SVENSK STANDARD
SS-EN 868-4:2017

Fastställd/Approved: 2017-02-13
Publicerad/Published: 2017-02-15
Utgåva/Edition: 3
Språk/Language: engelska/English
ICS: 11.080.30; 55.040

Förpackningsmaterial för medicintekniska produkter avsedda för sterilisering i sluten förpackning – Del 4: Papperspåsar – Krav och provningsmetoder

Packaging for terminally sterilized medical devices – Part 4: Paper bags – Requirements and test methods

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka
Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet
Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence
As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work
We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception
With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00

Europastandarden EN 868-4:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 868-4:2017.

Denna standard ersätter SS-EN 868-4:2009, utgåva 2.

The European Standard EN 868-4:2017 has the status of a Swedish Standard. This document contains the official version of EN 868-4:2017.

This standard supersedes the Swedish Standard SS-EN 868-4:2009, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB 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 Förlag AB, 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 868-4

February 2017

ICS 11.080.30

Supersedes EN 868-4:2009

English Version

Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 4: Sacs en papier - Exigences et méthodes d'essai

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 4 December 2016.

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: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 868-4:2017 E

Contents

Page

European foreword

This document (EN 868-4:2017) 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 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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 868-4:2009.

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 series EN ISO 11607 "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 and EN ISO 11607-2.

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 paper bags manufactured from paper specified in EN 868-3, 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.

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 868-3, *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 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 11140-1, *Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1)*

EN ISO 11607-1:2009+A1:2014, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+AMD1:2014)*

EN ISO 11607-2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*

ISO 6588-2:2012, *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*

ISO 9197, *Paper, board and pulps — Determination of water-soluble chlorides*

ISO 9198, *Paper, board and pulp — Determination of water-soluble sulfates*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2009+A1:2014 apply.

4 Requirements

4.1 General

For any preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 and EN ISO 11607-2 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 868–4 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-4 shall contain a statement whether EN ISO 11607-1 and EN ISO 11607-2 are 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, 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, can apply.

4.2 Construction and design

4.2.1 General

4.2.1.1 The bags shall be manufactured from single web paper specified in EN 868-3.

4.2.1.2 The following terms shall be used to describe the design of the bag:

a) back – the surface of the bag with a longitudinal seam;

b) front – the surface of the bag with no longitudinal seam;

c) unlipped – where the length of both the front and back surfaces are the same and the front surface has a thumb cut (9 ± 3) mm deep and not less than 15 mm wide;

d) lipped – where the length of the back surface is greater than the length of the front surface by not less than 10 mm and not more than 25 mm;

e) gusseted – where the construction of the bag includes side panels;

f) ungusseted – where the longitudinal edges of the front and back surfaces are contiguous;

g) seal top – where there is a continuous strip of seal adhesive on the inner surface of the front, back and gussets (if gusseted) of the top of the bag;

h) plain top – where there is no seal adhesive.

4.2.1.3 The adhesive(s) used in the construction of the bag shall be water resistant and non-corrosive, subsequently referred to as “construction adhesive(s)”.

4.2.2 Bottom seal formation

The bottom seal shall be formed by using one of the following methods:

a) the bottom shall be double folded with each fold bonded with “construction adhesive”, or

b) the bottom shall be sealed across the entire width with a “construction adhesive” or with a seal not less than 6,5 mm in depth, or

c) the bottom shall be sealed across the entire width as described in b) and then folded once, or more, each fold being bonded with (a) construction adhesive(s) or with a heat seal.

4.2.3 Back seam construction

4.2.3.1 The longitudinal seam shall be made at the back of the bag with a continuous double line of “construction adhesive(s)”.

4.2.3.2 A coloured adhesive shall be used to enable a simple visual check on the continuity of both glue lines.

4.2.3.3 The dye shall not impair the adhesive.

4.3 Process indicator

If one or more Type 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.

4.4 Seal strip

4.4.1 For bags with a seal closure the seal adhesive shall be applied as a continuous strip to the inner surface of the front, back and (if gusseted) the gussets of the bag.

4.4.2 The width of the seal strip shall be (25 ± 3) mm for bags with a width not exceeding 200 mm and (40 ± 3) mm for bags with a width exceeding 200 mm.

4.4.3 The top edge of the seal strip shall be positioned not less than 2 mm and not more than 10 mm from the lower lip or bottom of the thumb cut.

4.5 Performance requirements and test methods

NOTE See Annex D for repeatability and reproducibility of the test methods: sulphate content and chloride content. For information on statement of precision and/or bias, repeatability and reproducibility of other test methods, see EN ISO 11607-1:2009+A1:2014, Table B.1.

4.5.1 The pH of the aqueous extract of the paper and adhesive sandwich shall be within the range 4,5 to 8,0 when tested in accordance with Annex B.

4.5.2 The chloride content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with Annex B.

4.5.3 The sulphate content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium sulphate, shall not exceed 0,25 % when tested in accordance with Annex B.