SLOVENSKI STANDARD
SIST EN 868-1:2000

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Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 1. del: Splošne zahteve in preskusne metode

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

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 1: Allgemeine Anforderungen und Prüfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 1: Exigences générales et méthodes d'essai

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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 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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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.

This Standard is the first of a series of Draft European Standards concerned with packaging materials and systems for medical devices which are to be sterilized. These other Draft European Standards currently are:

prEN 868-2 Packaging materials and systems for medical devices which are to be sterilized – Part 2: Sterilization wrap – Requirements and test methods

prEN 868-3 Packaging materials and systems for medical devices which are to be sterilized – Part 3: Paper for use in the manufacture of paper bags (specified in Part 4 of this Standard) and in the manufacture of pouches and reels (specified in Part 5 of this Standard) – Requirements and test methods

prEN 868-4 Packaging materials and systems for medical devices which are to be sterilized – Part 4: Paper bags – Requirements and test methods

prEN 868-5 Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat sealable pouches and reel material manufactured from paper and plastic – Requirements and test methods

prEN 868-6 Packaging materials and systems for medical devices which are to be sterilized – Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and test methods

prEN 868-7 Packaging materials and systems for medical devices which are to be sterilized – Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and test methods

prEN 868-8 Packaging materials and systems for medical devices which are to be sterilized – Part 8: Re-usable containers for steam sterilizers conforming to prEN 285 – Requirements and test methods

Introduction

This standard specifies general requirements and test methods for all packaging materials and systems intended for use as packaging for medical devices which are to be terminally sterilized in their packaging.

Subsequent standards in this series (prEN 868-2 et sequence) specify particular requirements for a range of commonly used packaging materials and systems. It is intended that compliance with one of the subsequent particular standards can be used to demonstrate conformance with one or more of the requirements of this part (general requirements) as specified in the particular standard.

The adequacy of a packaging system depends additionally on the manner in which each unit is closed or sealed. Attention is drawn to the need to validate and monitor the packaging process (see also European Standards on quality systems and ISO 11607).

1 Scope

1.1 This European Standard specifies the requirements and test methods for packaging materials and systems:

– which are used for packaging of medical devices which are to be terminally sterilized; and

– which are intended to maintain sterility of the device.

NOTE 1: This standard has been developed as a means to show compliance with relevant European Directives. If health care facilities e. g. hospitals do not place medical devices on the market, they are not covered by these Directives. Nevertheless, such health care facilities can fulfil the same requirements as manufacturers but can use alternative means to demonstrate conformity to this standard.

NOTE 2: Compliance with other Parts of prEN 868 series can be used to demonstrate compliance with one or more of the requirements of this standard.

1.2 This standard does not apply to packaging materials and systems used for packaging aseptically manufactured products.

1.3 This European Standard does not describe a quality assurance system for control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see e. g. EN ISO 9001, EN ISO 9002, EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system can be applied.

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 20187
Paper, board and pulps – Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187 : 1990)

3 Definitions

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

3.1 bioburden: Population of viable micro-organisms on an item.

3.2 closure: Means used to close a package where no seal is formed; e. g. by repeated folding to construct a tortuous path.

3.3 closure integrity: Characteristics of the closure which ensures that it presents a microbial barrier.

3.4 final pack: Pack in which a medical device is sterilized.

NOTE: In addition to the primary pack a secondary and/or transport pack can be included.

3.5 microbial barrier: Ability to prevent the ingress of micro-organisms.

3.6 packaging material: Any material used in the fabrication or sealing of a packaging system or primary pack.

3.7 packaging system: One or more packaging materials assembled into a single unit intended as part or all of a primary pack.

3.8 primary pack: Sealed or closed packaging system which forms a microbial barrier, enclosing a medical device.

3.9 seal: Result of joining of surfaces together.

NOTE: e. g. by use of adhesives, thermal fusion or gaskets.

3.10 seal integrity: Characteristics of the seal which ensures that it presents a microbial barrier.

3.11 secondary pack: Pack containing one or more medical devices, each in its primary pack.

3.12 sterile: Condition of a medical device that is free from viable micro-organisms [EN 556].

3.13 terminally sterilized: Term for medical devices which are sterilized after being completely sealed or enclosed in at least the primary pack.

3.14 transport pack: Pack containing one or more primary and/or secondary packs intended to provide the necessary protection during transport and storage.

4 Requirements

NOTE: Guidance on the interpretation of these requirements is given in Annex A.

4.1 General

4.1.1 The conditions under which the packaging material and/or system is produced, stored, transported and handled shall be established, controlled and documented, if applicable, in order to ensure that:

– the conditions are compatible with the use for which the packaging material and/or system is designed

and

– the performance characteristics of the packaging material and/or system is maintained.

As a minimum, the following shall be considered for all packaging materials and/or systems:

– temperature range;
– pressure range;
– humidity range;
– maximum rate of change of the above, where necessary;
– exposure to sunlight or UV light;
– cleanliness;
– bioburden.

NOTE: The bioburden of the packaging material and/or system should be considered when determining the sterilization process parameters.

4.1.2 Raw materials used for the manufacture of packaging materials may be virgin or reclaimed materials, provided that the source, history and traceability of all raw materials, especially recycled materials, shall be known and controlled to ensure that the finished product will consistently meet the requirements of this standard.

NOTE: With current commercial technologies, it is unlikely that reclaimed material other than manufacturing waste will be sufficiently controlled to allow its safe use for medical device packaging.

4.2 Sterilization process compatibility of packaging materials and systems

4.2.1 Sterilization process specified

It shall be demonstrated and documented that the packaging material and/or system is suitable for use in the sterilization process for which it is intended by the manufacturer of the packaging material and/or system. This shall include a demonstration that packaging materials and/or systems have, when necessary, sufficient permeance to air and the sterilant in order to permit the attainment of the required conditions for sterilization and to permit removal of sterilant after sterilization when assembled into a specified form for loading into the sterilizer.

NOTE: It is recommended to use a sterilizer designed, constructed and operating within the requirements of the relevant European Standards e. g. EN 285 and prEN 1422.

4.2.2 Sterilization process not specified and/or sterilization process not covered by European Standards

When the packaging material and/or system is not specified as intended for the sterilization process which will be used or the sterilization process is one for which there is no applicable Harmonized Standard, the suitability of the packaging material and/or system for the sterilization process shall be established. This shall be done by validation of the final pack in the sterilization process in accordance with EN 550, EN 552 and EN 554 or other methods of demonstrated equivalence.

NOTE: For sterilization processes not covered by EN 550, EN 552 or EN 554, the validation should include determination that the final pack is sufficiently permeable to all physical and chemical agents which affect the efficacy of the sterilization process.

4.3 Design

4.3.1 General requirements

The packaging material and/or system shall be designed to minimize the safety hazard to user or patient under the intended specified use.

The design of the final pack shall include consideration of at least the following:

– the compatibility of the packaging material and/or system with the medical device i. e. that the packaging has no adverse effect on the medical device and vice-versa (see 4.3.2);

– the compatibility of the packaging material and/or system with the sterilization process (see 4.2);

– the compatibility of the packaging material and/or system with the labelling system (see 4.3.3.);

– the physical, chemical and microbial protection provided by the packaging material and/or system;

– the compatibility of the packaging material and/or system with the users requirements at the point of use e. g. aseptic opening.

4.3.2 Compatibility with the medical device

The suitability of the packaging material and/or system for use with the particular medical device shall be determined. This shall include limiting values for physical characteristics of both the medical device as well as the stresses which will be imposed during sterilization and subsequent transport and storage.

Factors to be considered shall include:

– the mass and configuration of the medical device to be packed;
– the presence of sharp edges or protrusions;
– the need for physical and other protection;
– the sensitivity of the medical device to particular risks e. g. radiation, moisture, mechanical shock, static discharge.

NOTE: Documented historical evidence can be used for packaging materials and/or systems which have previously been used satisfactorily.

4.3.3 Compatibility with the labelling system

The labelling system shall:

– not adversely affect the compatibility of the packaging material and/or system with the sterilization process to be used;
– not be rendered illegible by the sterilization process to be used;
– not be printed or written in ink of a type which may be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system nor change colour to an extent which renders the label illegible.

For labels fixed to the surface of the packaging material and/or system the attachment system shall withstand exposure to the sterilization process and the manufacturer´s defined storage and transport conditions.

NOTE: Labelling can take a number of forms, e.g.:

– labelling printed or written directly on the packaging material and/or system;
– labels consisting of another layer of material attached to the surface of the packaging material and/or system by adhesive, fusion etc..

4.4 Toxicity

Packaging materials and/or systems shall not release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.

NOTE: Evidence that the packaging material and/or systems does not contain material known to be toxic in sufficient quantity to cause a health hazard should be sufficient to meet this requirement.

4.5 Biocompatibility

If necessary, the biocompatibility of the packaging materials and/or systems shall be assessed with regard to the intended use of the medical device.

NOTE: For selection of test methods for biocompatibility see prEN ISO 10993-1.

4.6 Sterility maintenance

The packaging materials and/or systems assembled in the form in which they will be presented to the sterilizers, when assembled, stored, transported and used in accordance with the manufacturer´s instructions, shall maintain the sterility of the contents from the time at which they are rendered sterile to the expiry date specified or to the point of use.

This shall be demonstrated by testing microbial barrier properties.

In the absence of an applicable standardized final pack test method, verification of microbial barrier performance characteristics can be obtained by reference to subsidiary particular requirements for single components of the primary pack for which compliance can be more readily demonstrated. These tests shall be carried out on the packaging material, or combination of packaging materials, in the form in which they are intended to constitute the microbial barrier.

NOTE 1: The loss of sterile package integrity is usually regarded as event-related rather than time-related.

NOTE 2: The maintenance of sterility by a packaging material and/or system is judged by the ability of the packaging to prevent the ingress of micro-organisms. Many factors affect the extent of such ingress. These include, but are not limited to:

- the level of micro-organisms in the environment;
- the sizes of particles on which the micro-organisms occur;
- environmental conditions of temperature, humidity and pressure and the rate of change of these conditions;
- flow rates through the layers of packaging material;
- pore size and other filtration parameters of the packaging material.

In order to determine which of the particular performance requirements have to be verified the packaging material and/or system shall be classified, if appropriate, for the following criteria

a) Air impermeability of the packaging material
b) Microbial barrier properties of the packaging material
c) Microbial barrier properties of permeable closures (filter assembly; tortuous path)
d) Impermeability and continuity of seals formed by fusion or adhesion
e) Impermeability of seals not formed by fusion or adhesion (i. e. sealing gaskets or valves).

NOTE 3: Guidance for this classification is given in Annex B.

4.7 Storage and transport

The packaging material and/or system shall be wrapped to provide the protection necessary to maintain the performance characteristics of the packaging material and/or system during storage and transport under the specified conditions, if applicable.

5 Test methods

5.1 The rationale for the selection of test methods, the variables to be determined, and the acceptance criteria shall be documented.

For some of the requirements, internationally accepted validated test methods are not yet available. Until such time that these tests are available, the applied test method shall be validated and documented.

NOTE: The listing of test methods in the informative annexes of this standard does not eliminate the need for validation nor does it exclude other validated test methods.

5.2 Conditioning of test samples

Unless otherwise specified in the test method, test samples shall be conditioned in accordance with the method given in EN 20187 at (23 ± 1) °C and (50 ± 2) % relative humidity.

6 Documentation

All test procedures, and the results obtained used to demonstrate compliance with the requirements of this standard shall be fully documented and retained securely for a specified period of time considering factors as e. g. expiry date of the packaging material and/or system, traceability.

7 Information

The following information shall be supplied, if applicable:

a) the nature and extent of any identified risks associated with the use of the packaging material and/or system;

b) any particular restriction on use;

c) any specific handling requirements;

d) any specific storage conditions;

e) the sterilization process for which the packaging material and/or system are intended;

f) any known restrictions on environmental conditions during use;

g) the type, size and grade of the packaging material and/or system;

h) batch number or other means of tracing the manufacturing history;

i) for re-usable packaging materials and/or systems,instructions on the frequency and nature of maintenance;

j) any information pertinent to the packaged medical device as may be required (see prEN 1041);

k) the expiry date of the packaging material and/or system;

NOTE: Conformity with prEN 868-2 and the following Parts should also be stated, if relevant.