SLOVENSKI STANDARD
SIST EN 866-5:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov - 5. del: Posebni sistemi za uporabo sterilizacije s paro nizke temperature in s formaldehidom

Biological systems for testing sterilizers and sterilization processes - Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 5: Spezielle Systeme für den Gebrauch in Sterilisatoren mit Niedertemperatur-Dampf und Formaldehyd

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Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 5: Systemes particuliers destinés a etre utilisés dans des stérilisateurs a la vapeur d'eau et au formaldéhyde a basse température

Ta slovenski standard je istoveten z: EN 866-5:1999

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

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EUROPEAN STANDARD

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Biological systems for testing sterilizers and sterilization processes - Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 5: Systèmes particuliers destinés à être utilisés dans des stérilisateurs à la vapeur d'eau et au formaldéhyde à basse température

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 5: Spezielle Systeme für den Gebrauch in Sterilisatoren mit Niedertemperatur-Dampf und Formaldehyd

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

EN 866 consists of the following Parts under the general title "Biological systems for testing sterilizers and sterilization processes"

Part 1: General requirements
Part 2: Particular systems for use in ethylene oxide sterilizers
Part 3: Particular systems for use in moist heat sterilizers
Part 4: Particular systems for use in irradiation sterilizers
Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers
Part 6: Particular systems for use in dry heat sterilizers
Part 7: Particular requirements for self-contained systems for use in moist heat sterilizers
Part 8: Particular requirements for self-contained systems for use in ethylene oxide sterilizers

In addition CEN/TC 102 Working Group 7 has prepared EN 867 consisting of the following parts under the general title "Non-biological systems for use in sterilizers"

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

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 June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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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.

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Introduction

This European standard specifies the performance requirements for biological indicators supplied ready for use and for suspensions of test organisms supplied either for the preparation of biological indicators or for the inoculation of product for use in validation studies on low temperature steam and formaldehyde sterilization processes.

The biological indicators specified in this standard are not intended for use in any process other than low temperature steam and formaldehyde sterilization. The use of a biological indicator in a process other than that stated by the manufacturer can give dangerously misleading results.

The use of a biological system for testing a sterilization process does not imply that the system will respond equally to inadequate levels of all the critical variables of the process.

The performance of a biological indicator can be affected by the conditions of storage prior to use, the methods of use, and the techniques employed after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed and biological indicators should be transferred to the specified recovery conditions as soon as possible after exposure to the process. Biological indicators should not be used beyond the expiry date of the manufacturer.

Biological indicators should always be used in combination with a physical and/or chemical monitoring in demonstrating the efficacy of a sterilizing process. When a physico-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 biological indicators.

1 Scope

This Part of EN 866 specifies requirements for inoculated carriers and biological indicators intended for use in assessing the performance of sterilizers employing low temperature steam and formaldehyde as the sterilant over a sterilizing temperature range of 55 °C to 80 °C.

2 Normative references

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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.

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EN 866-1 : 1997
Biological systems for testing sterilizers and sterilization processes – Part 1: General requirements

3 Definitions

For the purposes of this European Standard, the definitions given in EN 866-1 apply together with the following.

3.1 Low temperature steam and formaldehyde: A process incorporating forced air removal which allows exposure of wrapped goods to steam at sub-atmospheric pressure, and thus at temperature less than 100 °C, with the admission of formaldehyde gas.

4 General Requirements

The requirements of EN 866-1 : 1997 shall apply.

5 Test organisms

The test organisms shall be spores of *Bacillus stearothermophilus* or other strains or organisms of demonstrated equivalent performance as required by this standard.

NOTE: *Bacillus stearothermophilus* NCIB 8224, DSM 6790 and ATCC 10149 have been found to be suitable.

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6 Population of test organisms

6.1 Replicate determination of the viable count on the same batch of suspension shall be within ± 35 % of the nominal population.

6.2 The number of recoverable test organisms on each biological indicator shall be controlled during manufacture to be either within ± 50 % of the nominal population stated by the manufacturer or within the minimum and maximum populations stated by the manufacturer.

6.3 Retrospective determination of the count shall be made by performing a viable count under the culture conditions on a suspension of test organisms obtained by physical removal of the test organisms from the carrier through ultrasonication, shaking with glass beads, or other appropriate, validated methods. Counts obtained shall be regarded as acceptable if they are within - 50 % and + 300 % of the nominal population stated by the manufacturer or the midpoint between the minimum and maximum populations stated by the manufacturer.

NOTE: The method specified by the manufacturer for removal of organisms from the carrier should be used.

6.4 For inoculated carriers or biological indicators intended for use in routine monitoring the nominal number of spores shall be not less than 1×10^6 per unit and shall be stated in increments not greater than $0{,}1 \times 10^6$.

NOTE: Inoculated carrier and/or biological indicators supplied for other purposes e. g qualification, validation or other specific test, can require other nominal populations.

7 Carriers

7.1 The suitability of the carrier for use in low temperature steam and formaldehyde sterilization processes shall be demonstrated in accordance with the requirements in 6.1, 6.2 and Annex A of EN 866-1 : 1997.

7.2 The exposure conditions to be used to establish compliance shall be:

- Temperature – not less than 85 °C
- Relative humidity – not less than 90 %
- Formaldehyde concentration – not less than 80 mg/l
- Exposure time – not less than 2 h

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NOTE: These conditions have been selected to represent a realistic challenge to the carrier whilst remaining within the practical limits of an low temperature steam and formaldehyde sterilization process.

8 Resistance

8.1 General

The manufacturer shall state the *D* value of each batch of biological indicators or inoculated carriers in minutes to one decimal place. The manufacturer shall state the accuracy with which the *D* value was determined (e. g. ± 0,1 min). This accuracy shall not exceed ± 0,3 min.

8.2 Biological indicators and inoculated carriers intended for use in routine monitoring

8.2.1 The *D* values obtained by both the survivor curve method and MPN method (see Annex B of EN 866-1 : 1997) for the spore population on the inoculated carriers shall be not less than 3 min when exposed to (10 ± 2) mg/l formaldehyde in steam at (70 ± 1) °C when determined in accordance with the method given in Annex A.

8.2.2 When both of the reference methods in Annex A have been used, the *D* value obtained by the two methods shall be such that the higher value obtained does not exceed the lower value by more than 50 % of the lower value.

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8.3 Biological indicators intended for use in validation, qualification and other specific tests

NOTE: Biological indicators and inoculated carriers intended for use in validation, qualification and other specific tests have not specific requirements for the population or resistance of test organisms to allow users flexibility in devising test programs. The D value and population are determined and stated (see 6.3 and 6.4, 8.1, 8.3 a) and 8.3 b)).

When the purchaser specifies requirements other than those in 8.2 for biological indicators and inoculated carriers intended for use in validation, qualification and other specific tests the following shall apply:

a) The D values shall be determined by both the survivor curve method and the MPN method by exposure to (10 ± 2) mg/l formaldehyde in steam at (70 ± 1) °C in accordance with the method given in Annex A;

b) The D value obtained by the two methods shall be such that the higher value obtained does not exceed the lower value by more than 50 % of the lower value. Both D values shall be stated.

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Annex A (normative)

Determination of resistance to low temperature steam and formaldehyde sterilization

A.1 Apparatus: Low temperature steam and formaldehyde biological indicator resistometer

A.1.1 The equipment shall be capable of maintaining the conditions given in table A.1 within the limits given for exposure periods between 1 min and 60 min to an accuracy of ± 10 s. In addition the equipment shall be capable of exposures of not less than 2 h.

Table A.1: Conditions

Variable	For resistance studies see clause 8	For carrier studies see clause 7
formaldehyde	(10 ± 2) mg/l	≥ 80 mg/l
temperature	(70 ± 1) °C	≥ 85 °C
relative humidity	≥ 90 %	≥ 90 %

A.1.2 The equipment shall be provided with means to evacuate the reaction chamber to less than 10 kPa to permit adequate air removal prior to admission of the sterilant and to exhaust the sterilant at the end of the exposure period. Air admitted at the end of the cycle shall be filtered through a filter having the ability to remove not less than 99,9 % of 0,5 µm particles.

A.1.3 The chamber and door shall be provided with means to maintain the temperature of the inner surfaces at the required operating temperature.

A.1.4 The time taken to achieve the required gas concentration from commencement of gas admission shall not exceed 60 s and the time to evacuate to 10 kPa at the end of the exposure period shall not exceed 60 s.

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A.1.5 The supply of formaldehyde gas to the chamber shall ensure that neither liquid solutions of formaldehyde nor particles of polymer are admitted to the chamber.

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A.1.6 The equipment shall be capable of automatic operation and shall be provided with a system for recording temperature, pressure and humidity within the chamber which is independent of the control function and such that the limits of error on the recording equipment do not exceed 50 % of the tolerance allowed for each control variable.

NOTE: For example the chamber temperature is required to be controlled within ± 1 K and thus the maximum allowable error limit on the temperature recorder is ± 0,5 K.

A.2 Procedure

A.2.1 Operation of the resistometer

A.2.1.1 Load the inoculated carriers onto a suitable sample holder.

A.2.1.2 Pre-heat the resistometer chamber to (70 ± 1) °C.

A.2.1.3 Place the loaded sample holder in the chamber, close the chamber and leave for the time required to allow the temperature to stabilise.