SLOVENSKI STANDARD
SIST EN 868-8:2000

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Embalažni materiali in sistemi za medicinske pripomočke, ki jih je treba sterilizirati - 8. del: Ponovno uporabljivi vsebniki za parne sterilizatorje po EN 285 - Zahteve in preskusne metode

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

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte - Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 - Anforderungen und Prüfverfahren

Matériaux et systemes d'emballages pour les dispositifs médicaux devant etre stérilisés - Partie 8: Conteneurs réutilisables de stérilisation pour stérilisateurs a la vapeur d'eau conformes a l'EN 285 - Exigences et méthodes d'essai

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EUROPEAN STANDARD
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Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés - Partie 8: Conteneurs réutilisables de stérilisation pour stérilisateurs à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

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This European Standard was approved by CEN on 13 May 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. 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.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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 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 December 1999, and conflicting national standards shall be withdrawn at the latest by December 1999.

This Standard is one of a series of Draft European Standards concerned with packaging materials and systems for medical devices which are to be sterilized. This series consists of the following parts:

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

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

EN 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 EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) – Requirements and test methods

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

EN 868-5 Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self sealable pouches and reels of paper and plastic film construction – Requirements and test methods

EN 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

EN 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

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

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

Part 1 of this series of European standards 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.

1 Scope

This Part of the series of EN 868 provides examples of particular requirements and test methods for re-usable containers for steam sterilization.

It introduces no additional requirements to the general requirements of Part 1 but provides guidance based upon various elements of former, relevant national standards.

As such, the particular requirements in 4.2 to 4.7 can be used to demonstrate compliance with one or more but not all of the requirements of Part 1.

The containers specified in this part of the standard are intended to be used as a packaging system during the sterilization of medical devices in steam sterilizers conforming to EN 285 and the subsequent transportation and storage of those devices.

NOTE 1: When it is intended to use the containers in a steam sterilizer not conforming to EN 285 the sterilization performance of the container in the specific sterilization cycle to be used is validated by the user. Other attributes of the container are also reviewed for compatibility with the sterilizer cycle e. g. operating temperature.

NOTE 2: When goods are required to be multiply wrapped in order to fulfil the general requirements, they should first be packaged in a sterilization packaging material (e. g. a material as specified in other parts of this series of standards).

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 285 : 1996
Sterilization – Steam sterilizers – Large sterilizers

EN 868-1 : 1997
Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods

EN 10088-1
Stainless steels – Part 1: List of stainless steels

ISO 4017
Hexagon head screws – Product grades A and B

ISO 4582
Plastics – Determination of changes in colour and variations in properties after exposure to daylight under glass, natural weathering or artificial light

3 Definitions

For the purposes of this European Standard, the definitions of EN 868-1 and of EN 285 apply.

4 Requirements

4.1 General

The requirements of EN 868-1 apply.

NOTE: The following particular requirements and test methods can be used to demonstrate compliance with one or more – but not all – of the requirements of EN 868-1.

4.2 Requirements for construction and design

4.2.1 Shape and dimension

4.2.1.1 The container shall be in the general form of a parallelepipedal box.

NOTE: Slight curvature or camber of the flat surfaces can be acceptable. Rounding of the corners is desirable.

4.2.1.2 The container including all connected parts e. g. handles shall fit within one sterilization module (see EN 285).

NOTE 1: If the container does not fit within one sterilization module, but complies with all other requirements of this part of the standard, the manufacturer can claim compliance with EN 868-1 but not with EN 868-8.

NOTE 2: For guidance on dimensions see informative Annex A.

4.2.1.3 For ease of cleaning all internal corners shall be radiused.

4.2.2 Lids and lid-latching devices

4.2.2.1 Access to the interior of the container shall be provided by a lid. Demountable lids shall be designed and constructed so that either:

– for the same manufacturers product of the same model, any lid will fit any base of the same size; or

– each lid and base will be marked with a unique and corresponding number and the warning clearly and durably marked on both components "Use only with corresponding lid/base number" or equivalent phrase. The marking shall be designed to be legible throughout the working life of both components.

4.2.2.2 The lid shall be secured to the base during use by locking devices.

4.2.3 Tamper evident closure system

4.2.3.1 Every container shall have a 'tamper evident' closure system.

4.2.3.2 The 'tamper evident' closure system shall give clear indication whether or not the container has been opened.

NOTE: A container is considered to be opened when the lid and base of the container are separated sufficiently to compromise the closure between them.

4.2.3.3 If the 'tamper evident' closure system is not a single-use disposable item, i. e. does not irrevocably break when opened. then a special tool, key, code or treatment shall be required to re-set the closure system.

4.2.4 Gasket

4.2.4.1 The interface between the lid and base shall be provided with a closure gasket. The closure formed by the gasket with the lid latched in position shall provide microbiological barrier properties as specified in 4.6 of EN 868-1 : 1997.

For impermeable gaskets compliance shall be tested in accordance with Annex G of EN 868-1 : 1997. For permeable gaskets compliance shall be tested in accordance with Annex D of EN 868-1 : 1997.

4.2.4.2 The gasket shall be accessible for cleaning. Frequency and method of maintenance shall be specified by the manufacturer (see 4.7).

4.2.5 Handles

4.2.5.1 Each container shall be provided with not less than two carrying handles.

4.2.5.2 The handles shall be attached to the container centred on the normal projected vertically from the mid-point of the short side of the container.

4.2.5.3 Each handle shall provide a space not less than 80 mm wide by 40 mm deep to allow insertion of the fingers for carrying purposes.

4.2.5.4 The handles shall be smooth and rounded with a nominal escribed radius of not less than 2,5 mm.

4.2.5.5 The handles, their means of attachment to the container, and the container itself shall be sufficiently robust to support the weight of the filled container without permanent deformation when tested in accordance with Annex B.

4.2.6 Stacking capability

4.2.6.1 The top and base of each container shall be sufficiently strong to allow stacking and shall be fitted with means to ensure that all containers of the same nominal size and of the same provenance shall stack securely.

After the test in accordance with Annex C, the container shall show no permanent deformation and shall have unchanged performance characteristics.

When tested in accordance with Annex D, the tested container shall stack securely.

4.2.6.2 The containers shall be designed and constructed so that when stacked and loaded into the sterilizer in the manner specified by the manufacturer they will allow free passage of steam and/or air between containers.

Compliance shall be tested by the performance tests carried out as described in Annex B to E.

4.2.7 Sterilant Port

4.2.7.1 Each container shall be provided with a sterilant port in one or more of its principle surfaces.

4.2.7.2 The sterilant port shall be designed to meet the following requirements.

1) It shall permit the attainment of the specified sterilization conditions.
Compliance shall be tested in accordance with Annex E.

2) It shall permit adequate drying when processed in a sterilizer conforming to EN 285.
Compliance shall be tested in accordance with Annex F.

3) It shall permit microbial barrier properties during removal, transport and subsequent storage as specified in 4.6 of EN 868-1 : 1997.
Compliance shall be tested in accordance with applicable barrier tests (see 4.6 of EN 868-1 : 1997). In the absence of a final pack test compliance may be demonstrated by:

a) material barrier test for permeable materials according to Annex D of EN 868-1 : 1997 (e. g. for filters);

b) permeable seal test according to Annex E of EN 868-1 : 1997 (e. g. for permeable gaskets, filters, valves, tortuous path seals);

c) impermeable seal test according to Annex G of EN 868-1 : 1997 (e. g. for impermeable gaskets or valves).

NOTE: The drain is considered to be a sterilant port.

4.2.7.3 Frequency, method of cleaning and maintenance of the sterilant port shall be specified by the manufacturer (see 4.7).

4.2.8 Load

A full size container, i. e. of one sterilization module size, shall be designed and constructed to allow a total load of up to 10 kg to be sterilized in a sterilizer conforming to EN 285.

Fractional sizes shall accommodate proportionally smaller loads.

4.3 Visual inspection

The container shall be constructed to facilitate visual inspection of the essential parts of the container (e. g. filters, valves, gasket, locks, etc).

These essential parts, and the manner in which they shall be inspected, shall be specified by the manufacturer (see 4.7).

4.4 Service life

4.4.1 Service life for the container

Unless a maximum number of use-cycles is indicated by the manufacturer, the materials and construction of the container shall be such that the container will have a serviceable life of not less than 500 use-cycles. If any quality of the container or its components is not use-cycle related but time related, a minimum lifetime shall be stated.

All material requirements below shall be considered in view of the expected use-cycles or lifetime.

Compliance shall be demonstrated by using the test methods of 4.2.7 and 4.5.

If the service life shall be demonstrated by accelerated ageing procedures, the ageing procedure according to Annex G shall be used.

4.4.2 Service life for gaskets

The service life of a reusable gasket shall be stated by the manufacturer as the minimum number of cycles which can be run and the shelf life.

The service life of the gasket shall be not less than 100 use cycles or 6 months, whichever is the less.

Compliance shall be demonstrated by using the test methods of 4.2.7 and 4.5.

If the service life shall be demonstrated by accelerated ageing procedures, the ageing procedure according to Annex G shall be used.

4.5 Material requirements

4.5.1 The container and its components shall be able to withstand (both chemical and physical) steam sterilization in a sterilizer conforming to EN 285 without any adverse effects on the container or its components.

Compliance shall be tested by:

1) carrying out the test of the final pack (see 4.6 of EN 868-1 : 1997) on a container which has been subjected to the stated number of use cycles and

2) carrying out the test of the final pack (see 4.6 of EN 868-1 : 1997) on a container which has been subjected to 5 use-cycles, stored under ambient conditions with the lid closed for 6 months and then subjected to 5 further use-cycles.

4.5.2 The container and its reusable components shall be able to withstand proper cleaning procedures as indicated by the manufacturer without adverse effect to the container or its components.

Compliance shall be tested by:

1) carrying out the test of the final pack (see 4.6 of EN 868-1 : 1997) on a container which has been subjected to the stated number of cleaning procedures as indicated by the manufacturer and

2) carrying out the test of the final pack (see 4.6 of EN 868-1 : 1997) on a container which has been subjected to 5 use-cycles, stored under ambient conditions with the lid closed for 6 months and then subjected to 5 further use-cycles.

4.5.3 The container and its components shall be made of materials which are lightstable under the conditions of use. Compliance shall be tested in accordance with ISO 4582.

4.5.4 If the container and/or its components are made from different materials, there shall be no negative interaction (e. g. contact-corrosion) between the materials.

Compliance shall be deemed to be met, if the performance test according to 4.5.1 and 4.5.2 has been carried out successfully.

4.5.5 When the container is used as intended, the materials used for the container or its components shall not build up any electrostatic charge.

4.5.6 The material, design, construction and surface finish shall facilitate easy internal and external disinfection and cleaning.

4.6 Marking

Containers shall be marked with manufacturer or suppliers name or trademark.

4.7 Information to be supplied by the manufacturer

The following information shall be supplied by the manufacturer:

– specification of the essential parts (see 4.3);