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Embalaža za končno sterilizirane medicinske pripomočke - 4. del: Papirnate vrečke - Zahteve in preskusne metode

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

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

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

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

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

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

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Foreword

This document (prEN 868-4:2015) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 868-4:2009.

Annex A provides details of significant technical changes between this draft 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).

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 needs to 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.

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 draft European Standard provides 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.

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.

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

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

ISO 6588-2:2005, *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

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

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

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: sulfate content and chloride content. For information on statement of precision and/or bias, repeatability and reproducibility of other test methods, see Table B.1 in EN ISO 11607-1:2009/A1:2014.

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 sulfate content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium sulfate, 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.

4.6.2 Protective packaging

Each unit of protective package shall be legibly and durably marked with the following information:

a) description of contents including the size, or a size code, for the bag;

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) the recommended storage conditions.

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, see in particular Directive 93/42/EEC, Annex I, Section 13.

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