SLOVENSKI STANDARD
SIST EN 866-6:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov - 6. del: Posebni sistemi za uporabo sterilizacije s suho toploto

Biological systems for testing sterilizers and sterilization processes - Part 6: Particular systems for use in dry heat sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 6: Spezielle Systeme für den Gebrauch in Heißluft-Sterilisatoren

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 6: Systemes particuliers destinés a etre utilisés dans des stérilisateurs a chaleur seche

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Biological systems for testing sterilizers and sterilization processes - Part 6: Particular systems for use in dry heat sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 6: Systèmes particuliers destinés à être utilisés dans des stérilisateurs à chaleur sèche

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 6: Spezielle Systeme für den Gebrauch in Heißluft-Sterilisatoren

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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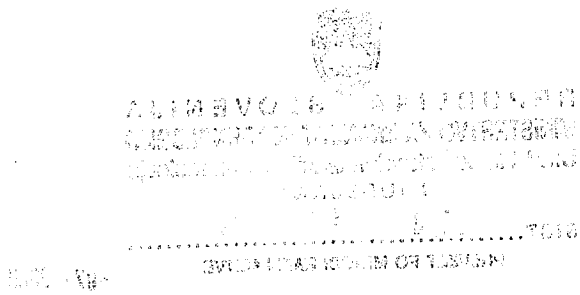

Foreword

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.

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.

Introduction

This European standard specifies the performance requirements for biological indicators supplied ready for use and for the suspensions of test organisms supplied either for the preparation of biological indicators or for the inoculation of products for use in validation studies and routine monitoring of dry heat sterilization processes.

The biological indicators specified in this standard are not intended for use in any process other than dry heat 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 stated by 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 dry heat sterilizers operating at temperatures in the range 140 °C to 250 °C.

NOTE: The indicators specified in this standard are not suitable for assessing depyrogenation processes.

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

EN 866-3
Biological systems for testing sterilizers and sterilization processes – Part 3: Particular systems for use in moist heat sterilizers

3 Definitions

For the purposes of this European Standard the definitions given in EN 866-1 and EN 866-3 apply.

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 subtilis* or other strains or organisms of demonstrated equivalent performance as required by this standard.

NOTE: *Bacillus subtilis* CIP 77.18, NCIMB 8054, DSM 675 and ATCC 9372 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 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 the 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 population 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 carriers and/or biological indicators supplied for other purposes e. g. qualification, validation or other specific tests can require other nominal populations.

7 Carriers

7.1 The suitability of the carrier for use in dry heat 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:

– Dry heat at not less than 260 °C for not less than 60 min.

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 by both the survivor curve method and the MPN method (see NOTE 2 in clause 10 of EN 866-1 : 1997) for the spore population on the inoculated carriers shall be not less than 5,0 min when exposed to dry heat at (160 ± 1) °C when determined in accordance with the method given in Annex A.

8.2.2 The D value of the spores on the inoculated carrier or biological indicator shall be determined at not less than two other temperatures in the range 150 °C to 200 °C by either of the two methods given. These data shall be used to calculate the z value, which shall not be less than 20 °C.

8.2.3 When the manufacturer specifies that the inoculated carrier or biological indicator is for use at only one temperature, 8.2.2 shall not apply.

8.2.4 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, 8.3a) and 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 dry heat at (160 ± 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;

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 for which the inoculated carrier is designed.

The description 'for dry heat sterilization' shall be used to indicate that the inoculated carrier or biological indicator is suitable for use over the temperature range 140 °C to 250 °C. In all other cases the specific process temperature and exposure time shall be given e. g. 160 °C for 120 min;

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 160 °C except where the inoculated carrier or biological indicator is designed for only one specific process temperature and exposure time where the specified temperature shall be used in determining the D value;

l) instructions for disposal of the inoculated carriers or biological indicators;

m) the z value, where this has been determined (see 8.2.2 and 8.3c)).

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

Annex A (normative)

Determination of resistance to dry heat sterilization

A.1 Apparatus: Dry heat biological indicator resistometer

A.1.1 The equipment shall be capable of maintaining the following conditions within the limits given for exposure periods between 15 s and 240 min to an accuracy of ± 10 s.

Temperature range 140 °C to 250 °C; Accuracy ± 1,0 K.

A.1.2 The equipment shall be provided with means to ensure that the temperature throughout all parts of the chamber is maintained within the specified temperature limits.

NOTE: This will normally require forced ventilation with a mechanical device such as a blower.

A.1.3 Air admitted at any time during the cycle shall be filtered through a filter having the ability to remove not less than 99,9 % of 0,5 µm particles.

A.1.4 The chamber shall be equipped with means to permit the admission and removal of specimens. This shall be such that the time taken to insert or remove a specimen does not exceed 5 s and shall be so constructed and operated that use of the system does not cause the temperature in the chamber to change more than ± 2 °C and allows restoration of the set temperature within 1 min.

A.1.5 The equipment shall be provided with a system for recording temperature within the chamber which is independent of the control function. The limits of error on the recording equipment, at the operational temperature, shall not exceed ± 0,5 K.

A.1.6 The time for the temperature rise of a specimen placed within the resistometer chamber shall not exceed 120 s.

A.1.7 At the end of the exposure period the temperature of the test specimen shall be reduced to 100 °C or less in a period not exceeding 60 s.

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 the required operating temperature e. g. (160 ± 1) °C.

A.2.1.3 Place the loaded sample holder in the chamber. Leave for the time previously determined as necessary for the test being undertaken.

A.2.1.4 Maintain these conditions for the required exposure period.

A.1.2.5 At the end of the above cycle remove the sample holder from the chamber and cool.

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 piece 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 sterile distilled water.

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