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

EVS EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 868-4:2025 sisaldab Euroopa standardi EN 868-4:2025 ingliskeelset teksti.	This Estonian standard EVS-EN 868-4:2025 consists of the English text of the European standard EN 868-4:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.04.2025.	Date of Availability of the European standard is 30.04.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.30

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-4

April 2025

ICS 11.080.30

Supersedes 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 European Standard was approved by CEN on 14 March 2025.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN 868-4:2025 E

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European foreword

This document (EN 868-4:2025) 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 October 2025, and conflicting national standards shall be withdrawn at the latest by October 2025.

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 868-4:2017.

EN 868-4:2025 includes the following significant technical changes with respect to EN 868-4:2017:

a) The scope was revised for clarity and aligned with other parts of EN 868

b) Normative reference to EN ISO 187 was added.

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

d) 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 requirements apply.

e) Clause 7 “Sterilization compatibility” was added, aligned with the other parts of EN 868 series.

f) Clause 9.2 “Environmental declarations” was added and aligned with the other parts of EN 868 series.

g) The list of major changes was moved to the foreword, thus the Annex with “Details of significant technical changes between this European Standard and the previous edition” (former Annex A) was deleted.

h) New Clause “Environmental aspects” was added to each test method in Annexes A – B.

i) 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.*

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

The EN ISO 11607 series of standards consists of two parts under the general title “Packaging for terminally sterilized medical devices”. EN ISO 11607-1 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. EN ISO 11607-2 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.

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)*

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*