SLOVENSKI STANDARD
SIST EN 868-7:2009

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Nadomešča:
SIST EN 868-7:2000

Embalaža za končno sterilizirane medicinske pripomočke - 7. del: Papir, oplemeniten z lepilom, za izdelavo embalažnih enot pri toplotnem lepljenju za uporabo v medicini pri sterilizaciji z etilenoksidom ali obsevanjem - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 7: Klebemittelbeschichtetes Papier für die Herstellung von siegelfähigen Verpackungen für medizinische Zwecke zur Sterilisation mit Ethylenoxid oder Strahlen - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 7: Papier enduit d'adhésif pour la fabrication d'emballages thermoscellables à usage médical pour stérilisation à l'oxyde d'éthylène ou par irradiation - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 868-7:2009**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-7

May 2009

ICS 11.080.30

Supersedes EN 868-7:1999

English Version

Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods

Matériaux d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 7: Papier enduit d'adhésif pour la fabrication d'emballages thermoscellables à usage médical pour stérilisation à l'oxyde d'éthylène ou par irradiation - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 7: Klebemittelbeschichtetes Papier für Niedertemperatur-Sterilisationsverfahren - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 23 April 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Foreword

This document (EN 868-7:2009) 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 868-7:1999.

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 EN 868 series.

1 Scope

This part of EN 868 provides test methods and values for sealable adhesive coated paper manufactured from paper complying with EN 868-6, 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 materials specified in this part are intended to be used for ethylene oxide or irradiation sterilization.

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 4.3 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 this part of EN 868 are intended for single use only.

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

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)*

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 pulps — 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 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 Materials

The adhesive coating shall not react with, contaminate, transfer to or adversely affect the product packed in it, before, during or after sterilization.

4.3 Performance requirements and test methods

4.3.1 When the paper is to be used to manufacture packaging intended to be irradiation sterilized only, it is not necessary for it to have wet strength properties or any permeability to air, so 4.3.11 and 4.3.16 need not apply.

4.3.2 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.

4.3.3 The average mass of 1 m² of the conditioned coated paper when tested in accordance with EN ISO 536 shall be within ± 7,5 % of the nominal value stated by the manufacturer.

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

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

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

4.3.7 The uncoated paper 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 m²when tested in accordance with Annex B.

4.3.8 The internal tearing resistance of the conditioned paper shall be not less than 300 mN in both machine and cross directions when tested in accordance with EN 21974.

4.3.9 The air permeance of the conditioned coated paper shall be not less than 0,2 µm/Pa · s and not more than 6,0 µm/Pa · s when tested in accordance with ISO 5636-3.

4.3.10 The bursting strength of the conditioned paper shall be not less than 200 kPa when tested in accordance with EN ISO 2758.

4.3.11 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.

4.3.12 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 C.

4.3.13 When tested in accordance with Annex D, the average of the pore diameters of the ten test coated pieces shall be lower than or equal to 20 µm. No value shall be greater than 30 µm.

4.3.14 The coating shall be continuous and regular with no uncoated areas or discontinuity in the coating pattern which could provide gaps or channels in a seal when tested and examined in accordance with Annex E.

4.3.15 The tensile strength of the conditioned paper shall be not less than 4,0 kN/m in machine direction and not less than 2,0 kN/m in cross direction when tested in accordance with EN ISO 1924-2.

4.3.16 The wet tensile strength of the paper shall be not less than 0,80 kN/m in machine direction and not less than 0,40 kN/m in cross direction when tested in accordance with ISO 3781.

4.3.17 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 method).

4.3.18 The mass per unit area of seal adhesive coating shall be within ± 2 g/m² of that stated by the manufacturer when tested in accordance with Annex F.

4.3.19 The seal strength of the coated paper shall be greater than 0,08 kN/m (1,20 N/15 mm) but not so strong as to cause fibre tear when tested in accordance with Annex G.

Report whether the tail was supported or unsupported, see G.5.

4.4 Marking of 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 in millimetres or nominal width of rolls in millimetres and length in metres;

g) the recommended storage conditions;

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

h) nominal mass in grams per square metre.

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.

Annex A
(informative)

Details of significant technical changes between this European Standard and the previous edition

Changes between this European Standard and EN 868-7:1999 are the following:

a) changes in order to align this European Standard with the EN ISO 11607 series, in particular by:

   1) amending the main element of the title, the scope and the terminology;

   2) using EN ISO 11607-1 as normative reference regarding the general requirements for materials, sterile barrier systems and packaging systems;

   3) deleting requirements that are covered by EN ISO 11607 (such as requirements on raw materials, conditioning, quality of the material with regard to tears, creases, localised thickening, leaching of toxic substances);

b) the specific element of the title of this European Standard has been amended to indicate that the material covered by this European Standard can be applied to low temperature sterilization processes;

c) in addition to a) first dash, the scope has been modified to:

   1) explain that other requirements might be of relevance for additional materials being used inside a sterile barrier system;

   2) clarify that the materials covered by this European Standard are intended for single use only;

d) an explanatory note has been inserted to refer the user of this European Standard to the general requirements on conditions during production and handling with respect to their impact on the product in EN ISO 11607;

e) informative details on Bendtsen roughness of the surface of the paper have been deleted;

f) requirements on marking have been amended;

g) requirements on information to be provided by the manufacturer have been amended;

h) the test method on fluorescence has been inserted (this test method is based on DIN 58953-6 that was previously cited in this European Standard);

i) test reports in the annexes have been amended;

j) test method on the determination of the seal strength has been amended;

k) informative annex on dimensions and tolerances has been deleted;

l) text has been revised editorially (e.g. by updating normative and informative references).

NOTE This list is not exhaustive.