SLOVENSKI STANDARD
SIST EN 868-6:2017

01-april-2017

Nadomešča:

SIST EN 868-6:2009

Embalaža za končno sterilizirane medicinske pripomočke - 6. del: Papir za sterilizacijske procese z nizko temperaturo - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 6: Papier für Niedertemperatur-Sterilisationsverfahren - Anforderungen und Prüfverfahren

Matériaux et systèmes d'emballage pour les dispositifs médicaux stérilisés au stade terminal - Partie 6 : Papier à destination des procédés de stérilisation à basses températures - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: EN 868-6:2017

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging
55.040	Materiali in pripomočki za pakiranje	Packaging materials and accessories

SIST EN 868-6:2017 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-6

February 2017

ICS 11.080.30

Supersedes EN 868-6:2009

English Version

Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 6: Papier pour des procédés de stérilisation à basse température - Exigences et méthodes d'essai

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 6: Papier für Niedertemperatur-Sterilisationsverfahren - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 4 December 2016.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 868-6:2017 E

Contents

Page

European foreword

This document (EN 868-6:2017) has been prepared by Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices", 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 868-6:2009.

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 and associated equipment for processing of medical devices" 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 organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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.

General requirements for all types of sterile barrier systems are provided by 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 European Standard specifies test methods and values for paper used in the manufacture of preformed sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard.

Paper specified in this European Standard is intended for use in part or complete manufacture of pouches and form and fill packs and lidding material for trays.

NOTE 1 The paper specified in this part of the EN 868 series is suitable for the manufacture of sterile barrier systems to be used in ethylene oxide, irradiation or low temperature steam formaldehyde sterilization processes and to produce coated paper according to EN 868–7.

NOTE 2 Paper according to EN 868–3 can also be used for these sterilization processes.

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

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)*

EN ISO 535, *Paper and board - Determination of water absorptiveness - Cobb method (ISO 535)*

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 1974, *Paper - Determination of tearing resistance - Elmendorf method (ISO 1974)*

EN ISO 2758, *Paper - Determination of bursting strength (ISO 2758)*

EN ISO 11607-1:2009+A1:2014, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+AMD1:2014)*

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 6588-2:2012, *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 11607-1:2009+A1:2014 apply.

4 Requirements

4.1 General

For any material, preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 shall 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 4.2 can be used to demonstrate compliance with one or more but not all of the requirements of EN ISO 11607-1.

NOTE 1 Compliance to EN 868–6 does not automatically mean compliance to EN ISO 11607-1.

A confirmation of compliance to EN 868-6 shall contain a statement whether EN ISO 11607-1 is covered.

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, can apply.

4.2 Performance requirements and test methods

NOTE See Annex D for repeatability and reproducibility of the test methods: pore diameters, sulphate content, chloride content and water repellency. For information on statement of precision and/or bias, repeatability and reproducibility of other test methods, see EN ISO 11607-1:2009+A1:2014, Table B.1.

4.2.1 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 4.2.11, 4.2.12 and 4.2.15 need not apply.

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, hot extraction method.

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 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.6 The sulphate content of the paper, 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 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.7 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.

4.2.8 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.

4.2.9 The internal tearing resistance of the conditioned paper shall be not less than 300 mN in both machine and cross direction when tested in accordance with EN ISO 1974.

4.2.10 The air permeance of the conditioned paper shall be not less than 0,2 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.

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

4.2.12 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.

4.2.13 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.

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

4.2.15 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.

4.2.16 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.

4.2.17 The surface absorbency of each side of the paper shall be not more than 20 g/m^2 when tested in accordance with EN ISO 535 using a 60 s exposure time (Cobb method).

4.3 Marking

4.3.1 Transport packaging

The transport packaging shall be legibly and durably marked with the following information:

a) reference, stock or catalogue number;

b) quantity;

c) the name or trade name and address of the manufacturer;

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

Individual units shall be legibly and durably marked with the information a), b), d), e) and name or trade name according to 4.3.1.

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

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

Annex A
(informative)

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

Changes between this European Standard and EN 868-6:2009 are the following:

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

   1) elucidating the requirements given by EN ISO 11607-1 as general requirements for this standard;

   2) formulating the significance and limits of the requirements of this standard with respect to the requirements given by EN ISO 11607-1;

   3) linking the test methods with regard to information on statement of precision and bias, repeatability and reproducibility to EN ISO 11607-1:2009+A1:2014, Table B.1;

b) the test method on fluorescence is in accordance with ISO 2470-2. The test method according Annex B has been deleted;

c) updating of the following test methods by a statement of repeatability and reproducibility:

   1) Method for the determination of water repellency as per Annex B;

   2) Method for the determination of pore size as per Annex C;

d) providing of informative data for repeatability and reproducibility of the following test methods as per Annex D:

   1) method for the determination of water repellency as per Annex B;

   2) method for the determination of pore size as per Annex C;

   3) chloride content;

   4) sulphate content;

e) updating of the bibliography.

NOTE This list is not exhaustive.