SLOVENSKI STANDARD
oSIST prEN 868-7:2024

01-junij-2024

Embalaža za končno sterilizirane medicinske pripomočke - 7. del: Papir z lepilno prevleko za sterilizacijske procese z nizko temperaturo - Zahteve in preskusne metode

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

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

Emballages 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: **prEN 868-7**

ICS:

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 868-7

April 2024

ICS 11.080.30

Will supersede EN 868-7:2017

English Version

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

Emballages 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

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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.

This draft European Standard was established by CEN 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.

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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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Ref. No. prEN 868-7:2024 E

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European foreword

This document (prEN 868-7:2024) 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 868-7:2017.

This document includes the following significant technical changes with respect to EN 868-2:2017:

a) The document was renumbered to limit the list numbering to 3 levels only for better readability.

b) Clause 4 “General requirements” was slightly revised for clarity and aligned with the other parts of EN 868 series and a statement was added clarifying when acceptance criteria apply.

c) Clause 6 “Sterilization compatibility” was added, aligned with the other parts of EN 868 series.

d) Clause 8.2 “Environmental declarations” was added and aligned with the other parts of EN 868 series.

e) List of major changes were moved to Foreword, thus Annex A was deleted.

f) New Clause “Environmental aspects for testing” was added to each test method in Annexes A – E.

g) New Annex G regarding environmental aspects was added.

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).

Introduction

The EN ISO 11607 series of standards 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 of standards have been developed mainly for materials and sterile barrier systems used in health care facilities sterilization processes. Materials complying with part 7 of the EN 868 series can also be used for industrial sterilization. The EN 868 series of standards can be used to demonstrate compliance with one or more of the requirements specified in EN ISO 11607-1.

Considering CEN Guide 4 [1] and the CEN environmental checklists, this revision has been complemented with a new annex with guidance to encourage users to also include environmental aspects when applying the EN 868 series of standards with the objective to minimize the environmental impact. Environmental aspects have also been included into the description of test methods with the same objective.

1 Scope

This document specifies test methods and values for sealable adhesive coated paper manufactured from paper complying with EN 868-6, used as single-use sterile barrier systems and/or single-use packaging systems for terminally sterilized medical devices by the means of low temperature sterilization processes.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 ISO 187, *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 11607-1:2020, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)*

EN ISO 14021, *Environmental labels and declarations — Self-declared environmental claims (Type II environmental labelling) (ISO 14021)*

EN ISO 14025, *Environmental labels and declarations — Type III environmental declarations — Principles and procedures (ISO 14025)*

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 6588-2:2021, *Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 9197, *Paper, board and pulps — Determination of water-soluble chlorides*

ISO 9198, *Paper, board and pulp — Determination of water-soluble sulfates*

ASTM F88/F88M:2023, *Standard Test Method for Seal Strength of Flexible Barrier Materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1:2020 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

4 General requirements

4.1 For any material, preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 shall apply.

NOTE 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 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 Clause 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 EN 868-7 does not automatically mean compliance to EN ISO 11607-1.

4.3 All acceptance criteria in Clause 5 shall be applied for testing materials before sterilization.

4.4 A confirmation of compliance to EN 868-7 shall contain a statement whether EN ISO 11607-1 is covered.

5 Performance requirements and test methods

5.1 General

NOTE 1 See Annex F 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 11607-1:2020, Table B.1.

NOTE 2 Test methods included in Annex C "regularity of seal adhesive coatings on paper", Annex D "Determination of mass per unit area of uncoated paper and adhesive coating" and Annex E "Determination of seal strength and visual inspection of adhesive coating" have no statement of precision and bias or repeatability and reproducibility, yet.

5.1.1 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 5.1**3** and 5.1**8** need not apply.

5.1.2 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.

5.1.3 The average mass of 1 m^2 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.

5.1.4 The pH of an aqueous extract of the coated paper shall be not less than 5 or greater than 8 when tested in accordance with ISO 6588-2, hot extraction method.

5.1.5 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 6588-2:2021, 7.2 except that 2 ml of potassium chloride solution is not added.

5.1.6 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 6588-2:2021, 7.2 except that 2 ml of potassium chloride solution is not added.

5.1.7 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.

5.1.8 When exposed at (25,0 ± 1,0) 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.

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

5.1.9 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 ISO 1974.

5.1.10 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.

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

5.1.12 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.

5.1.13 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 A.

5.1.14 When tested in accordance with Annex B, 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.

5.1.15 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 C.

5.1.16 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.

5.1.17 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.

5.1.18 The surface absorbency of each side of the paper shall be not more than 20 g/m² when tested in accordance with EN ISO 535 using a 60 s exposure time (Cobb method).

5.1.19 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 D.

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

6 Sterilization compatibility

6.1 The sterilization processes applicable to the packaging materials under the scope of this document shall be defined by the manufacturer of the packaging material.

6.2 The sterilization compatibility of the packaging materials shall be evaluated following the requirements of EN ISO 11607-1. The effects shall be evaluated considering the intended sterilization process(es) and intended number of cycles.

NOTE Sterilization processes generally have an effect on material properties, therefore evaluation of sterilization compatibility involves a risk-based assessment considering the characteristics of the material and its application to define the properties to be evaluated, which typically include material strength properties relevant for maintenance of sterility after sterilization.

7 Labelling

7.1 Transport packaging

The transport packaging shall be legibly and durably labelled 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 8601-1;

e) lot number[1];

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

g) the recommended storage conditions;

h) nominal mass in grams per square metre;

i) intended for single use only.

7.2 Labelling of individual units

Individual units shall be legibly and durably labelled with the information a), b), d), e) and name or trade name according to 7.1.

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