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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov - 8. del: Posebne zahteve za sisteme s pripravljenimi biološkimi indikatorji pri uporabi sterilizacije z etilenoksidom

Biological systems for testing sterilizers and sterilization processes - Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 8: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Ethylenoxid-Sterilisatoren

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 8: Exigences particulieres pour les systemes autonomes d'indicateurs biologiques destinés a etre utilisés dans des stérilisateurs a l'oxyde d'éthylene

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Biological systems for testing sterilizers and sterilization processes - Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 8: Exigences particulières pour les systèmes autonomes d'indicateurs biologiques destinés à être utilisés dans des stérilisateurs à l'oxyde d'éthylène

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 8: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Ethylenoxid-Sterilisatoren

This European Standard was approved by CEN on 25 November 1999.

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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.

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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 indicators supplied ready for use. These systems are intended primarily for use 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 866-2 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, ethylene oxide sterilization processes.

The use of the indicators specified in this standard are described in EN 550.

The biological indicators specified in this standard are not intended for use in any process other than ethylene oxide 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 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 550), irrespective of the results obtained from the biological indicators.

1 Scope

This Part of EN 866 specifies requirements for self-contained biological indicator systems intended for use in the routine monitoring of the performance of sterilizers employing ethylene oxide gas as the sterilant. These are intended for use in sterilizers employing pure ethylene oxide or admixtures of the gas with diluent gases, over a sterilizing temperature range of 20 °C to 65 °C.

NOTE 1: EN 1422 specifies the performance and test requirements for ethylene oxide sterilizers.

NOTE 2: EN 550 specifies, inter alia, the requirements for routine monitoring of ethylene oxide sterilization.

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

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 i. e. minutes.

4 General requirements

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

5 Test organisms

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

NOTE: *Bacillus subtilis var. niger* NCTC 10073, ATCC 9372, DSM 2277, DSM 675 and CIP 77.18 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 not be less than 1×10^6 per unit and shall be stated in increments not greater than $0{,}1 \times 10^6$.

7 Carriers

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

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

– Temperature	≥	55 °C
– Relative humidity	≥	70 %
– Gas concentration	≥	800 mg/l
– Exposure time	≥	6 h

NOTE: These conditions have been selected to represent a realistic, but severe, challenge to the carrier whilst remaining within the practical limits of an ethylene oxide 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 exposed to the following conditions:

– Temperature	≥	55 °C
– Relative humidity	≥	70 %
– Gas concentration	≥	800 mg/l
– Exposure time	≥	6 h

NOTE 1: The self-contained biological 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.

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

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

Compliance shall be tested by observation of the assembled materials before and after exposure to the following conditions:

– Temperature	≥	55 °C
– Relative humidity	≥	70 %
– Gas concentration	≥	800 mg/l
– Exposure time	≥	6 h

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 A.2.1.

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 and the nominal temperature at which it was determined (i. e. 30 °C or 54 °C). The manufacturer shall state the accuracy with which the survival-kill window value was determined (e. g. ± 0,5 min). This accuracy shall not exceed ± 1,0 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 biological indicators when exposed to (600 ± 30) mg/l ethylene oxide at (30 ± 1) °C and (60 ± 10) % relative humidity or to (600 ± 30) mg/l ethylene oxide at (54 ± 1) °C and (60 ± 10) % relative humidity. The *D* value shall be not less than 12,5 min under the conditions at 30 °C and/or not less than 2,5 min under the conditions and 54 °C. 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 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).

9.4 Either:

a) the survival exposures shall not be less than 50 min and not greater than 120 min and the kill exposure shall be not less than 125 min and not greater than 300 min when determined at (600 ± 30) mg/l ethylene oxide at (30 ± 1) °C and (60 ± 10) % relative humidity, in accordance with the method in Annex B.

or

b) the survival exposures in the self-contained biological indicator system shall be not less than 10 min and not greater than 21 min and the kill exposure in the self-contained biological indicator system shall be not less than 25 min and not greater than 53 min when determined at (600 ± 30) mg/l ethylene oxide at (54 ± 1) °C and (60 ± 10) % relative humidity, in accordance with the method in Annex B.

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

9.5 When both of the reference methods given 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.

Annex A (normative)

Determination of growth inhibition by component materials, dimensional stability and the suitability of growth medium

A.1 Equipment and materials

A.1.1 Suspension of test organisms, of the same strains and prepared in the same manner as the organisms to be used for inoculation of carriers. The suspension shall be of known population, determined by viable count, to permit dispensing of aliquots with a population of between 10 and 100 viable organisms.

This aliquot should have a volume not exceeding 10 % of the volume of growth medium recommended by the manufacturer.

A.1.2 Resistometer complying with the resistometer described in Annex B.

A.1.3 Growth medium of the same type and in the same volume as stated for the recovery of the biological indicator in normal use.

A.1.4 Incubator, set to the temperature stated for the recovery of the biological indicator in normal use.

A.2 Determination of growth inhibition of materials of construction

A.2.1 Procedure

A.2.1.1 Take a representative sample of twelve uninoculated carriers and divide it into six lots of two.

A.2.1.2 Determine the maximum surface area of the container (primary pack) and the growth medium container which will be in contact with the growth medium at the start of incubation (the contact area). Take sufficient pieces of material from which the primary pack and the growth medium container are constructed (the container sample) to provide a total surface area equivalent to twice the contact area. These pieces shall be of such a size that they will be completely covered by the volume of growth medium used. No allowance shall be made for the increase in contact area with the primary pack.

A.2.1.3 Place each of the two carriers of each of three of these lots in a primary container together with the container sample and then expose them to the sterilization process.

A.2.1.4 Set the operational conditions of the resistometer to the required conditions for the carrier studies (see 7.2).

A.2.1.5 After exposure to the process, as soon as possible but in any case within 30 min of the end of the process, aseptically transfer an aliquot of the untreated growth medium to each container. Care shall be taken to ensure that all the container samples are covered by the growth medium.

A.2.1.6 Record the time taken to complete the transfer.

A.2.1.7 Incubate the growth medium at the stated temperature for 2 h, remove it from the incubator and inoculate it with a volume of the test organism suspension calculated to contain between 10 and 100 viable organisms. Return the inoculated media to the incubator and incubate it for the time stated by the manufacturer for the recovery of biological indicators under the normal conditions of use.

A.2.1.8 For the negative control, transfer two carriers and a container sample, not exposed to the process, to each of the three containers containing the normal aliquot of growth medium, incubate them for 2 h, inoculate them with 10 to 100 test organisms, and incubate them for the stated recovery period in the same manner as described above.

A.2.1.9 For the positive control, incubate three containers, each containing the normal aliquot of growth medium but containing no carriers or container samples, for 2 h, inoculate them with 10 to 100 test organisms and incubate them for the stated recovery period in the same manner as described above.

A.2.1.10 At the end of the stated recovery period remove all nine containers from the incubator and examine them for viable organisms in accordance with the manufacturers instructions.