SLOVENSKI STANDARD
SIST EN 866-4:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov - 4. del: Posebni sistemi za uporabo sterilizacije z obsevanjem

Biological systems for testing sterilizers and sterilization processes - Part 4: Particular systems for use in irradiation sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 4: Spezielle Systeme für den Gebrauch in Strahlensterilisatoren

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Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 4: Systemes particuliers destinés a etre utilisés dans des stérilisateurs a irradiation

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SIST EN 866-4:2000 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 866-4

December 1999

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English version

Biological systems for testing sterilizers and sterilization processes - Part 4: Particular systems for use in irradiation sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 4: Systèmes particuliers destinés à être utilisés dans des stérilisateurs à irradiation

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 4: Spezielle Systeme für den Gebrauch in Strahlensterilisatoren

This European Standard was approved by CEN on 19 June 1999.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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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 species 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 which may be used in validation studies on, and routine monitoring of, irradiation sterilization processes.

The biological indicators specified in this standard are not intended for use in any process other than irradiation 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, 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 any expiry date stated by the manufacturer.

Biological indicators should always be used in combination with physical and/or chemical monitoring in demonstrating the efficacy of a sterilizing process. Under most circumstances irradiation sterilization processes should be validated and monitored by physical measurement and the use of dosimeters. Biological indicators provide no additional assurance except in special circumstances. When a physico-chemical variable of a sterilizing process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, (see also EN 552) 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 irradiation sterilizers. These are intended for use in sterilizers employing an electron beam or gamma irradiation. They are not intended for use with absorbed doses greater than 45 kGy.

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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.

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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 absorbed dose: Quantity of radiation energy imparted per unit mass of matter.

4 General requirements

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

5 Test organisms

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

NOTE: *Bacillus pumilus* CIP 3.83, DSM 361, CIP 77.25, DSM 492, ATCC 14884 and ATCC 27142 have been found to be suitable.

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6 Population of test organisms

6.1 Replicate determinations of the viable count on the same batch of suspensions 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, validation 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 1×10^7 per unit and shall be stated in increments not greater than $0{,}1 \times 10^7$.

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

7 Carriers

7.1 The suitability of the carrier for use in irradiation 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 a dose of not less than 70 kGy.

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

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8 Resistance

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8.1 General

The manufacturer shall state the D value of each batch of biological indicators or inoculated carriers in kilograys. The manufacturer shall state the accuracy with which the D value was determined (e. g. ± 0,5 kGy). This accuracy shall not exceed ± 0,5 kGy.

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 NOTE 2 in clause 10 in EN 866-1 : 1997) for the spore population on the inoculated carriers shall not be less than 1,9 kGy when determined in accordance with the method given in Annex A.

8.2.2 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.

8.3 Biological indicators intended for use in other specific tests

NOTE: Biological indicators and inoculated carriers intended for use in validation, qualification and other specific tests have no 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), 8.3 b).

When the purchaser specifies requirements other than those in 8.2 for biological indicators and inoculated carriers intended for use in 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 in an irradiator 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 irradiation sterilization

A.1 Apparatus

A.1.1 The following text specifies the performance requirements for apparatus used to determine the resistance of inoculated carriers or biological indicators to irradiation by either accelerated electrons or gamma rays.

NOTE: This Annex does not specify any details of the safety precautions necessary for the operation of sources of irradiations, particularly those incorporating radioactive materials. Attention is drawn to the existence of legal requirements and Codes of Practise for the operation of such equipment in many countries.

A.1.2 The equipment shall be capable of delivering absorbed doses to water in incremental steps of (0,8 ± 0,1) kGy.

A.1.3 The equipment shall be provided with a sample holder capable of supporting both inoculated carriers and the system of dosimetry in the same geometric arrangement. During irradiation, the inoculated carrier shall be surrounded by sufficient water equivalent material to act as a dosimetric system and to ensure electronic equilibrium.

A.1.4 The system of dosimetry shall be capable of determining absorbed doses to water with an accuracy of ± 3 % and shall be traceable to National Standards.

NOTE: In order to achieve this level of accuracy in dose determination, reference dosimeters should be used. Guidance on dosimetry is given in EN 552.

A.1.5 Means shall be provided to measure the temperature attained at the sample during irradiation.

NOTE: This facility is required to permit temperature compensation to be applied to the determination of the absorbed dose.

A.2 Procedure

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A.2.1 Irradiating the samples

A.2.1.1 Load the inoculated carriers or biological indicators into the sample holder and incorporate the dosimetric system.

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A.2.1.2 Expose the loaded sample holder to the required nominal irradiation dose.

A.2.1.3 After exposure, remove the sample holder from the equipment.

A.2.1.4 Determine the delivered irradiation dose (to water).

A.2.1.5 Repeat step A.2.1.1 to A.2.1.4 inclusive for each exposure value required.

A.2.2 Survivor curve method for determination of D value

A.2.2.1 As soon as possible, but in any case within 2 h, physically remove the spores from the test pieces into aqueous suspension by ultrasonication, shaking with glass beads or other method previously validated as capable of effectively removing the spores. Record the time at which the test piece was transferred into aqueous suspension.

NOTE: For bacterial endospores, sterile distilled water should be used. Other micro-organisms can require other validated sterile suspending media.

A.2.2.2 Determine the viable count of the suspension obtained using the recovery medium and conditions stated by the manufacturer

A.2.3 Most probable number method for determination of D value

A.2.3.1 As soon as possible, but in any case within 2 h, aseptically transfer each inoculated carrier into a container of recovery medium.

A.2.3.2 Use the recovery medium stated by the manufacturer and incubate in accordance with the manufacturers instructions.

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A.3 Determination of resistance

Determine the resistance by both the survivor curve method and the MPN method (see Annex B of EN 866-1 : 1997).

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