SLOVENSKI STANDARD
oSIST prEN 868-2:2024

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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

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

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2 : Enveloppe de stérilisation - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **prEN 868-2**

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

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prEN 868-2

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English Version

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

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2 : Enveloppe de stérilisation - 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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European foreword

This document (prEN 868-2:2024) 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 868-2:2017.

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 5 “Performance requirements”: materials used solely for irradiation sterilization are excluded from the requirements regarding wet tensile strength of the wrap.

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

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

f) List of major changes were moved to foreword, thus Annex A was deleted.

g) New Clause “Environmental aspects for testing” was added to each test method in Annexes A to C.

h) New Annex E 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 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).

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. 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 sterilization wrap made of

— single-use creped paper

— single-use nonwoven materials

— reusable woven textile materials

used as sterile barrier systems and/or packaging systems for terminally sterilized medical devices.

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

EN ISO 811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test (ISO 811)*

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 9073-3, *Nonwovens — Test methods — Part 3: Determination of tensile strength and elongation at break using the strip method (ISO 9073-3)*

EN ISO 9237, *Textiles — Determination of permeability of fabrics to air (ISO 9237)*

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

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

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 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*

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 868-2 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 868-2 shall contain a statement whether EN ISO 11607-1 is covered.

5 Performance requirements and test methods

5.1 General

5.1.1 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.

5.1.2 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.

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

5.1.4 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 6588-2:2021, 7.2, except that 2 ml of potassium chloride solution is not added.

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

5.1.6 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.

5.1.7 When exposed at 25 cm from a UV light source, the material shall not have per 0,01 m² 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 B.

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

NOTE For test method, see e.g. EN ISO 9073-9 [2] and Annex A.

5.2 Specific requirements for wrap made of creped paper

5.2.1 The wrap shall be creped to give increased flexibility.

5.2.2 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.

5.2.3 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 B.

5.2.4 When tested in accordance with Annex C, 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.

5.2.5 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.

5.2.6 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. For materials solely used for irradiation sterilization, this requirement may be excluded.

5.3 Specific requirements for wrap made of nonwoven material

5.3.1 General

NOTE A nonwoven material for sterile barrier systems can be manufactured by different technologies, e.g. wet laid nonwoven processes or Spunbond Meltblown Spunbond (SMS) processes.