SLOVENSKI STANDARD
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Nebiološki sistemi za uporabo v sterilizatorjih - 3. del: Specifikacija za indikatorje razreda B za uporabo v Bowie-Dickovem preskusu

Non-biological systems for use in sterilizers - Part 3: Specification for Class B indicators for use in the Bowie and Dick test

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 3: Festlegungen für Indikatoren der Klasse B für den Bowie-Dick-Test

Systemes non-biologiques destinés a etre utilisés dans des stérilisateurs - Partie 3: Spécification pour les indicateurs de la Classe B destinés a etre utilisés dans l'essai de Bowie-Dick

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English version

Non-biological systems for use in sterilizers - Part 3: Specification for Class B indicators for use in the Bowie and Dick test

Systèmes non-biologiques destinés à être utilisés dans des stérilisateurs - Partie 3: Spécification pour les indicateurs de la Classe B destinés à être utilisés dans l'essai de Bowie-Dick

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 3: Festlegungen für Indikatoren der Klasse B für den Bowie-Dick-Test

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CEN

European Committee for Standardization
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Contents

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 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

The Bowie and Dick test was conceived as a test for successful air removal from high vacuum porous load sterilizers[1]). A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due either to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, are circumstances which can lead to a failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

A failure of the Bowie and Dick test is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure.

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods and porous loads. As such it is performed during the demonstration of conformance of steam sterilizers to EN 285 and as a routine test of performance in EN 554. The method of carrying out the test is described in EN 285.

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[1]) Bowie, J.H., Kelsey, J.C., and Thompson, G.R., Lancet, i, p. 586 (1963)

A test pack for the Bowie and Dick test consists of two components:

a) a small standardised test load and

b) a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described[2]), utilized Huckaback Towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

1 Scope

This European Standard specifies the requirements for an indicator to be used in the Bowie and Dick test for steam sterilizers for wrapped goods, e. g. instruments and porous materials. An indicator for this purpose is a Class B indicator as described in Part 1 of this Standard.

An indicator complying to this European Standard is to be used in combination with the standard test pack as described in EN 285. This Standard does not detail requirements for the standard test pack but specifies the performance of the indicator.

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 285 : 1996
Sterilization – Steam sterilizers – Large sterilizers

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

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 ISO 9001 : 1994
Quality systems – Model for quality assurance in design/ development, production, installation and servicing (ISO 9001 : 1994)

ISO 5-1
Photography – Density measurements – Part 1: Terms symbols and notations

ISO 5-3
Photography – Density measurements – Part 3: Spectral conditions

ISO 5-4 : 1995
Photography – Density measurements – Part 4: Geometric conditions for reflection density

ISO 2248
Packaging – Complete, filled transport packages – Vertical impact test by dropping

ISO 5457
Technical drawings – Sizes and layout of drawing sheets

ISO 5636-3
Paper and board – Determination of air permeance (medium range) – Part 3: Bendtsen method

3 Definitions

For the purposes of this standard, the definitions given in EN 867-1 and EN 285 apply.

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[2]) Bowie, J.H., Kelsey, J.C., and Thompson, G.R., Lancet, i, p. 586 (1963)

4 General requirements

4.1 The requirements of Part 1 of this Standard apply.

4.2 Test samples shall be conditioned in accordance with EN 20187 prior to testing for performance.

5 Indicator system format

The indicator system format shall meet the following requirements:

a) It shall consist of indicator reagent uniformly distributed on a substrate to cover not less than 30 % of the surface area of the substrate. The distance between adjacent areas of indicator reagent shall not exceed 20 mm.

NOTE: The pattern of indicator reagent distribution should permit easy comparison of the colour change at the margin with the colour change in the central region.

b) It shall have an air porosity greater than 3,4 μm/Pa s when tested in accordance with ISO 5636-3 at an air pressure of 1,47 kPa.

c) It shall have sufficient strength to withstand steam sterilization.

Compliance shall be tested in accordance with Annex A.

d) It shall have a substrate of a colour which is uniform to visual observation.

e) It shall have a difference in reflectance density of not less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer.

Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be A4 size to ISO 5457.

6 Performance requirements

6.1 The indicator shall meet the following requirements:

a) It shall show a uniform colour change complying 5.1 e) after exposure to dry saturated steam at $(134^{+1,5}_{0})$ °C for 3,5 min ± 5 s or after exposure to dry saturated steam at $(121^{+1,5}_{0})$ °C for 15 min ± 5 s or both.

Compliance shall be tested in accordance with Annex C.

b) When placed in the centre of a standard test pack, show a non-uniform colour change when the temperature at the centre of the standard test pack is 2 K lower than the temperature of the chamber drain of the steam exposure apparatus (see Annex H).

Compliance shall be tested in accordance with Annex J.

With some indicators a slight colour change can occur. This shall be acceptable if the change that occurs is slight or markedly different from that brought about by exposure to steam in accordance with 6.1 a) and within the limits specified by the manufacturer.

c) It shall show no discernible colour change after exposure to dry heat at (140 ± 2) °C for not less than 30 min.

Compliance shall be demonstrated in accordance with Annex D.

d) It shall not visibly transfer indicator reagent to the material of the test load in intimate contact with the indicator during processing.

Compliance shall be demonstrated in accordance with Annex F.

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

If any change in the indicator occurs during ageing it shall be different to the change on exposure to dry saturated steam (as described in 6.1 a)) and have either inactivated the indicator so that no further change can take place or not affected the performance of the indicator with respect to the requirements of 6.1 a) and 6.1 b).

Compliance shall be tested in accordance with Annex G or by performance testing after accelerated ageing in accordance with Annex E.

7 Packaging and Labelling

7.1 Each substrate on which an indicator reagent has been deposited shall be marked with the operating temperature(s) for which the product is designed to be used.

7.2 Each indicator shall be marked with a unique code from which the manufacturing history can be traced and at least the information given below.

Adjacent to each heading there shall be a clear space not less than 5 mm x 20 mm for the user to enter the required information at the time of use.

Site

Machine No

Date

Supervisor

Department

Operator

Result

Figure 1: Example of a suitable format

NOTE: Other formats can be used.

7.3 Each indicator shall be provided with space for the user to record essential cycle information under the headings:

a) Department;

b) Machine-No;

c) Cycle-No;

d) Operator;

e) Date;

f) Result;

g) Supervisor.

7.4 The product shall be packed in such a way as to allow easy separation of individual units of product and to protect the product from moisture, dust, sunlight and damage in normal transit to the extent necessary to ensure that the indicator retains its performance throughout the stated shelf life when stored in accordance with the manufacturer's instructions.

The manufacturer shall retain documentary evidence demonstrating compliance.

7.5 The outside of each carton shall be marked with the operating temperature at which the product is suitable for use.

7.6 The information supplied by the manufacturer (see 6.2 c) of EN 867-1 : 1997) shall include sufficient instruction on the use of the indicator to enable correct interpretation of the test results.

8 Quality Assurance

8.1 The quality system shall ensure that an acceptable quality level (AQL) of 1,0 or less is maintained for performance requirements given in 6.1 a) and 6.1 b).

NOTE: The AQL is the maximum number of defects per hundred units that, for the purpose of sampling inspection, can be considered satisfactory as a process average.

8.2 Suitable records shall be maintained to ensure that, in the event of a defect arising, faulty batches can be recalled from use.

8.3 The manufacturing and distribution records shall be retained for a period of five years, or twice the declared shelf life of the product whichever is the less. These records shall be maintained in accordance with the requirements of 4.16 of EN ISO 9001 : 1994.

Annex A (normative)

Procedure for determining strength after steam sterilization

A.1 Apparatus

A.1.1 A steam exposure apparatus complying with Annex H.

A.1.2 Standard test pack complying with Annex L.

A.1.3 Steam supply complying with 13.3.2 to 13.3.4 of EN 285 : 1996.

A.2 Procedure

A.2.1 Expose the indicator, within a standard test pack, to three successive steam exposures at the stated operating temperature of the indicator system.

A.2.2 Remove the standard test pack from the exposure apparatus and perform a drop test in accordance with ISO 2248 from a height of 1 m onto a firm horizontal surface.

NOTE: Concrete or terrazzo surfaces are suitable.

A.2.3 Remove the indicator from the standard test pack and visually examine for damage.

A.2.4 Repeat this test for each of three separate production batches of the indicator system.

Annex B (normative)

Method for the estimation of the visual difference between the colour of the substrate and the changed (or unchanged) indicator system by determination of the relative reflectance density

B.1 Apparatus

B.1.1 A steam exposure apparatus complying with Annex H.

B.1.2 A photoelectric reflectance photometer complying with the requirements of B.3.2.

B.2 Principle

The relative reflectance density, see Part 1 of ISO 5 of the changed indicator and the substrate are determined in accordance with the methods given below which are based on Part 3 and Part 4 of ISO 5 to which reference should also be made.

Relative reflectance density $D_{Rf} = -\log 10 R_f$

$R_f = \Phi_c/\Phi_{ce}$

where Φ_c is the reflected flux from the indicator and Φ_{ce} is the reflected flux from the substrate.

To completely define a type of density spectrally, it is necessary to specify the light source, optics and spectral response of the measuring system.

B.3 Measurement

B.3.1 Illumination

The relative spectral power distribution of the incident flux shall conform to CIE standard illuminant D_{65}.

NOTE: This is regarded as equivalent to "Daylight – cloudy northern sky".

B.3.2 Measuring instrument

B.3.2.1 General

The measuring instrument shall be a photoelectric instrument giving within 0,3 % an indicated reading proportional to the intensity of light reflected from the surface under test.

B.3.2.2 Optical geometry

The measuring instrument shall have optical geometry conforming to the requirements of Part 4 of ISO 5; this includes illumination of the specimen at angles between 40 ° and 50 °, viewed along the normal (0 °) with an angle of acceptance (observer angle) of 10 °.

The dimensions of the measurement aperture of the instrument shall permit the measurement aperture to be entirely filled with substrate or indicator.

NOTE: To minimise measurement errors the optical system should be equipped with a polarising filter if the surface to be measured is highly reflecting e. g. a plastic coated surface.

B.3.2.3 Spectral response

For the visual reflectance density, the combined spectral sensitivity of the receiver and spectral characteristics of the components on the efflux section of the measuring instrument shall match the spectral luminance efficiency in photopic vision, designated $V_{(\lambda)}$. The product of $V_{(\lambda)}$ and the reflection densitometer illuminance S_A, wavelength by wavelength, defines the spectral products that the measuring instrument shall have to provide comparison of visual densities. The spectral product of the measuring instrument shall be within ± 20 % of the values given in table B.1.

NOTE 1: The logarithms of the products are given in table B.1.

NOTE 2: These conditions assume that there is no fluorescence in the optical elements of the instrument or the sample.

B.3.2.4 Calibration

NOTE: Reflectance density is determined using a perfectly-reflecting and perfectly-diffusing material as a reference standard. Such a material does not exist but the response that would theoretically be obtained from such a material can be compared with a suitable secondary reference standard e. g. compressed barium sulphate, enamelled metal plaques which can then be used to calibrate the densito-meter.

The measuring instrument shall be calibrated against reference samples previously calibrated by National Reference Laboratory.

The instrument shall indicate values within ± 3 % of the calibrated values of the reference samples.

B.3.2.5 Background

While readings of the reflectance density of the substrate and the indicator are being made the sample shall be in contact with a backing material which is spectrally non-selective and diffuse-reflecting and which has an ISO reflection density greater than 1,50 (see Annex A of ISO 5-4 : 1995).

B.4 Method

B.4.1 Sample conditioning

Samples shall be conditioned to, and in equilibrium with, (23 ± 2) °C and (50 ± 5) % Relative Humidity when tested.

NOTE: Standardised conditions are recommended because some materials change density with variations in temperature and relative humidity.