only in sterilizers of sufficient size to accommodate the process challenge device with no part of the process challenge device closer than 20 mm from the vessel wall; in the case of the porous load process challenge device the total internal volume of the vessel is not less than 10 l.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated into it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 285:1996
Sterilization – Steam sterilizers – Large sterilizers.

EN 866-3
Biological systems for testing sterilizers and sterilization processes – Part 3: Particular systems for use in moist heat sterilizers.

EN 867-1
Non-biological systems for use in sterilizers – Part 1: General requirements.

EN 867-3:1997
Non-biological indicator systems for use in sterilizers – Part 3: Specification for Class B indicators for use in the Bowie and Dick test.

EN 867-4
Non-biological systems for use in sterilizers – Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration.

prEN 13060-2
Small steam sterilizers – Part 2: Particular requirements and test methods for type B sterilizers, intended for the sterilization of wrapped solid, hollow and porous products.

prEN 13060-4
Small steam sterilizers – Part 4: Particular requirements and test methods for type S sterilizers, intended for the sterilization of products specified by the manufacturer of the sterilizer.

EN 20187
Paper, board and pulps – Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187:1990).

EN 20534
Paper and board – Determination of thickness and apparent bulk density or apparent sheet density (ISO 534:1988).

EN ISO 3696:1995
Water for analytical laboratory use – Specification and test methods (ISO 3696:1987).

EN ISO 5457:1999
Technical product documentation– Sizes and layout of drawing sheets (ISO 5457:1999).

ISO 10012-1
Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment.

3 Terms and definitions

For the purposes of this European Standard, the definitions given in EN 867-1 and the following definitions apply:

3.1
hollow load
devices having a minimum diameter of 2 mm or greater and no point internally at a distance greater than 1500 times the minimum internal diameter from direct open connection with the surrounding environment

3.2
process challenge device
object which simulates the worst case of conditions for attainment of the specified sterilization conditions within the items to be sterilized

NOTE The device is so constructed that a biological or non-biological indicator system can be placed within the device in the position which it is most difficult for the sterilizing agent to reach. The design of the process challenge device depends on the nature of the goods to be sterilized and the sterilization procedure.

3.3
total internal volume
volume of water at 20 °C which would be required to fill the hollow load process challenge device, including the space which would, in use, be occupied by the indicator system

3.4
free capsule volume
capsule volume excluding the volume occupied by the indicator system

3.5
indicator system volume
volume of water at 20 °C which would fill a space bounded by the maximum external dimensions of the indicator system

3.6
capsule volume
internal volume of that part of the hollow load process challenge device intended to accommodate the indicator system determined as the volume of water at 20 °C which would be required to fill the capsule

4 Requirements

4.1 General

4.1.1 The requirements of EN 867-1 shall apply.

4.1.2 Samples of non-biological indicators shall be conditioned in accordance with EN 20187 prior to testing for performance.

4.1.3 The combination of process challenge device and indicator system shall be specified as providing a test system for either a porous load (see 4.2, 4.3 and 4.4) or a hollow instrument load (see 4.5 and 4.6).

4.1.4 When used in accordance with the manufacturer's instructions the indicator system, in combination with any specified process challenge device, shall provide indication of failure to attain steam penetration with a sensitivity sufficient to ensure that a satisfactory result will give confirmation that steam penetration would be attained in a sterilizer load of the type specified.

4.1.5 Indicator systems intended for use with re-usable user-assembled process challenge devices shall not visibly transfer indicator reagent to the material of the process challenge device during processing.

Pre-assembled process challenge devices and indicator systems intended for use with the single-use user-assembled process challenge devices shall not transfer indicator reagent to the material of the process challenge device during processing to an extent which impairs the utility of the product.

Compliance shall be demonstrated by visual examination after testing in accordance with the requirements of 4.3.3 and 5.3.2 as appropriate.

4.2 Process challenge device for porous load

4.2.1 The process challenge device for porous loads shall be a standardised test pack for assessing the performance in the sterilization of porous loads in small steam sterilizers.

4.2.2 The pack shall be constructed from plain cotton sheets, bleached to a good white and each having an approximate size of 450 mm x 300 mm. Edges other than selvage shall be oversewn, not hemmed.

4.2.3 The number of threads per 10 mm in the warp shall be (30 ± 6) and the number of threads per 10 mm in the weft shall be (27 ± 5).

4.2.4 The mass per unit area shall be (185 ± 5) g . m^{-2}.

4.2.5 The sheets shall be washed when new and when soiled. During the washing process the sheets shall not be subjected to any fabric conditioning agent.

4.2.6 After washing the sheets shall be dried and aired, but not ironed or calendered.

4.2.7 Before use the sheets shall be stored, unfolded and well separated, for at least 1 h in an environment at a temperature between 20 °C and 30 °C and at a relative humidity of 40 % to 70 %.

4.2.8 After airing, the sheets shall be folded to approximately 110 mm x 150 mm and stacked to a height of approximately 120 mm after compressing by hand. The pack shall be wrapped in a single sheet of the same fabric and secured with tape not exceeding 19 mm in width. The total weight of the pack shall be (900 ± 30) g.

NOTE 1 When forming the pack, consecutive sheets should be stacked with the folded side alternating to ensure an even stack.

NOTE 2 Packs which are not used within 1 h of preparation can be stored until required, providing the environmental conditions are maintained within the limits specified above.

NOTE 3 After use the sheets will become compressed. When the weight of sheets used to form a stack 120 mm high exceeds 1000 g, the sheets should be discarded.

4.3 Indicator systems for use in the porous load process challenge device

4.3.1 The indicator systems are intended for use in a standard test pack of the type specified in this standard (see 4.2).

4.3.2 The indicator system shall comply with the requirements of EN 867-1 and, in addition, the substrate on which an indicator reagent has been deposited shall be marked with the information "For use in small steam sterilizers".

4.3.3 The indicator shall comply with the requirements of EN 867-3:1997 except that:

a) the indicator system shall be A6 size to EN ISO 5457:1999; replacing EN 867-3:1997, 5 g);

b) the standard test pack used for evaluation of performance requirements shall be in accordance with 4.2 of this European Standard; replacing EN 867-3:1997 annex L;

c) the steam exposure apparatus shall be as described in annex A of this European Standard;

d) the operating cycle(s) of the steam exposure apparatus shall be as described in annex B of this European Standard.

4.4 Alternative indicators equivalent to the porous load process challenge device test

The indicator shall comply with the requirements of EN 867-4 except that for the purpose of demonstration of equivalence the performance shall be compared with thermometric monitoring of the porous load process challenge device test pack (see 4.2) and the operational cycle(s) of the steam exposure apparatus described in annex A shall be as described in annex B of this European Standard.

4.5 Process challenge devices for hollow instrument loads (hollow load process challenge device)

4.5.1 Under the conditions of use, the materials from which the hollow load process challenge device is made shall not release any substances in such quantities that would constitute a health risk or which will adversely affect the performance of indicator systems with which it is intended to be used when tested in accordance with 5.1.

NOTE For further information see EN ISO 10993-1 and ISO 14538.

4.5.2 The pH of a hot aqueous extract shall be within the range 6,5 to 7,5 when determined by the method given in 5.1.1.2.

NOTE Many non-biological indicator systems are dependent for their colour change on a change in pH, or undergo reactions in which the reaction rate is dependent on pH. Materials which can leach acids or alkalis into indicator systems are not suitable for general use.

4.5.3 The hollow load process challenge device shall be constructed of material which is neither porous nor permeable to air or steam under the conditions of use (see clause 5).

4.5.4 The material(s) of which the hollow load process challenge device is constructed shall not absorb water to any significant extent and shall not cause an increase in mass greater than 5 % when tested as described in 5.1.1.3.

Such water as can be absorbed shall:

a) not cause dimensional changes sufficient to affect adversely the compliance of the hollow load process challenge device with the performance requirements of this European Standard or greater than a linear expansion of 2 % when tested as described in 5.1.1.3;

b) not be released during the sterilization process to an extent which would compromise the ability of the indicator system to demonstrate inadequate air removal when tested in accordance with 5.1.3.

4.5.5 The materials of which the hollow load process challenge device is constructed shall withstand exposure to the sterilization process for which it is intended:

a) without distortion, melting, corrosion or other failure which would impair its utility;

b) without any change occuring in the severity of the test as a result of thermal exposure

when tested as described in 5.1.5.

4.5.6 When the hollow load process challenge device is also intended to be used with biological indicators (or inoculated carriers) the material shall not release any substance to such an extent that it can inhibit the growth of low numbers of surviving micro-organisms on a biological indicator or inoculated carrier when tested by the method described in 5.1.4.

4.5.7 The hollow load process challenge device shall consist of a capsule to contain the indicator connected to a lumen, of uniform internal dimensions throughout its length. The capsule shall be of cylindrical construction and the internal volume shall be of uniform cross-section over its length. The process challenge device shall have the following specification:

– Wall thickness: (0,5 ± 0,025) mm;

– Internal diameter: (2,0 ± 0,1) mm;

– Length: (1 500 ± 15) mm;

– Capsule mass: (10,0 ± 0,1) g;

– Free capsule volume: (6 ± 1) % of the total internal volume minus the capsule volume;

– Material of construction: Polytetrafluorethylene (PTFE).

NOTE Other materials of demonstrated equivalence may be used. When different materials are used, the wall thickness and capsule mass can be varied appropriately.

4.5.8 The capsule for containing the indicator system shall be equipped with a demountable cap or similar device to permit the positioning and removal of the indicator system and shall provide an effective seal against the passage of air and/or steam.

4.5.9 The design of the capsule shall ensure that the indicator system:

– is retained securely in the intended position;

– does not obstruct the lumen, unless this was part of the design intent;

– can be removed easily for examination after use.

4.5.10 The free capsule volume (see 4.5.7) shall be terminal and of uniform cross-section.

NOTE The ratio of the volume of the receptacle to the free internal volume is a critical factor in determining the difficulty for steam penetration to the indicator.

4.5.11 When requested by the purchaser, the process challenge device manufacturer shall make available an alternative demountable cap or closure with provision for incorporating a temperature sensor (e. g. thermocouple or Pt 100 element) to sense the temperature of the free space in the capsule volume adjacent to the indicator system.

4.6 Indicator systems for use in the hollow load process challenge device

4.6.1 The indicator system shall be designed to be used in conjunction with a hollow load process challenge device (see 4.5).

4.6.2 When the indicator system and hollow load process challenge device are not supplied as an assembled unit the indicator supplier shall provide the purchaser/user with details of any limitations concerning the design of hollow load process challenge device with which the indicator is intended to be used.

4.6.3 The indicator shall be designed and manufactured to respond to a combination of temperature and time, in the presence of moisture to effect a clearly discernible colour change which shall be used to demonstrate attainment of satisfactory conditions for sterilization.