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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

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Europastandarden EN 868-4:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 868-4:2009.

Denna standard ersätter SS-EN 868-4, utgåva 1.

The European Standard EN 868-4:2009 has the status of a Swedish Standard. This document contains the official English version of EN 868-4:2009.

This standard supersedes the Swedish Standard SS-EN 868-4, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-4

May 2009

ICS 11.080.30

Supersedes EN 868-4:1999

English Version

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

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 4: Sacs en papier - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 868-4:2009: E

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Foreword

This document (EN 868-4:2009) 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 868-4:1999.

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 paper bags manufactured from paper specified in Part 3 of EN 868, 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 4.6 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 868–3, *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 (ISO 1924-2:1994)*

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 6588-2:2005, *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 11607-1:2006 apply.

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 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 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.

4.4 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

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.

4.5.4 The tensile strength of the back seam joint of each bag seal shall be not less than 2,20 kN/m per unit width, when tested in accordance with Annex C.

4.6 Marking

4.6.1 Bags

The bag shall be clearly marked with:

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

b) a process indicator(s) if applicable;

c) the manufacturer's or supplier's name or trade name;

d) lot number[1];

e) nominal dimensions and/or identification code.

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