SLOVENSKI STANDARD
SIST EN 868-5:2009

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Nadomešča:
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Embalaža za končno sterilizirane medicinske pripomočke - 5. del: Vrečke in zvitki papirja z možnostjo tesnjenja (samolepilni) iz poroznega materiala in s plastičnimi folijami - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösem Material und Kunststoff-Verbundfolie - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 5: Sachets et gaines thermoscellables et auto-scellables en papier et en film plastique - Exigences et méthodes d'essai

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ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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EUROPEAN STANDARD

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English Version

Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 5: Sachets et gaines thermoscellables constitués d'une face matière poreuse et d'une face film plastique - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösem Material und Kunststoff-Verbundfolie - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 23 April 2009.

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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 CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN 868-5:2009) 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 November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 868-5:1999.

Annex A provides details of significant technical changes between this European Standard and the previous edition.

EN 868 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

Part 2: Sterilization wrap — Requirements and test methods;

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;

Part 4: Paper bags — Requirements and test methods;

Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods;

Part 6: Paper for low temperature sterilization processes — Requirements and test methods;

Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods;

Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods;

Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods;

Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods.

In addition, ISO/TC 198 "Sterilization of health care products" in collaboration with CEN/TC 102 "Sterilizers for medical purposes" has prepared the EN ISO 11607 series "Packaging for terminally sterilized medical devices". The EN ISO 11607 series specifies general requirements for materials, sterile barrier systems and packaging systems (Part 1) and validation requirements for forming, sealing and assembly processes (Part 2).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

The EN ISO 11607 series consists of two parts under the general title "Packaging for terminally sterilized medical devices". Part 1 of this series specifies general requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. Part 2 of this series specifies validation requirements for forming, sealing and assembly processes.

Every sterile barrier system shall fulfil the requirements of EN ISO 11607-1.

The EN 868 series can be used to demonstrate compliance with one or more of the requirements specified in EN ISO 11607-1.

During the revision of EN 868 parts 2 to 10 CEN/TC 102/WG 4 recognized Resolution CEN/BT 21/2003 relating to the implementation of the uncertainty of measurement concept in standards. Following this Resolution and the corresponding guidance, CEN/TC 102/WG 4 has initiated a review of the test methods needed to show compliance with the requirements specified in EN 868 parts 2 to 10 with the intention that the information required by CEN/BT 21/2003 be available for inclusion in EN 868 parts 2 to 10 during one of their next revisions.

CEN/TC 102/WG 4 also appreciates the initiatives of CEN with regard to the minimization of adverse environmental impacts by standards. It was agreed that this subject should be given priority during the next edition of the EN ISO 11607 series that is the basic reference for all parts of the series EN 868.

1 Scope

This part of EN 868 provides test methods and values for sealable pouches and reels manufactured from porous materials complying with either EN 868 part 2, 3, 6, 7, 9 or 10 and plastic film complying with Clause 4 used as sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

NOTE 1 The need for a protective packaging may be determined by the manufacturer and the user.

This part of EN 868 only introduces performance requirements and test methods that are specific to the products covered by this part of EN 868 but does not add or modify the general requirements specified in EN ISO 11607-1.

As such, the particular requirements in 4.2 to 4.5 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

The materials specified in this part of EN 868 are intended for single use only.

NOTE 2 When additional materials are used inside the sterile barrier system in order to ease the organization, drying or aseptic presentation (e.g. inner wrap, container filter, indicators, packing lists, mats, instrument organizer sets, tray liners or an additional envelope around the medical device) then other requirements, including the determination of the acceptability of these materials during validation activities, may apply.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 868-2, *Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods*

EN 868-3, *Packaging for terminally sterilized medical devices — 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 868-6, *Packaging for terminally sterilized medical devices — Part 6: Paper for low temperature sterilization process — Requirements and test methods*

EN 868-7, *Packaging for terminally sterilized medical devices — Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods*

EN 868-9, *Packaging for terminally sterilized medical devices — Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods*

EN 868-10, *Packaging for terminally sterilized medical devices — Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods*

EN ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)*

EN ISO 11607-1:2006, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ASTM D 882:1995, *Test Methods for Tensile Properties of the Thin Plastic Sheeting*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2006 and the following apply.

3.1
healthcare facility
location where patients are medically treated and/or medical devices are terminally sterilized

EXAMPLE Hospital, dentist office, practitioner.

4 Requirements

4.1 General

The requirements of EN ISO 11607-1 apply.

NOTE 1 EN ISO 11607-1:2006, 5.1.4 refers to conditions during production and handling with respect to their impact on the product (e.g. electrostatic conductivity, bioburden if applicable).

NOTE 2 For validation requirements for forming, sealing and assembly processes, see EN ISO 11607-2.

4.2 Materials

4.2.1 Porous material

The porous material shall comply with the requirements of either EN 868 part 2, 3, 6, 7, 9 or 10.

When the porous material is to be used to manufacture preformed sterile barrier systems intended to be irradiation sterilized only, requirements for wet strength properties or permeability to air need not apply.

4.2.2 Plastic film

4.2.2.1 The plastic film shall be a composite of two or more layers. When tested after the intended sterilization process in accordance with Annex B the plastics interply bond shall not separate nor become cloudy.

4.2.2.2 The plastic film shall be free from pinholes when tested in accordance with Annex C.

4.2.2.3 When examined by unaided normal or corrected vision in transmitted light (daylight or good artificial light) the plastic film shall be free from foreign matter and/or other imperfections that would adversely affect compliance with the requirements of 4.5.

NOTE Slight continuous surface irregularities arising from the extrusion of the plastic film is not regarded as a defect.

4.2.2.4 The plastic film shall be sealable to the porous material under the conditions specified by the manufacturer (see Clause 5, NOTE 1).

4.2.2.5 The breaking factor of the plastics film shall be not less than 20 N per 15 mm width when tested in accordance with ASTM D 882:1995 (Method A).

4.3 Construction and design

4.3.1 Reel material shall be constructed from one layer of porous material and one layer of plastics film, sealed together along parallel sides.

Pouches shall be constructed from one layer of porous material and one layer of plastic film by sealing three sides and may include an area to effect closure of the pouch.

4.3.2 The overall width of the seal(s) shall be not less than 6 mm. For ribbed seals, the sum of the widths of the ribs shall be not less than 6 mm.

4.3.3 The distance between the end of a pouch and the nearest edge of the width wise seal shall be sufficient to enable the two webs to be separated and peeled apart.

NOTE The side seals can extend beyond the width wise seal to the end of the pouch provided that this does not impair peelability.

4.3.4 One of the materials of a pouch shall:

a) be provided with a thumb notch not more than 12 mm deep at either the top or bottom of the pouch or at both ends. The bottom of the notch shall be at least 1 mm from the seal; or

b) be lipped such that the length of one web is greater than the length of the other web by not less than 1,0 mm.

4.3.5 The pouch and/or reel shall be closed according to the manufacturer's instructions.

NOTE 1 For validation requirements for forming, sealing and assembly processes, see EN ISO 11607-2.

NOTE 2 The closure and or sealing system may give the possibility to indicate whether or not the seal has been opened.

4.4 Process indicator

If one or more Class I indicator(s) (process indicator(s)) are printed on the pouches and tubes, the indicator's performance shall comply with the requirements of EN ISO 11140-1. Each individual indicator shall be not less than 100 mm² in area. Indicators shall not be affected by the sealing procedure.

4.5 Performance requirements and test methods

4.5.1 When tested in accordance with the method described in Annex D the strength of the seal joint shall be not less than required for the intended purpose, both before and after being subjected to the sterilization process.

NOTE 1 The specification for seal strength before and after exposure to sterilization processes can differ.

Minimum value for seal strength in (healthcare facility) shall be 1,5 N per 15 mm for steam sterilization processes and 1,2 N per 15 mm for other sterilization processes.

NOTE 2 For applications outside healthcare facilities, requirements are given in EN ISO 11607.

Report whether the tail was supported or unsupported, see D.6.

4.5.2 The seal shall be continuous and cover the specified width. There shall be no disruption of the surface of the porous material adjacent to the seal lines upon opening. Compliance shall be tested in accordance with Annex E.

4.5.3 For paper according to EN 868-3 and EN 868-6 the direction of the peel marked on the product shall correspond to that direction which ensures least fibre disturbance. Compliance shall be tested in accordance with Annex F.

4.6 Marking

4.6.1 Pouches and reels

4.6.1.1 Pouches and reel material shall be clearly marked with the following information unless agreed otherwise between the supplier and the customer:

a) the words "Do not use if the sterile barrier system is damaged" or other equivalent phrase;

b) lot number[1];

c) the manufacturers name or trade name;

d) process indicator(s) if applicable;

e) the direction of peel which will ensure the least fibre tear for reels;

f) nominal dimensions and/or identification code.

4.6.1.2 The product shall not be printed on any surface which is designed to come into direct contact with the items to be packaged.

4.6.1.3 For lot number, process indicator, peel direction, and nominal dimensions or identification code (see 4.6.1.1 b), d), e) and f), the print repeat interval on reel material shall be not greater than 155 mm. For other information mentioned in 4.6.1.1 a) and c), the print repeat interval shall be not greater than 310 mm.

4.6.2 Protective packaging

Each unit of the protective packaging shall be legibly and durably marked with the following information:

a) description of contents including the size, or/and an identification code, for the pouch or reel and reference to this Standard;

b) quantity;

c) the manufacturer's or supplier's name or trade name, and address;

d) date of manufacture in accordance with ISO 8601;

e) lot number[1];

f) the recommended storage conditions.

5 Information to be supplied by the manufacturer

The manufacturer shall supply instructions for recommended sealing and/or closure conditions and for the monitoring of critical parameters of seal and/or closure integrity.

NOTE 1 For validation of closure and sealing conditions, see EN ISO 11607-2.

1 A reference number in order to trace the manufacturing history of the product.

NOTE 2 For heat seals these parameters include the range of temperature, pressure and time.

NOTE 3 For requirements on information to be provided by the manufacturer national or regional legislation can apply, see in particular Directive 93/42/EEC, Annex I, Section 13.