SLOVENSKI STANDARD
SIST EN 866-3:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov – 3. del: Posebni sistemi za uporabo sterilizacije z vlažno toploto

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

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 3: Spezielle Systeme für den Gebrauch in Sterilisatoren mit feuchter Hitze

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 3: Systemes particuliers destinés a etre utilisés dans des stérilisateurs a la chaleur humide

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

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 3: Systèmes particuliers destinés à être utilisés dans des stérilisateurs à la chaleur humide

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 3: Spezielle Systeme für den Gebrauch in Sterilisatoren mit feuchter Hitze

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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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 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 biological systems for testing 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
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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 indicator systems for use in ethylene oxide sterilizers

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

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

This 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 and routine monitoring of, moist heat sterilization processes. The use of the indicators specified in this standard are described, inter alia, in EN 285.

The biological indicators specified in this standard are not intended for use in any process other than moist heat sterilization. The use of an inappropriate 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 allow necessarily the same level of sensitivity in response 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 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 sterilization process. When a physico-chemical variable of a sterilization process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, (see also EN 554) 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 moist heat sterilizers and sterilization processes operating at temperatures in excess of 100 °C.

NOTE: EN 285 specifies the performance and test requirements for large steam sterilizers for wrapped goods and porous loads.

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

3 Definitions

For the purposes of this standard, the definitions given in EN 866-1 apply, together with the following:

3.1 z value: For a thermal sterilization process, the change in exposure temperature which corresponds to a tenfold change in D value.

4 General requirements

The requirements of EN 866-1 : 1997 shall apply except for 7.2 and 9.2 which are replaced by clause 9 of this standard.

5 Test organisms

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

NOTE: *Bacillus stearothermophilus* NCTC 10003 and ATCC 7953, DSM 22 and CIP 5281 have been found to be suitable.

6 Population of test organisms

6.1 Replicate determinations 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 within ± 50 % of the nominal population 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 mid point between the minimum and maximum populations stated by the manufacturer.

NOTE: Guidance on the selection of validation of methods for the removal of micro-organisms from the carrier is given in EN 1174-2.

6.4 For inoculated carriers or biological indicators intended for use in routine monitoring the nominal number of spores shall be not less than 1×10^5 per unit and shall be stated in increments not greater than $0,1 \times 10^5$. (See also 8.2.2).

When the purchaser specifies a nominal number of spores of 1×10^6 or greater for use in routine monitoring the population shall be stated in increments of not more than $0,1 \times 10^6$.

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

7 Carriers

7.1 The suitability of the carrier for use in moist heat sterilization processes shall be demonstrated in accordance with 6.1 and 6.2 of EN 866-1 : 1997 and Annex A of this standard.

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

- exposure to dry saturated steam at not less than the manufacturer's stated maximum;
- exposure temperature + 5 °C for not less than 30 min.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C shall be used.

NOTE: These conditions have been selected to represent a realistic challenge to the carrier while remaining within the practical limitations of a moist heat 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 ± 0,2 min.

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

8.2.1 The D values obtained for the spore population on the inoculated carriers shall be not less than 1,5 min when exposed to dry saturated steam at (121 ± 1) °C when determined in accordance with the method given in Annex A. (see 10.2 of EN 866-1 : 1997)

8.2.2 When the $\log_{10}$ of the nominal population is multiplied by the D_{121} value in minutes the product shall be not less than 10.

8.2.3 The D value of the spores on the inoculated carrier shall be determined at not less than two other temperatures in the range 110 °C to 130 °C by either of the two methods given. These data shall be used to calculate the z value, which shall be not less than 6 °C.

8.2.4 When the manufacturer specifies that the inoculated carrier or biological indicator is for use at only one temperature, 8.2.3 shall not apply.

8.2.5 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.

8.3 Biological indicators intended for use in qualification, validation and 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), 8.3b].

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 (121 ± 1) °C in accordance with the methods 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.

c) If specified by the purchaser the D value of the spores on the inoculated carrier shall be determined at not less than two other temperatures by either of the two methods given. These data shall be used to calculate the z value.

9 Packaging and labelling

Each package containing a number of inoculated carriers or biological indicators shall be accompanied by the following information:

a) name of test organism;

b) culture collection number;

c) the nominal number of test organisms per inoculated carrier;

d) a unique code from which the manufacturing history can be traced;

e) the number of inoculated carriers or biological indicators;

f) the recommended storage conditions;

g) the expiry date;

h) the manufacturers name and address or other means of identification;

i) the sterilization process or range of sterilization processes for which the inoculated carrier or biological indicator is designed;

j) directions for use; this shall include the culture conditions to be used after exposure to the sterilization process;

k) the resistance of the test organisms, expressed as the D value at 121 °C except where the inoculated carrier or biological indicator is designed for only one specific process temperature and exposure time when the specified temperature shall be used in determining the D value;

l) the z value, where this has been determined (see 8.2.3 and 8.3 c)).

NOTE: This requirement replaces 7.2 and 9.2 of EN 866-1 : 1997.