SLOVENSKI STANDARD
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Nebiološki sistemi za uporabo v sterilizatorjih - 1. del: Splošne zahteve

Non-biological systems for use in sterilizers - Part 1: General requirements

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 1: Allgemeine Anforderungen

Systemes non-biologiques destinés a etre utilisés dans des stérilisateurs - Partie 1: Exigences générales

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Non-biological systems for use in sterilizers - Part 1: General requirements

Systèmes non-biologiques destinés à être utilisés dans des stérilisateurs - Partie 1: Exigences générales

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - 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

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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 non-biological systems for testing sterilizers. These 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

In addition, CEN/TC 102 Working Group 7 has prepared a series of European Standards describing biological indicators for use in 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 systems for use in ethylene oxide sterilizers

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 other standards in preparation by CEN/TC 102) and for the validation and process control of sterilization (EN 550, EN 552, EN 554) describe performance tests for sterilizers and methods of validation and routine control, respectively.

This standard specifies the general requirements for non-biological indicators and subsequent parts specify the particular requirements for non-biological indicators for particular applications and for defined tests of particular sterilization processes. The use of the indicators specified in this standard are described in EN 285, EN 550, EN 552 and EN 554.

The non-biological indicators specified in this standard are not intended for use in any process other than that specified. The use of an inappropriate indicator can give dangerously misleading results.

The performance of a non-biological indicator can be affected by the conditions of storage prior to use, the methods of use, and the conditions of storage after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed precisely. Non-biological indicators should not be used beyond any expiry date stated by the manufacturer.

When a physical and/or 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 non-biological indicators.

1 Scope

This European Standard specifies general requirements for indicators which are not dependent for their action on the presence or absence of living organisms, and which are used to monitor the presence or attainment of one or more of the variables required for a satisfactory sterilization process.

This standard does not specify requirements for the use of biological systems.

NOTE: Biological test systems are regarded as those tests which are dependent for their interpretation on the demonstration of viability of an organism. Test systems of this type are considered in EN 866 'Biological systems for testing sterilizers and sterilization processes'.

The requirements of this part of EN 867 apply to all indicator systems specified in subsequent parts of EN 867, 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 28601
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 European Standard the following definitions apply:

3.1 graduated response: A progressive visible change occurring on exposure to one or more process variables allowing assessment of the level achieved.

3.2 defined end-point: The visible change occurring after exposure to the specified variable (s) at a level equal to or greater than that specified for the indicator.

3.3 indicator: The indicator system in the form in which it is intended to be used.

3.4 indicator reagent: The active ingredient or combination of ingredients before conversion into the indicator.

3.5 indicator system: The combination of the indicator reagent and its substrate.

4 Classification

NOTE: In subsequent parts of this standard indicators are classified by their intended use and, within each of these classifications, by the process for which they are designed to be used.

4.1 Process indicators – Class A

Process indicators are intended for use with individual packs of product intended to be sterilized to demonstrate that the pack has been exposed to the process. They may be designed to react to one or more of the critical process variables but may be designed to achieve their end-point reaction after exposure to sub-optimal levels of the process variable.

Process indicators have a defined end-point reaction.

4.2 Indicators for use in specific tests – Class B

These indicators are designed for use in a specific test procedure defined in the relevant sterilizer/sterilization standard.

These indicators may have a graduated response or a defined end-point reaction.

4.3 'Single-variable' indicators – Class C

'Single-variable' indicators are designed to monitor the attainment of the required value of one critical variable in the sterilization process.

'Single variable' indicators may have a graduated response or a defined end-point reaction.

4.4 'Multi-variable' indicators – Class D

'Multi-variable' indicators are designed to monitor the attainment of the required value of two or more critical variables in the sterilization process.

'Multi-variable' indicators may have a graduated response or a defined end-point reaction.

5 General Requirements

5.1 General

5.1.1 The requirements of this section shall apply to all indicators unless specifically excluded or amended in a subsequent part of this standard.

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

NOTE: EN ISO 9001 and EN ISO 9002 and of the EN 45000 series describe requirements for quality systems for manufacture and testing.

5.2 Labelling

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

5.3 Test methods

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

5.4 Marking

5.4.1 Each indicator shall be clearly marked with the type of process for which it is intended to be used and the class of indicator as defined in this standard (see 4.1 to 4.4 inclusive).

If the use of the indicator is limited to specific sterilization cycles, this information shall also be stated or coded on the indicator e. g. steam 15 min 121 °C.

Where the size or format of the indicator does not permit this information to be stated in a font of 6 characters per centimeter, or larger, the information shall be provided on the label and/or instructions for use .

5.4.2 Abbreviated descriptions of the process, if used, shall be in accordance with the following symbols:

STEAM

– all steam sterilization processes

DRY

– all dry heat sterilization processes

EO

– all ethylene oxide sterilization processes

IRRAD

– all ionising radiation sterilization processes

FORM

– all steam/formaldehyde sterilization processes

5.5 Performance Requirements

5.5.1 The change which occurs after exposure of the indicator to the specified conditions shall be clearly visible to the naked eye and shall be either from light to dark or shall be a change from one colour to a distinctly different colour.

5.5.2 The manufacturer shall retain documentary evidence that the indicator does not release any substance known as toxic, in sufficient quantity to cause a health hazard, before during or after the sterilization process for which it is designated.

NOTE: Until relevant European or International standards are published National Regulations apply.

5.5.3 The condition of the indicator after exposure to a sterilization process, during which all the variables met or exceeded the specified level to produce a defined end-point or a known graduated response shall remain visually unchanged for a period of not less than six months, from the date of use, when stored under the conditions specified by the indicator manufacturer.

The manufacturer shall state any change which can occur on storage for periods greater than six months (see 6.2).

NOTE: Incompletely changed indicators can deteriorate on storage; either returning to the unchanged condition or slowly completing the change reaction. If this can occur this should be stated by the manufacturer (see 6.2). Such indicators can not be suitable for use as a permanent record.

6 Labelling and instructions for use

6.1 The label of each package of indicators, or the technical information leaflet supplied with the package, shall state:

a) the class and process for which the indicator is designed;

b) the storage conditions, before and after use;

c) the expiry date under the specified storage conditions;

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

e) any safety precautions required during use;

f) the manufacturer's or supplier' s name and address.

6.2 The label of each package of indicators, or the technical information leaflet supplied with the package or available to each customer, or user, on request shall state:

a) the change that is intended to occur; and for colour change indicators where the colour change cannot be adequately described, examples of the expected colour range for both changed and unchanged indicators;

b) the minimum conditions required to effect the change;

c) any specific instructions for use essential to ensure correct functioning of the indicator;

d) any interfering substances or conditions which are known to adversely affect the performance of the indicator;

e) the manufacturer's or supplier's name and address;

f) the storage conditions for the indicator after use;

g) the nature of any change which can occur on storage for completely and incompletely changed indicators (see clause 5).