SLOVENSKI STANDARD
oSIST prEN 868-3:2015

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Embalaža za končno sterilizirane medicinske pripomočke - 3. del: Papir za izdelavo papirnatih vrečk (specifikacija EN 868-4) in papir za izdelavo vrečk in neskončnih zvitkov (specifikacija EN 868-5) - Zahteve in preskusne metode

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

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 3: Papier zur Herstellung von Papierbeuteln (festgelegt in EN 868-4) und zur Herstellung von Klarsichtbeuteln und -schläuchen (festgelegt in EN 868-5) - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 3 : Papier utilisé dans la fabrication des sacs en papier (spécifiés dans l'EN 868-4) et dans la fabrication de sachets et gaines (spécifiés dans l'EN 868-5) - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: prEN 868-3

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EUROPEAN STANDARD

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English Version

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

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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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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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Foreword

This document (prEN 868-3:2015) 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 Enquiry.

This document will supersede EN 868-3:2009.

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, used in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) 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 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

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.

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

NOTE Applicable sterilization methods are specified by the manufacturer.

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 20187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187:1990)*

EN 20535, *Paper and board — Determination of water absorptiveness — Cobb method (ISO 535:1991)*

EN 21974, *Paper — Determination of tearing resistance (Elmendorf method) (ISO 1974:1990)*

EN ISO 536, *Paper and board — Determination of grammage (ISO 536)*

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

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 2470-2, *Paper, board and pulps — Measurement of diffuse blue reflectance factor — Part 2: Outdoor daylight conditions (D65 brightness)*

ISO 3689, *Paper and board — Determination of bursting strength after immersion in water*

ISO 3781, *Paper and board — Determination of tensile strength after immersion in water*

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

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 material, preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 apply. Statements on compliance with prEN 868-3 shall include statements on compliance with EN ISO 11607-1.

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 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 868–3 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to prEN 868-3 shall contain a statement whether EN ISO 11607-1 is covered.

4.2 Performance requirements and test methods

NOTE See Annex D for repeatability and reproducibility of the test methods: pore diameters, sulfate content, chloride content and water repellency. 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.

4.2.1 The requirements of 4.2.11 and 4.2.15 do not apply to materials solely used in irradiation sterilization packaging.

4.2.2 No colour shall leach out of the paper. Compliance shall be tested by visual examination of a hot aqueous extract prepared in accordance with the method given in ISO 6588-2.

4.2.3 The average mass of 1 m^2 of the conditioned paper when tested in accordance with EN ISO 536 shall be within ± 5 % of the nominal value stated by the manufacturer.

4.2.4 The pH of an aqueous extract of the paper shall be not less than 5 nor greater than 8 when tested in accordance with ISO 6588-2.

4.2.5 The chloride content of the paper, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with ISO 9197 using a hot extract prepared in accordance with ISO 6588-2:2005, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.6 The sulfate content of the paper, calculated as sodium sulfate, shall not exceed 0,25 % when tested in accordance with ISO 9198, using a hot extract prepared in accordance with ISO 6588-2:2005, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.7

4.2.7.1 When tested in accordance with ISO 2470-2, the material shall not exhibit an increase in D65 brightness, due to the optical brightener agents, of more than 1 %; calculated as the ratio of the D65 brightness measured with the 420 nm UV-cut-off filter in place to the D65 brightness measured without 420 nm UV-cut-off filter.

4.2.7.2 When exposed at 25 cm from a UV light source, the material shall not have per 0,01 m^2 more than five fluorescent spots, each having an axis greater than 1 mm.

NOTE The UV light to be used is the one described as per Annex B.

4.2.8 The internal tearing resistance of the conditioned paper shall be not less than 550 mN in both machine and cross direction when tested in accordance with EN 21974.

4.2.9 The air permeance of the conditioned paper shall be not less than 3,4 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

4.2.10 The bursting strength of the conditioned paper shall be not less than 230 kPa when tested in accordance with EN ISO 2758.

4.2.11 The wet bursting strength of the paper shall be not less than 35 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.

4.2.12 The water repellency of the paper shall be such that the penetration time is not less than 20 s when tested in accordance with Annex B.

4.2.13 When tested in accordance with Annex C, the average of the pore diameters of the 10 test pieces shall be lower than or equal to 35 µm. No value shall be greater than 50 µm.

4.2.14 The tensile strength of the conditioned paper shall be not less than 4,40 kN/m in machine direction and not less than 2,20 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.2.15 The wet tensile strength of the paper shall be not less than 0,90 kN/m in machine direction and not less than 0,45 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.16 The surface absorbency of each side of the paper shall be not more than 20 g/m^2 when tested in accordance with EN 20535 using a 60 s exposure time (COBB method).

4.3 Marking

4.3.1 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 or nominal width of rolls in millimetres and length in metres;

h) the recommended storage conditions.

4.3.2 Labelling of individual units

Labelling of individual units shall be legibly and durably marked with the information a), b), c), e) and f) according to 4.3.1.

NOTE Examples for individual units are reels or stacks of sheet material.

5 Information to be supplied by the manufacturer

For requirements on information to be provided by the manufacturer national or regional legislation may 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.