SLOVENSKI STANDARD
oSIST prEN 868-10:2017

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Embalaža za končno sterilizirane medicinske pripomočke - 10. del: Netkani materiali iz poliolefinov, oplemeniteni z lepilom - Zahteve in preskusne metode

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

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 10: Klebemittelbeschichtete Faservliesmaterialien aus Polyolefinen - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 10 : Matériaux non tissés à base de polyoléfines enduits d'adhésif - Exigences et méthodes d'essai

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EUROPEAN STANDARD

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prEN 868-10

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English Version

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

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 10 : Matériaux non tissés à base de polyoléfines enduits d'adhésif - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 10: Klebemittelbeschichtete Faservliesmaterialien aus Polyolefinen - Anforderungen und Prüfverfahren

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.

This draft European Standard was established by CEN 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-CENELEC Management Centre has the same status as the official versions.

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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 868-10:2017) 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 868-10:2009.

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 adhesive coated nonwoven materials of polyolefines, manufactured from nonwovens complying with EN 868-9 used for 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 858-10 *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 20811, *Textiles - Determination of resistance to water penetration - Hydrostatic pressure test*

EN ISO 1974, *Paper - Determination of tearing resistance - Elmendorf method (ISO 1974:2012)*

EN ISO 536, *Paper and board - Determination of grammage (ISO 536:2012)*

EN ISO 1924-2, *Paper and board - Determination of tensile properties - Part 2: Constant rate of elongation method (20 mm/min) (ISO 1924-2:2008)*

EN ISO 2758, *Paper - Determination of bursting strength (ISO 2758:2014)*

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 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 6588-2, *Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction*

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

ASTM D2724-07:2015, *Standard Test Methods for Bonded, Fused, and Laminated Apparel Fabrics*

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 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 4.3 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 868–10 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-10 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 The coated material shall be translucent or opaque and made of continuous filaments of polyolefines of a high level of purity and shall not release any substances in such quantities as could constitute a health risk.

NOTE Attention is drawn to EN ISO 10993-1.

4.2.2 The coated material shall not react with, contaminate, transfer to, or adversely affect the product packed in it, before, during or after sterilization.

4.3 Performance requirements and test methods

4.3.1 No colour shall leach out of the material. Compliance shall be tested by visual examination of a hot extract prepared in accordance with the method given in ISO 6588-2 modified to test temperature of (60 ± 5) °C.

4.3.2 The average mass of 1 m^2 of the conditioned material when tested in accordance with EN ISO 536 shall be within ± 15 % of the nominal value stated by the manufacturer.

4.3.3 The tensile strength of the conditioned material shall be not less than 4,8 kN/m in the machine direction and not less than 5,0 kN/m in the cross direction when tested in accordance with EN ISO 1924-2.

4.3.4 The internal tearing resistance of the conditioned material shall be not less than 1 000 mN in both machine and cross directions when tested in accordance with EN ISO 1974.

4.3.5 If the nature of the material allows a delamination to be initiated, the delamination factor of the conditioned material shall be not less than 1 N/25,4 mm when tested in accordance with ASTM D2724-07:2015.

4.3.6 The bursting strength of the conditioned material shall be not less than 575 kPa when tested in accordance with EN ISO 2758.

4.3.7 The air permeance of the conditioned material shall be not less than 0,3 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

This requirement need not to apply to materials solely for use in irradiation sterilization packaging.

4.3.8 The resistance to water penetration of the conditioned material shall be determined using the hydrostatic head test based on EN 20811. Test results and test conditions shall be documented.

4.3.9 The mass per unit of the seal adhesive coating shall be within ± 2 g/m² of that stated by the manufacturer. Compliance shall be tested in accordance with the method given in Annex B.

4.3.10 The seal strength of the coated material shall be greater than 0,08 kN/m when tested in accordance with Annex C.

Report whether the tail was supported or unsupported, see C.5.

4.3.11 The coating shall be continuous and regular with no uncoated areas or discontinuity in the coating pattern which could provide gaps or channels in a seal.

NOTE The test method for the determination of the continuity of the coating depends on the applied coating system.

4.4 Marking of the protective packaging

The protective packaging shall be legibly and durably marked with the following information:

a) reference, stock or catalogue number;

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) nominal mass in grams per square metre;

g) nominal sheet size in millimetres or nominal width of rolls in millimetres and length in metres;

h) any specific storage conditions, if applicable.

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.

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.

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

Annex A
(informative)

Details of significant technical changes between this European Standard and the previous edition

Changes between this European Standard and EN 868-10:2009 are the following:

a) normative references have been updated;

b) references to ASTM standards have been added;

c) changes in order to align this European Standard with the EN ISO 11607 series, in particular by

   1) elucidating the requirements given by EN ISO 11607-1 as general requirements for this standard;

   2) formulating the significance and limits of the requirements of this standard with respect to the requirements given by EN ISO 11607-1;

d) the test method for determination of seal strength and mode of specimen failure as per Annex C has been amended;

e) bibliography has been updated.

NOTE This list is not exhaustive.