SLOVENSKI STANDARD
SIST EN 866-2:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov – 2. del: Posebni sistemi za uporabo sterilizacije z etilenoksidom

Biological systems for testing sterilizers and sterilization processes - Part 2: Particular systems for use in ethylene oxide sterilizers

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 2: Spezielle Systeme für den Gebrauch in Ethylenoxid-Sterilisatoren

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 2: Systemes particuliers 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 2: Particular systems for use in ethylene oxide sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 2: Systèmes particuliers destinés à être utilisés dans des stérilisateurs à l'oxyde d'éthylène

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 2: Spezielle Systeme für den Gebrauch in Ethylenoxid-Sterilisatoren

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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 Technical Committee 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
prEN 866-5	Biological systems for testing sterilizers and sterilization processes - Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers
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, 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 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, irrespective of the results obtained from the biological indicators. (See also EN 550).

1 Scope

This part of EN 866 specifies requirements for inoculated carriers and biological indicators intended for use in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas as the sterilant. These are intended for use in sterilizers employing pure ethylene oxide gas or admixtures of the gas with diluent gases, over a sterilizing temperature range of 20 °C to 65 °C.

NOTE: prEN 1422 specifies the performance and test requirements for ethylene oxide sterilizers. EN 550 specifies the requirements for the validation and routine monitoring of ethylene oxide sterilization.

2 Normative References

This European Standard incorporates by dated or undated references 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 Standard, the definitions given in EN 866-1 apply.

4 General requirements

The requirements of EN 866-1 shall apply.

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 standard.

NOTE: *Bacillus subtilis* NCTC 10073, DSM 2277, ATCC 9372 or CIP 7718 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 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 and validation of methods for the removal of microorganisms 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 1×10^6 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 eg qualification, validation and other specific tests, may require other nominal populations.

7 Carriers

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

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

- Temperature - not less than 55 °C;
- Relative Humidity - not less than 70 %;
- Gas concentration - not less than 800 mg· l^{-1};
- Exposure time - not less than 6 h.

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

8 Resistance

8.1 General

The manufacturer shall state the D value of each batch of biological indicators or inoculated carriers to an accuracy of ± 0,5 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 12,5 min when exposed to (600 ± 30) mg · l^{-1} ethylene oxide at (30 ± 1) °C and (60 ± 10) % Relative Humidity and/or not less than 2,5 min when exposed to (600 ± 30) mg · l^{-1} ethylene oxide at (54 ± 1) °C and (60 ± 10) % Relative Humidity determined in accordance with the method given in Annex A.
(See 10.2 of EN 866-1 : 1997).

NOTE: A temperature coefficient of inactivation of the test organism of not less than two can be used to relate these D values to other temperatures when all other conditions remain constant.

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 and inoculated carriers intended for use in validation, qualification 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), 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 exposure to (600 ± 30) mg · l^{-1} ethylene oxide at (30 ± 1) °C and (60 ± 10) % Relative Humidity and when exposed to (600 ± 30) mg · l^{-1} ethylene oxide at (54 ± 1) °C and (60 ± 10) % Relative Humidity in accordance with the methods given in Annex A.

b) The D value obtained 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.

Annex A (normative)

Method for the determination of resistance to ethylene oxide sterilization.

A.1 Apparatus: Ethylene oxide biological indicator resistometer

A.1.1 The equipment shall be capable of maintaining the conditions given in table A.1 within the limits given for exposure periods between 1 min and 120 min to an accuracy of ± 10 s. In addition, the equipment shall be capable of exposure of not less than 6 h.

Table A.1: Conditions

Variable	For resistance studies see clause 8	For carrier studies see clause 7
ethylene oxide temperature relative humidity	(600 ± 30) mg/l (30 ± 1) °C or (54 ± 1) °C (60 ± 10) %	not less than 800 mg/l not less than 55 °C not less than 70 %
NOTE 1: Forced circulation may be required to maintain the conditions in the resistometer chamber uniform within the specified limits. NOTE 2: Resistometers intended for use with mixtures of ethylene oxide and inert gases may be required to withstand high internal pressures eg. 650 kPa.		

A.1.2 The equipment shall be provided with means to evacuate the reaction chamber to less than 10 kPa within 2 min to permit adequate air removal prior to admission of the sterilant and to exhaust the sterilant at the end of the exposure period. Air admitted at the end of the cycle shall be filtered through a filter having the ability to remove not less than 99,9 % of 0,5 μm particles.

A.1.3 The time to achieve the required gas concentration from commencement of gas admission shall not exceed 60 s and the time to exhaust the gas to 10 kPa at the end of the exposure period shall not exceed 60 s.

A.1.4 The chamber and door shall be provided with means to maintain the temperature of the inner surfaces of the chamber at the required operating temperature.

A.1.5 The supply of ethylene oxide gas to the chamber shall be filtered, evaporated to gas phase and preheated to ensure that neither liquid ethylene oxide nor particles of polymer are admitted to the chamber.

A.1.6 The equipment shall be capable of automatic operation and shall be provided with a system for recording temperature, pressure and humidity within the chamber which is independent of the control function and such that the limits of error on the recording equipment do not exceed 50 % of the tolerance allowed for each control variable.

For example the chamber temperature shall be required to be controlled within ± 1 K and thus the maximum allowable error limit on the temperature recorder is ± 0,5 K.