SLOVENSKI STANDARD
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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov - 7. del: Posebne zahteve za sisteme s pripravljenimi biološkimi indikatorji pri uporabi sterilizacije z vlažno toploto

Biological systems for testing sterilizers and sterilization processes - Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 7: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Dampf-Sterilisatoren

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 7: Exigences particulieres pour les systemes autonomes d'indicateurs biologiques destinés a etre utilisés dans les stérilisateurs a la vapeur d'eau

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Biological systems for testing sterilizers and sterilization processes - Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 7: Exigences particulières pour les systèmes autonomes d'indicateurs biologiques destinés à être utilisés dans des stérilisateurs à la vapeur d'eau

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 7: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Dampf-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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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.

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 self-contained biological indicator systems supplied ready for use. These systems are intended for use primarily as routine monitors. When it is intended to use self-contained biological indicators in routine monitoring, the chosen indicator system should be employed along with any other chosen indicator system during the process development and validation stages. EN 866-3 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 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 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 specific 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 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, (see also EN 554) irrespective of the results obtained from the biological indicator.

1 Scope

This Part of EN 866 specifies the requirements for self-contained biological indicator systems intended for use in monitoring the performance of moist heat sterilizers operating at temperatures in excess of 100 °C.

NOTE 1: EN 285 specifies the performance and test requirements for large steam sterilizers for porous loads and wrapped goods.

NOTE 2: Hermetically sealed ampules containing micro-organisms suspended in a growth medium with colour change indicator are only suitable for use in sterilizers intended to process aqueous liquids in sealed containers and are not included within this standard.

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

3.1 self-contained biological indicator system: An inoculated carrier presented in a primary pack which also contains the growth medium required for recovery.

3.2 survival-kill window: The extent of exposure to a sterilization process under defined conditions when there is a transition from all biological indicators showing growth (survival exposure) to no biological indicators showing growth (kill exposure).

NOTE: The survival-kill window is calculated by the following formula:

Survival exposure $\geq$ ($\log_{10}$ (nominal population) - 2) $\times$ D value

Kill exposure $\geq$ ($\log_{10}$ (nominal population) + 4) $\times$ D value

The units for both survival and kill exposures will be the same as the units used for the D value.

4 General requirements

The requirements of EN 866-1 : 1997 shall apply except for 4.4, 6.3, clauses 8, 9 and 10.

5 Test organisms

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

NOTE: *Bacillus stearothermophilus* NCTC 10003, ATCC 7953, DSM 494, DSM 2027, DSM 22, DSM 5934, NCTC 10007, ATCC 12980 and CIP 52.81 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 used to prepare the biological indicators shall be within ± 35 % of the nominal population.

6.2 The number of recoverable test organisms in 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 the removal of test organisms from the carrier should be used.

6.4 The nominal number of spores shall be not less than 1×10^5 per unit and shall be stated in increments not greater than $0,1 \times 10^5$.

7 Carriers

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

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

– exposure to dry saturated steam at not less than the manufacturers stated maximum;

– exposure temperature + 5 °C for not less than 30 min.

If the manufacturer does not state a maximum exposure temperature or time, a temperature of 145 °C of 30 min shall be used.

NOTE: These conditions have been selected to represent a realistic, but severe, challenge to the carrier whilst remaining within the practical limits of a steam sterilization process.

8 Materials of construction

8.1 The materials of which the self-contained biological indicator system is made shall withstand exposure to the sterilization process for which it is intended without distortion, melting, corrosion or other failure which would impair its utility.

Compliance shall be tested by observation of the assembled materials before and after exposure to dry saturated steam at not less than the manufacturers stated maximum exposure temperature + 5 °C for not less than 30 min and at least twice the exposure time stated by the manufacturer.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C and an exposure time of 30 min shall be used.

NOTE 1: The self-contained biological indicator system should be sufficiently robust to withstand transport in the secondary pack and handling at the point of use without breakage.

NOTE 2: The design of the self-contained biological indicator system should be such that:

a) It will minimise the loss of the original inoculum of test organisms during transport and handling; and

b) It is appropriate to be located in a process challenge device without impairing the function of the process challenge device.

8.2 The utility of the growth medium shall not be impaired by exposure to the sterilization process.

Compliance shall be tested by inoculation of the assembled media and subsequent incubation after exposure to dry saturated steam at not less than the manufacturers stated maximum exposure temperature + 5 °C for not less than 30 min and at least twice the exposure time stated by the manufacturer.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C and exposure time of 30 min shall be used.

Compliance shall be tested in accordance with the method described in Annex A.

8.3 During or after the sterilization process the materials of which the self-contained biological indicator system is made shall neither retain nor release any substance to such an extent that there will be inhibition of the growth of low numbers of surviving test organisms under the culture conditions.

Compliance shall be tested in accordance with the method described in Annex A.

8.4 The manufacturer shall state the maximum and minimum values of each external dimension of the self-contained biological indicator system on request.

9 Resistance

9.1 The manufacturer shall state the survival-kill window of each batch of self-contained biological indicator systems in minutes to one decimal place. The manufacturer shall state the accuracy with which the survival-kill window value was determined (e. g. ± 0,1 min). This accuracy shall not exceed ± 0,5 min.

9.2 The manufacturer shall obtain a D value either by the survivor curve method or by the MPN method (see Annex B of EN 866-1 : 1997) for the spore population in the self-contained biological indicator system when exposed to dry saturated steam at (121 ± 1) °C. The D value so determined shall not be less than 1,5 min. This shall be determined in accordance with the method given in Annex A or a method of demonstrated equivalence.

9.3 The D value of the spores in the self-contained biological indicator system shall be determined to 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 not be less than 6 °C.

9.4 When the manufacturer specifies that the self-contained biological indicator system is for use at only one temperature, 9.3 shall not apply.

9.5 The *D* value determined in 9.2 and the nominal number of spores determined in 6.4 shall be used to calculate the survival and kill exposures in accordance with the equation in 3.2 (NOTE).

9.6 The survival exposures shall not be less than 4,5 min and not greater than 7,5 min and kill exposure shall not be less than 13,5 min and not greater than 22,5 min when determined in dry saturated steam at (121 ± 1) °C in accordance with the method in Annex B.

Fifty replicates shall be used to confirm both the survival exposure and the kill exposure.

9.7 When both of the reference methods in Annex B of EN 866-1 : 1997 have been used e. g. during third party verification, 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.

10 Packaging and labelling

Each secondary pack containing a number of self-contained 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 biological indicator;

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

e) the number of biological indicators;

f) the recommended storage conditions;

g) the expiry date;

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

i) the sterilization process or range of sterilization processes for which the biological indicator is designed; this shall include the maximum temperature and exposure time which are suitable for the product;

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 within the self-contained biological indicator system, expressed either as the survival-kill window at 121 °C, or at the specific process temperature (where the biological indicator is designed for only one specific process temperature other than 121 °C);

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

m) the z value of the test organisms within the self-contained biological indicator system over the temperature range 110 °C to 130 °C except where the biological indicator is designed for only one specific process temperature.

NOTE: This requirement replaces 6.2 and 8.2 of EN 866-1 : 1997.