SLOVENSKI STANDARD
SIST EN 868-7:2025

01-junij-2025

Nadomešča:
SIST EN 868-7:2017

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: **EN 868-7:2025**

ICS:

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

SIST EN 868-7:2025 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-7

April 2025

ICS 11.080.30

Supersedes 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 des dispositifs médicaux stérilisés au stade terminal - Partie 7 : Papier enduit d'adhésif pour des procédés de stérilisation à basse température - Exigences et méthodes d'essai

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

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

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

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European foreword

This document (EN 868-7:2025) 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of an identical text or by endorsement, at the latest by October 2025, and conflicting national standards shall be withdrawn at the latest by October 2025.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 868-7:2017.

EN 868-7:2025 includes the following significant technical changes with respect to EN 868-7:2017:

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, aligned with the other parts of EN 868 series.

e) Subclause 8.2 “Environmental declarations” was added and 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) A new Clause “Environmental aspects of testing” was added to each test method in Annexes A – E.

h) A 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;*