SVENSK STANDARD
SS-EN 868-10:2019

Fastställd/Approved: 2019-01-07
Utgåva/Edition: 3
Språk/Language: engelska/English
ICS: 11.080.30;55.040

Förpackningsmaterial för medicintekniska produkter avsedda för sterilisering i sluten förpackning – Del 10: Nonwoven-material av polyolefiner med fästmassa – Krav och provningsmetoder

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

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Europastandarden EN 868-10:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 868-10:2018.

Denna standard ersätter SS-EN 868-10:2009, utgåva 2.

The European Standard EN 868-10:2018 has the status of a Swedish Standard. This document contains the official version of EN 868-10:2018.

This standard supersedes the SS-EN 868-10:2009, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-10

December 2018

ICS 11.080.30

Supersedes EN 868-10:2009

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 European Standard was approved by CEN on 19 October 2018.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 868-10:2018 E

Contents

Page

European foreword

This document (EN 868-10:2018) 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 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 June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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

This document supersedes 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).

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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.

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 document 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 document.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 ISO 536, *Paper and board — Determination of grammage (ISO 536)*

ISO 811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

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

EN ISO 1974, *Paper — Determination of tearing resistance — Elmendorf method (ISO 1974)*

EN ISO 2758, *Paper — Determination of bursting strength (ISO 2758)*

EN ISO 11607-1:2017, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)*

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, *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 11607-1:2017 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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 4.3 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.

4.2.3 Conditioned material for testing shall comply with the test sample conditioning requirements of EN ISO 11607-1:2017, Clause 4.

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.

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.

NOTE This requirement can be ignored for 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 ISO 811. 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/m^2 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 1,2 N/15 mm 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;

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