SLOVENSKI STANDARD
SIST EN 866-1:2000

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Biološki sistemi za preskušanje sterilizatorjev in sterilizacijskih postopkov – 1. del: Splošne zahteve

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

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 1: Allgemeine Anforderungen

Systemes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 1: Exigences générales

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

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation - Partie 1: Exigences générales

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren - Teil 1: Allgemeine Anforderungen

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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

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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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.

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 irradiation sterilizers
prEN 866-5	Biological systems for testing sterilizers and sterilization processes – Part 5: Particular systems for low temperature steam formaldehyde sterilizers
prEN 866-6	Biological systems for testing sterilizers and sterilization processes – Part 6: Particular systems for 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

European Standards for sterilizers (EN 285 and prEN 1422) and for the validation and process control of sterilization (EN 550 and EN 554) describe performance tests for sterilizers and methods of validation and routine control, respectively.

This standard specifies the general requirements for biological indicators and subsequent parts specify the particular requirements for biological indicators for defined sterilization processes. The use of the indicators specified in this standard are described in EN 550 and EN 554.

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 biological indicators specified in this standard are not intended for use in any process other than that stated by the manufacturer. The use of a biological indicator in a process other than that stated by the manufacturer can give dangerously misleading results.

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 appropriate 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 and EN 554.

1 Scope

This part of EN 866 specifies general requirements for the manufacture of biological systems to be used in testing sterilizers and sterilization processes.

The requirements of this part of EN 866 apply to all biological systems specified in subsequent Parts of EN 866, unless the requirement is modified or added to by a subsequent Part, in which case the requirement of the particular Part will apply.

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 550
Sterilization of medical devices – Validation and routine control of ethylene oxide sterilization

EN 552
Sterilization of medical devices –Validation and routine control of sterilization by irradiation

EN 554
Sterilization of medical devices – Validation and routine control of sterilization by moist heat

EN 868-1
Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements – Requirements and test methods

EN 1174-1
Sterilization of medical devices – Estimation of the population of microorganisms on product – Part 1: Requirements

EN 28601 : 1992
Data elements and interchange formats – Information interchange – Representation of dates and times (ISO 8601 : 1988 and technical corrigendum 1 : 1991)

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 biological indicator: An inoculated carrier contained within its primary pack ready for use (see figure C.1 in Annex C).

3.2 biological systems: Those systems which depend for their function on the demonstration of viability of a test organism.

NOTE: This demonstration of viability can be achieved by any method suitable for indicating, qualitatively or quantitatively, either the metabolic activity or the replication of the organism. Tests based on physical or chemical detection of change in a particular chemical entity, whether or not this was originally derived or isolated from a biological system (e.g. an enzyme) are considered in the series EN 867 "Non-biological systems for use in sterilizers".

3.3 carrier: The supporting material on which the test organisms are deposited (see figure C.1 in Annex C).

3.4 culture collection number: The unique identification allocated by the recognized culture collection.

3.5 culture conditions: The manufacturer's stated combination of conditions including the growth medium with the period and temperature of incubation, used to promote germination, outgrowth and/or multiplication of the test organism.

3.6 D value (decimal reduction value): The time in minutes, or the absorbed irradiation dose in kilograys, required to secure inactivation of 90 % of the test organisms under stated exposure conditions.

3.7 inactivation: The loss of the ability of the test organisms to germinate, outgrow and/or multiply under culture conditions.

3.8 inoculated carrier: A carrier on which a defined number of test organisms has been deposited (see Figure C.1 in Annex C).

3.9 primary pack: The packaging system which protects the inoculated carrier from damage and contamination without preventing penetration of the sterilizing agent(s) (see figure C.1 in Annex C).

3.10 process challenge device: An object which simulates the worst case of conditions as they are given for the sterilizing agent(s) in the items of the goods to be sterilized. (see figure C.1 in Annex C).

NOTE 1: A device is so constituted that a biological indicator can be put in the place most difficult to reach by the sterilizing agent(s). The design of the process challenge device depends on the kind of goods to be sterilized and the sterilization procedure. The biological indicator should not interfere with the function of the process challenge device.

NOTE 2: In some process challenge devices an inoculated carrier can be used instead of a biological indicator.

3.11 recognized culture collection: An international depository authority under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent and Regulations.

3.12 resistometer: Equipment designed to create defined combinations of the physico-chemical variables of a sterilization process within defined limits.

3.13 secondary pack: The container in which biological indicators are packed for transport and storage.

3.14 spores: Bacterial endospores.

3.15 survivor curve: A graphical representation of inactivation against increasing exposure to stated conditions.

3.16 test organism: Microorganisms used for the manufacture of inoculated carriers.

3.17 total count: The number of test organisms in unit volume of a suspension, estimated by direct counting using light microscopy.

3.18 viable count: The number of viable test organisms in unit volume of a suspension, estimated by growth of discrete colonies under the stated culture conditions.

3.19 nominal number: The theoretical number of microorganisms based on the viable count.

4 General requirements

4.1 Manufacturing controls

4.1.1 The manufacturer shall establish, document and maintain a formal quality system to cover all operations required by this standard.

NOTE: European Standards of the ISO 9000 series and the EN 45000 series describe requirements for quality terms for manufacture and testing.

4.1.2 Traceability of manufacturing components (e.g., carrier, culture media and packaging material) shall be maintained.

4.1.3 Manufacturers of test organism suspension and/or biological indicators shall maintain adequate records in order to allow traceability of biological indicators and test organism suspension back to the culture obtained from the culture collection.

4.1.4 The procedures and methods in this standard shall be carried out by suitably trained and experienced microbiology laboratory staff.

4.2 Labelling

Where a date is required on labelling or information supplied with the product this shall be expressed in accordance with EN 28601.

4.3 Test methods

The test methods specified in this standard are reference methods. When alternative methods are used these shall be defined, validated and have proven correlation with the reference method.

4.4 Culture conditions

The culture conditions shall be demonstrated as being capable of recovering an inoculum of between 10 and 100 test organisms. The suspension of test organisms used shall be of the same strain and prepared in the same manner as the organisms to be used for inoculation of carriers. The population shall be determined by viable count of the same suspension used to provide the inoculum.

5 Test organisms and their preparation for the manufacture of inoculated carriers

5.1 The test organisms shall be of a defined strain, lodged with a recognized culture collection, and shall be unambiguously identified by reference to the culture collection number.

The test organism shall be of a strain suitable for handling without special containment facilities.

NOTE: When the strain of the test organism is not already lodged with a recognized culture collection the manufacturer should do so.

5.2 The originating inoculum for each batch of test organism suspension shall be:

- traceable to the reference culture lodged with the recognized culture collection, (see NOTE 1) and
- verified as to its identity and purity (see NOTE 2).

NOTE 1: The method(s) used for the maintenance of cultures of the test organism should be designed and maintained to ensure that the cultures are protected from contamination and induced changes in their inherent properties.

NOTE 2: Verification tests are specific for each strain of test organism and should be documented and validated by the manufacturer.

5.3 The culture medium and incubation conditions used for preparation of the test organism suspension shall be defined by the manufacturer.

These culture conditions shall produce consistently test organism suspensions meeting the performance requirements of this standard and the particular performance requirements in the relevant subsequent parts of this standard.

5.4 After growth, and where required sporulation, the test organisms shall be removed from the culture medium.

The method of harvesting and subsequent treatment shall ensure that the suspension to be used in the inoculation of carriers is free from residues of the culture medium which could influence adversely the performance of the inoculated carrier or biological indicator.

This shall not be required where the manufacturer has demonstrated that residues of the culture medium do not influence adversely the performance of the inoculated carrier or biological indicator.

5.5 The viable count of the suspension shall be determined.

NOTE: If the user requires information on the growth index of the test organism, this should be determined by expressing the viable count as a percentage of the total count.

5.6 The container and conditions for storage of suspensions of test organisms, together with their expiry date, shall be defined by the manufacturer. The conditions shall be monitored during storage. The container and conditions shall maintain consistently test organism suspensions meeting the performance requirements of this standard and the particular performance requirements in the relevant subsequent parts of this standard.

5.7 If the test organism suspension is distributed for the inoculation of carriers by a third party, each container shall be labelled with the following information:

a) the name of the test organism;

b) the culture collection number;

c) the nominal volume of the suspension in millilitres;

d) the viable count;

e) the recommended storage conditions;

f) the expiry date;

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

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

5.8 The manufacturer shall ensure that transport to a third party is carried out under controlled conditions compatible with the storage conditions specified for the suspension of test organisms.