SLOVENSKI STANDARD
SIST EN 868-2:2009

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Embalaža za končno sterilizirane medicinske pripomočke - 2. del. Sterilizacijski embalažni materiali za zavijanje - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Sterilisierverpackung - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 2: Enveloppe de stérilisation - Exigences et méthodes d'essai

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ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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EUROPEAN STANDARD

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Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 2: Enveloppe de stérilisation - Exigences et méthodes d'essai

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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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Foreword

This document (EN 868-2:2009) 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.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 868-2:1999.

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 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 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 EN 868 series.

1 Scope

This part of EN 868 provides test methods and values for materials for 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 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

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.

The materials specified in 4.2.2.1 to 4.2.2.3 of this part of EN 868 are intended for single use, the materials specified in 4.2.2.4 are intended for reuse.

NOTE 3 If the intended purpose according to the manufacturer of the material for sterile barrier system specifies the use as sterile field, then the additional requirements of the EN 13795 series 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 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 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

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

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

EN ISO 536, *Paper and board — Determination of grammage (ISO 536:1995)*

EN ISO 1924-2, *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method (ISO 1924-2:1994)*

EN ISO 2758, *Paper — Determination of bursting strength (ISO 2758:2001)*

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 13937-1, *Textiles — Tear properties of fabrics — Part 1: Determination of tear force using ballistic pendulum method (Elmendorf) (ISO 13937-1:2000)*

EN ISO 13938-1, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

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*

ISO 9237, *Textiles — Determination of the permeability of fabrics to air*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2006 and the following apply.

3.1
sterile field
area created by sterile drape material where aseptic technique is practised

NOTE A sterile field can be practised e.g. on a back table.

3.2
surgical drape
drape covering a patient or equipment to prevent transfer of infective agents

[see also EN 13795–1:2002]

4 Requirements

4.1 General

The requirements of EN ISO 11607–1 apply.

NOTE 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).

4.2 Performance requirements and test methods

4.2.1 General

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

4.2.1.2 The average mass of 1 m² of the conditioned wrap when tested in accordance with EN ISO 536 shall be within ± 5 % of the nominal value stated by the manufacturer.

4.2.1.3 The pH of an aqueous extract of the wraps shall be not less than 5 nor greater than 8 when tested in accordance with ISO 6588-2, hot extraction method.

4.2.1.4 The chloride content of the wrap, 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.

4.2.1.5 The sulphate content of the wrap, calculated as sodium sulphate, 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.

4.2.1.6 When tested in accordance with Annex B the wrap shall neither exhibit an increase in brightness due to the optical brightener of more than 1 % nor have more than five fluorescent spots, each having an axis greater than 1 mm per 0,01 m².

4.2.1.7 The manufacturer shall provide drapeability results and associated test method on request.

NOTE For test method, see e.g EN ISO 9073–9 and Annex C (informative).

4.2.2 Specific requirements

4.2.2.1 Plain paper

4.2.2.1.1 The internal tearing resistance of the conditioned wrap shall be not less than 500 mN in both machine and cross direction when tested in accordance with EN 21974.

4.2.2.1.2 The air permeance of the conditioned wrap shall be not less than 1,7 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

4.2.2.1.3 The bursting strength of the conditioned wrap shall be not less than 110 kPa when tested in accordance with EN ISO 2758.

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

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

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

4.2.2.1.7 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.2.2.1.8 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.2.1.9 The surface absorbency of each side of the paper shall be not more than 20 g/m² when tested in accordance with EN 20535 using a 60 s exposure time (Cobb test).

4.2.2.2 Creped Paper

4.2.2.2.1 The wrap shall be creped to give increased flexibility.

4.2.2.2.2 The elongation at break of the conditioned wrap shall be not less than 10 % in the machine direction and not less than 2 % in the cross direction when tested by measurement of the elongation in conjunction with the test for tensile strength in accordance with EN ISO 1924-2.

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

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

4.2.2.2.5 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.2.2.2.6 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.2.3 Nonwoven wrapping material

NOTE For the purpose of this specification, a nonwoven for sterile barrier systems can be described as a bonded web made of textile and/or non-textile fibres.

4.2.2.3.1 The internal tearing resistance of the conditioned nonwoven wrap shall be not less than 750 mN in the machine direction and 1 000 mN in the cross direction when tested in accordance with EN 21974.

4.2.2.3.2 The bursting strength of the conditioned nonwoven wrap shall be not less than 130 kPa when tested in accordance with EN ISO 2758.

4.2.2.3.3 The wet bursting strength of the nonwoven wrap shall be not less than 90 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.

4.2.2.3.4 The elongation at break of the conditioned nonwoven wrap shall be not less than 5 % in the machine direction and not less than 7 % in the cross direction when tested in accordance with EN ISO 1924-2.

4.2.2.3.5 The resistance to water penetration of the nonwoven wrap shall be determined using the hydrostatic head test based on EN 20811. This test method is currently under revision and considering other test conditions (use of support screen with an open area greater than 50 % in order to avoid early fabric rupture). Minimum requirements will be set as soon as the revised test method is available. Manufacturers may report test results.

4.2.2.3.6 The tensile strength of the conditioned nonwoven wrap shall be not less than 1,00 kN/m in machine direction and not less than 0,65 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.2.2.3.7 The wet tensile strength of the nonwoven wrap shall be not less than 0,75 kN/m in machine direction and not less than 0,50 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.2.4 Woven textile material

4.2.2.4.1 When the woven textile material is to be used to manufacture packaging intended to be irradiation sterilized only, it is not necessary for it to be permeable to air, so 4.2.2.4.6 need not to apply.

4.2.2.4.2 Requirements for the processing of reusable fabrics as given in EN ISO 11607-1:2006, 5.1.11 and 5.1.12 apply and should include the means to quantify and control the number of processing cycles.

4.2.2.4.3 The tensile strength, dry and wet, of the wrap shall be not less than 300 N in the warp and weft directions when tested in accordance with strip method of EN 29073-3.

4.2.2.4.4 The tear strength, dry and wet, of the wrap shall be not less than 6 N in the warp and weft directions when tested in accordance with EN ISO 13937-1. The samples for the "wet" test shall be prepared according to EN 29073-3.

4.2.2.4.5 The bursting strength “dry” and “wet” of the wraps shall not be less than 100 kPa when tested in accordance with EN ISO 13938-1. The preparation of samples for wet state testing shall be performed according to EN 29073-3.

4.2.2.4.6 The air permeability of the wrap shall be not more than 20 mm/s when tested in accordance with ISO 9237.

4.2.2.4.7 The resistance to water penetration of the woven textile material shall be determined using the hydrostatic head test based on EN 20811. This test method is currently under revision and considering other test conditions (use of support screen with an open area greater than 50 % in order to avoid early fabric rupture). Minimum requirements will be set as soon as the revised test method is available. Manufacturers may report test results.

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 sheet size or nominal width of rolls in millimetres and length in metres;

g) the recommended storage conditions.

4.3.2 Inner package

The inner package with sheets or inner label with reels shall be legibly and durably marked with the information a), b), c), e) and f) according to 4.3.1.

5 Information to be supplied by the manufacturer

The following information should be supplied in addition to EN ISO 11607-1:2006, Clause 7:

a) recommendations for particular applications of sterilization wrap (e.g. sterile barrier system, protective packaging, packaging system);

b) the nature and extent of any identified risks associated with the use of the packaging material and/or system;

c) any information pertinent to the packaged medical device as may be required (see EN 1041).

NOTE 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.