



**SLOVENSKI STANDARD**  
**oSIST prEN 868-4:2024**  
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**Embalaža za končno sterilizirane medicinske pripomočke - 4. del: Papirnate vrečke - Zahteve in preskusne metode**

Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 4: Papierbeutel - Anforderungen und Prüfverfahren

Emballage des dispositifs médicaux stérilisés au stade terminal - Partie 4 : Sacs en papier - Exigences et méthodes d'essai

**Ta slovenski standard je istoveten z: prEN 868-4**

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**ICS:**

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|-----------|------------------------|----------------------|
| 11.080.30 | Sterilizirana embalaža | Sterilized packaging |
| 55.080    | Vreče. Vrečke          | Sacks. Bags          |

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**DRAFT**  
**prEN 868-4**

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ICS 11.080.30

Will supersede EN 868-4:2017

English Version

## Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

Emballage des dispositifs médicaux stérilisés au stade  
terminal - Partie 4 : Sacs en papier - Exigences et  
méthodes d'essai

Verpackungen für in der Endverpackung zu  
sterilisierende Medizinprodukte - Teil 4: Papierbeutel -  
Anforderungen und Prüfverfahren

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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## European foreword

This document (prEN 868-4:2024) 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 868-4:2017.

This document includes the following significant technical changes with respect to EN 868-4:2017:

- a) Normative reference to EN ISO 187 was added.
- b) The document was renumbered to limit the list numbering to 3 levels only for better readability.
- c) 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.
- d) Clause 7 “Sterilization compatibility” was added, aligned with the other parts of EN 868 series.
- e) Clause 9.2 “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 – B.
- h) New Annex D 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.*

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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).

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## 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 and EN ISO 11607-2.

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.

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## prEN 868-4:2024 (E)

### 1 Scope

This document specifies test methods and values for single-use paper bags manufactured from paper specified in EN 868-3, 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 868-3, *Packaging for terminally sterilized medical devices — 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*

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 1924-2, *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method (20 mm/min) (ISO 1924-2)*

EN ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1)*

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 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*

<https://standards.iteh.ai/catalog/standards/sist/32b2c645-ba7d-4d0f-9388-eaf1db8ae867/osist-pren-868-4-2024>

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 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 preformed sterile barrier system or sterile barrier system, the requirements of EN ISO 11607-1 and EN ISO 11607-2 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 6 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 868-4 does not automatically mean compliance to EN ISO 11607-1.

**4.3** All acceptance criteria in Clause 6 shall be applied for testing materials before sterilization.

**4.4** A confirmation of compliance to EN 868-4 shall contain a statement whether EN ISO 11607-1 and EN ISO 11607-2 are covered.

## 5 Construction and design

### 5.1 General

**5.1.1** The bags shall be manufactured from single web paper specified in EN 868-3.

**5.1.2** The following terms shall be used to describe the design of the bag:

- a) back – the surface of the bag with a longitudinal seam;
- b) front – the surface of the bag with no longitudinal seam;
- c) unlippered – where the length of both the front and back surfaces are the same and the front surface has a thumb cut ( $9 \pm 3$ ) mm deep and not less than 15 mm wide;
- d) lippered – where the length of the back surface is greater than the length of the front surface by not less than 10 mm and not more than 25 mm;
- e) gusseted – where the construction of the bag includes side panels;
- f) ungusseted – where the longitudinal edges of the front and back surfaces are contiguous;
- g) seal top – where there is a continuous strip of seal adhesive on the inner surface of the front, back and gussets (if gusseted) of the top of the bag;
- h) plain top – where there is no seal adhesive.

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**5.1.3** The adhesive(s) used in the construction of the bag shall be water resistant and non-corrosive, subsequently referred to as “construction adhesive(s)”.

### 5.2 Bottom seal formation

The bottom seal shall be formed by using one of the following methods:

- a) the bottom shall be double folded with each fold bonded with “construction adhesive”, or
- b) the bottom shall be sealed across the entire width with a “construction adhesive” or with a seal not less than 6,5 mm in depth, or
- c) the bottom shall be sealed across the entire width as described in b) and then folded once, or more, each fold being bonded with (a) construction adhesive(s) or with a heat seal.

### 5.3 Back seam construction

**5.3.1** The longitudinal seam shall be made at the back of the bag with a continuous double line of “construction adhesive(s)”.

**5.3.2** A coloured adhesive shall be used to enable a simple visual check on the continuity of both glue lines.

**5.3.3** The dye shall not impair the adhesive.

### 5.4 Process indicator

If one or more Type I indicator(s) (process indicator(s)) are printed on the pouches and tubes, the indicator’s performance shall comply with the requirements of EN ISO 11140-1. Each individual indicator shall be not less than 100 mm<sup>2</sup> in area. Indicators shall not be affected by the sealing procedure.

### 5.5 Seal strip

**5.5.1** For bags with a seal closure the seal adhesive shall be applied as a continuous strip to the inner surface of the front, back and (if gusseted) the gussets of the bag.

**5.5.2** The width of the seal strip shall be  $(25 \pm 3)$  mm for bags with a width not exceeding 200 mm and  $(40 \pm 3)$  mm for bags with a width exceeding 200 mm.

**5.5.3** The top edge of the seal strip shall be positioned not less than 2 mm and not more than 10 mm from the lower lip or bottom of the thumb cut.

## 6 Performance requirements and test methods

### 6.1 General

NOTE See Annex C for repeatability and reproducibility of the test methods: sulphate content and chloride content. 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.

**6.1.1** The pH of the aqueous extract of the paper and adhesive sandwich shall be within the range 4,5 to 8,0 when tested in accordance with Annex A.

**6.1.2** The chloride content of the aqueous extract of the paper and adhesive sandwich, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with Annex A.