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

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 868-6:2025 sisaldab Euroopa standardi EN 868-6:2025 ingliskeelset teksti.	This Estonian standard EVS-EN 868-6:2025 consists of the English text of the European standard EN 868-6:2025.
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 868-6

April 2025

ICS 11.080.30

Supersedes EN 868-6:2017

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

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

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

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

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

Ref. No. EN 868-6:2025 E

Contents

Page

European foreword

This document (EN 868-6:2025) 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 868-6:2017.

EN 868-6:2025 includes the following significant technical changes with respect to EN 868-6:2017:

a) The scope of the document was amended for clarity and alignment with other parts of EN 868.

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 requirements apply.

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

e) Clause 8 “Environmental declarations” was added, aligned with the other parts of EN 868 series.

f) 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.

g) New Clause “Environmental aspects of testing” was added to each test method in Annexes A and 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.*

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.

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 6 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 paper used in the manufacture of single-use preformed sterile barrier systems and/or packaging systems for terminally sterilized medical devices by 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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 11607-1 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 1 Compliance to EN 868-6 does not automatically mean compliance to EN ISO 11607-1.

NOTE 2 This document introduces test methods in Annex A and Annex B. Annex C provides a statement on repeatability and reproducibility of the test methods for pore diameters, sulfate 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.

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

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

5 Performance requirements and test methods

5.1 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.

5.2 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.

5.3 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.

5.4 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.