SLOVENSKI STANDARD
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Nebiološki sistemi za uporabo v sterilizatorjih - 2. del: Indikatorji postopkov (razred A)

Non-biological systems for use in sterilizers - Part 2: Process indicators (Class A)

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 2: Prozeßindikatoren (Klasse A)

Systemes non-biologiques destinés a etre utilisés dans des stérilisateurs - Partie 2: Indicateurs de procédé (Class A)

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English version

Non-biological systems for use in sterilizers - Part 2: Process indicators (Class A)

Systèmes non-biologiques destinés à être utilisés dans des stérilisateurs - Partie 2: Indicateurs de procédé (Class A)

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 2: Prozeßindikatoren (Klasse A)

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents

Foreword

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

This Standard is one of a series of European Standards concerned with non-biological systems for testing 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

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
prEN 866-4	Biological systems for testing sterilizers and sterilization processes – Part 4: Particular systems for use in irradiation sterilizers
prEN 866-5	Biological systems for testing sterilizers and sterilization processes – Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers
prEN 866-6	Biological systems for testing sterilizers and sterilization processes – Part 6: Particular systems for use in dry heat sterilizers
prEN 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
prEN 866-8	Biological systems for testing sterilizers and sterilization processes – Part 8: Particular requirements for self-contained biological systems for use in ethylene oxide sterilizers

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 August 1997 and conflicting national standards shall be withdrawn at the latest by August 1997.

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

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

Introduction

European Standards for sterilizers (EN 285) and for the validation and process control of sterilization (EN 550, EN 552 and EN 554) describe performance tests for sterilizers and methods of validation and routine control, respectively.

This Part of EN 867 specifies the requirements for process indicators Class A as defined in Part 1 of EN 867.

The non-biological indicators specified in this standard are not intended for use in any process other than that specified. The use of an inappropriate indicator can give dangerously misleading results.

The performance of a non-biological indicator can be affected by the conditions of storage prior to use, the methods of use, and the conditions of storage after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed precisely. Non-biological indicators should not be used beyond any expiry date stated by the manufacturer.

When a physical and/or chemical variable of a sterilizing process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, irrespective of the results obtained from the non-biological indicators.

1 Scope

This European Standard specifies requirements for steam, ethylene oxide, irradiation, dry heat and steam/formaldehyde sterilization process indicators intended for use with individual packs of product to demonstrate that the pack has been exposed to the process. They can be designed to react to one or more of the critical process variables but can be designed to achieve their end-point reaction after exposure to sub-optimal levels of the process variable.

Process indicators can be printed directly on packaging material or presented as self adhesive labels, packaging tapes, tags, etc.

Process indicators have a defined end-point reaction.

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 in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 867-1 : 1997
Non-biological systems for use in sterilizers – Part 1: General requirements

prEN 868-2
Packaging materials and systems for medical devices which are to be sterilized – Part 2: Sterilization wrap – Requirements and tests

prEN 868-3
Packaging materials and systems for medical devices which are to be sterilized – Part 3: Paper for use in the manufacture of paper bags (specified in Part 4) and of pouches and reels (specified in Part 5) – Requirements and tests

prEN 868-4
Packaging materials and systems for medical devices which are to be sterilized – Part 4: Paper bags – Requirements and tests

prEN 868-6
Packaging materials and systems for medical devices which are to be sterilized – Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and tests

prEN 868-7
Packaging materials and systems for medical devices which are to be sterilized – Part 7: Adhesive coated paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and tests

3 Definitions

For the purposes of this standard the definitions of EN 867-1 and the following definitions apply:

3.1 bleed: lateral migration of the indicator reagent through the web of the substrate beyond the margins within which the indicator reagent was applied.

3.2 penetration: migration of indicator reagent through the web of the substrate through to the surface opposite the one to which the indicator reagent was applied.

3.3 off-set: transfer of indicator reagent to a material in intimate contact with the surface of the indicator.

4 General requirements

4.1 General

4.1.1 The requirements of Part 1 of this standard apply.

4.1.2 The indicator shall comply with the requirements of this standard for the duration of the shelf life specified by the manufacturer.

Compliance shall be tested in accordance with Annex A.

4.1.3 For process indicators with a shelf life, once changed, of greater than six months the manufacturer shall state the minimum shelf life of the changed indicator when stored under specified conditions (see also 5.5.3 of EN 867-1 : 1997).

4.2 Process indicators printed onto single-use packaging material

When printed onto single-use packaging material complying with Part 2, Part 3, Part 4, Part 6 and Part 7 of prEN 868, the indicator shall not bleed, offset or penetrate the substrate to which it is applied, before, during or after the sterilization process for which it is designed, or to which it can be subjected when used in accordance with the instructions for use (see clause 6 of EN 867-1 : 1997).

Compliance shall be tested by visual inspection of the indicator, its substrate, and a second layer of substrate in intimate contact with the indicator, before and after sterilization.

4.3 Process indicators not printed onto packaging material

The indicator shall not offset, or penetrate the substrate to which it is applied, or materials with which it is in contact before, during or after the sterilization process for which it is designed, or to which it can be subjected, when used in accordance with the instructions for use (see clause 6 of EN 867-1 : 1997).

Compliance shall be tested by visual inspection of the indicator, its substrate, and a second layer of substrate in intimate contact with the indicator, before and after sterilization.

5 Performance requirements

5.1 Process indicators for steam sterilization

5.1.1 After exposure to previously stabilised conditions giving dry heat at (140 ± 2) °C for (30 ± 1) min the indicator shall either show no change, or shall show a change which is markedly different to that occurring after exposure to the steam sterilization process.

5.1.2 The complete change indicating exposure to a steam sterilization process shall not occur until the indicator has been exposed to dry saturated steam for:

a) not less than 3 min at (121^{+3}_{0}) °C and
b) not less than 30 s at (134^{+3}_{0}) °C.

5.1.3 The indicator shall provide clear visual evidence of exposure to the process after being subjected to dry saturated steam for:

a) not more than 10 min at (121^{+3}_{0}) °C and
b) not more than 2 min at (134^{+3}_{0}) °C.

5.2 Process indicators for ethylene oxide sterilization

5.2.1 After exposure to (60 ± 2) °C at a relative humidity greater than 85 % for not less than 90 min the indicator shall either show no change or shall show a change markedly different from that occurring after exposure to the ethylene oxide sterilization process.

NOTE: This test is done without ethylene oxide being present and therefore should not be carried out in an ethylene oxide sterilizer where traces of the gas can be present.

5.2.2 The complete change indicating exposure to an ethylene oxide sterilization process shall not occur until the indicator has been exposed to (600 ± 30) mg/l ethylene oxide, (60 ± 10) % relative humidity at (30 ± 1) °C for not less than 5 min.

NOTE: The reaction of some ethylene oxide indicators can be impaired by the presence of carbon dioxide or other gas. Where the formulation is such that this can occur the indicator should be tested in a system employing not less than 80 % carbon dioxide or other gas in a mixture with the ethylene oxide (see 6.2 d) of EN 867-1 : 1997).

5.2.3 The indicator shall show clear visual evidence of exposure to the process after being subjected to (600 ± 30) mg/l ethylene oxide, (60 ± 10) % relative humidity at (30 ± 1) °C for not more than 30 min.

5.3 Process indicators for sterilization by ionising radiation

5.3.1 After exposure to UV light (from 240 mm to 280 nm) with an intensity of not less than 3,3 W/m² for not less than 120 min the indicator shall either show no change or shall show a change markedly different from that occurring after exposure to a radiation sterilization process.

5.3.2 The complete change indicating exposure to an irradiation sterilization process shall not occur until the indicator has been exposed to an absorbed dose of not less than 2 kGy.

5.3.3 The indicator shall show clear visual evidence of exposure to the process after being subjected to an absorbed dose of not more than 10 kGy.

5.4 Process indicators for dry heat sterilization

5.4.1 The complete change indicating exposure to a dry heat sterilization process shall not occur until the indicator has been exposed previously stabilized conditions giving a temperature of (160 ± 2) °C for not less than 20 min.

5.4.2 The indicator shall provide clear visual evidence of exposure to the process after being subjected to previously stabilized conditions giving a temperature of (160 ± 2) °C for not more than 40 min.

5.5 Process indicators for steam/formaldehyde sterilization

5.5.1 After exposure to dry saturated steam at (80 ± 2) °C for not less than 90 min the indicator shall either show no change or shall show a change which is markedly different from that occurring after exposure to the steam/formaldehyde sterilization process.

5.5.2 After exposure to dry heat at (80 ± 2) °C for not less than 90 min the indicator shall either show no change or shall show a change which is markedly different from that occurring after exposure to the steam/formaldehyde sterilization process.

5.5.3 The complete change indicating exposure to a steam/formaldehyde sterilization process shall not occur until the indicator has been subjected to (10 ± 2) mg/l formaldehyde in steam at (70 ± 2) °C for not less than 5 min.

5.5.4 The indicator shall provide clear visual evidence of exposure to the process after being subjected to (10 ± 2) mg/l formaldehyde in steam at (70 ± 2) °C for not more than 20 min.

5.5.5 For indicators produced for steam/formaldehyde sterilization cycles operating at temperatures below 65 °C the tests described in 5.5.3 and 5.5.4 shall be carried out at the maximum temperature and formaldehyde concentration specified by the manufacturer of the indicator (see also 6.2 a) and 6.2 b) of EN 867-1 : 1997).

6 Test methods

6.1 Tests for compliance with the requirements given in clause 5 shall be carried out by exposing the indicators to the conditions specified, within the tolerances given, and then visually examining the indicator for compliance.

6.2 During testing of steam sterilization process indicators for the effect of exposure to steam, the total time above 100 °C shall be as short as practicable and shall not exceed the defined exposure period by more than 20 s (see 5.1.2 and 5.1.3).

6.3 During testing of ethylene oxide indicators for the effect of exposure to ethylene oxide, the total period of ethylene oxide exposure shall be as short as practicable and shall not exceed the defined exposure period by more than 2 min (see 5.2.2 and 5.2.3).

6.4 During testing of steam/formaldehyde indicators for the effect of steam/formaldehyde, the total period of steam/formaldehyde exposure shall be as short as practicable and shall not exceed the defined exposure period by more than 2 min (see 5.5.3, 5.5.4 and 5.5.5).