SLOVENSKI STANDARD
oSIST prEN 868-5:2017

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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

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien 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 constitués d'une face matière poreuse et d'une face film plastique - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **prEN 868-5**

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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

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (prEN 868-5:2017) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 868-5:2009.

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 and associated equipment for processing of medical devices” 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).

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.

General requirements for all types of sterile barrier systems are provided by 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.

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 EN 868 series.

1 Scope

This European Standard specifies 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.

Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard.

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

Secretary remark (to be deleted by formal vote stage): CEN/TC 102/WG 4 proposes to change the Scope of the work item in order to align the scope with the recently published new editions of EN 868-2*, –3, 4- –6 and –7. Please consider that a positive ballot on* prEN 858-5 *during enquiry includes the approval of the revised scope.*

2 Normative references

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

EN 868-2:2017, *Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods*

EN 868-3:2017, *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 868-6:2017, *Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods*

EN 868-7:2017, *Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods*

prEN 868-9:2017, *Packaging for terminally sterilized medical devices — Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods*

prEN 868-10:2017, *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)*

EN ISO 11607-1:2009, *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 D882:2012, *Test Methods for Tensile Properties of the Thin Plastic Sheeting*

ASTM F88/F88M:2015, *Standard Test Method for Seal Strength of Flexible Barrier Materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2009 apply.

4 Requirements

4.1 General

For any material, preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 shall apply.

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 4.5 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

NOTE 1 Compliance to EN 868–5 does not automatically mean compliance to EN ISO 11607.

A confirmation of compliance to EN 868-5 shall contain a statement whether EN ISO 11607-1 is covered.

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, 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, can apply.

4.2 Materials

4.2.1 Porous material

The porous material shall comply with the requirements of Clause 4 of either EN 868-2:2017, EN 868-3:2017, EN 868-6:2017, EN 868-7:2017, prEN 868-9:2017 or prEN 868-10:2017.

If the intended method of sterilization is irradiation only, the requirements for wet strength properties and permeability to air for porous materials are not applicable.

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.

4.2.2.5 The breaking factor of the plastics film, machine direction and cross direction, shall be not less than 20 N per 15 mm width when tested in accordance with ASTM D882:2012 (Method A).

4.3 Construction and design

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

Pouches shall be constructed from one web of porous material and one web 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 Typ 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 mm^2 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.

For use for sterilization in healthcare facilities, the minimum value for seal strength shall be 1,5 N per 15 mm for steam sterilization and 1,2 N per 15 mm for other sterilization processes.

NOTE 2 Requirements for seal strength set forth in this Standard are valid for pouches and reels delivered as preformed sterile barrier systems to healthcare facilities and for healthcare facilities to create a sterile barrier system. For applications in industry, different values can be established based on the specific applications and on the validation requirements of EN ISO 11607.

NOTE 3 Healthcare facilities are locations where patients are medically treated and/or medical devices are terminally sterilized (e.g. hospital, dentist office, practitioner).

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 If applicable, for porous materials, 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 information required by EN ISO 11607-1. Additionally, the following information shall be provided unless agreed otherwise between the supplier and the customer:

a) the words "Do not use if the sterile barrier system is damaged", or symbol (see EN ISO 15223-1:2016, 5.2.8)

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.

4.6.1.4 Preformed sterile barrier systems placed on the market for delivery to healthcare facilities shall not be supplied individually labelled with a CE logo.

NOTE 1: This is to avoid confusion in terms of legal responsibility with the CE mark for the final product.

NOTE 2: For CE marking of transport and/or storage packaging, see 4.6.2 h).

4.6.2 Transport and/or storage packaging

Each unit of the transport and/or storage 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;

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