SLOVENSKI STANDARD
oSIST prEN 868-8:2026

01-marec-2026

Embalaža za končno sterilizirane medicinske pripomočke - 8. del: Ponovno uporabljivi vsebniki za parne sterilizatorje po EN 285 - Zahteve in preskusne metode

Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 - Anforderungen und Prüfverfahren

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 8 : Conteneurs réutilisables de stérilisation pour stérilisateurs à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **prEN 868-8**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

oSIST prEN 868-8:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 868-8

January 2026

ICS 11.080.30

Will supersede EN 868-8:2018

English Version

Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 8 : Conteneurs réutilisables de stérilisation pour stérilisateurs à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 - 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.

CEN members are the national standards bodies of 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 United Kingdom.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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. prEN 868-8:2026 E

Contents

Page

European foreword

This document (prEN 868-8:2026) 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 868-8:2018.

prEN 868-8:2026 includes the following significant technical changes with respect to EN 868-8:2018:

a) Clause 4 “General requirements” was slightly revised for clarity and aligned with the other parts of the EN 868 series, and a statement was added clarifying when acceptance criteria apply.

b) Clause 6 “Environmental declarations” was added and aligned with the other parts of EN 868 series.

c) 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.

d) New Clause “Environmental aspects for testing” was added to each test method in Annexes B, D, E, F and G.

e) New Annex I regarding environmental aspects was added.

EN 868 series 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 constructed of porous materials and plastic film — 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 large steam sterilizers — Requirements and test methods;*

— *Part 9: Uncoated nonwoven materials of polyolefins — Requirements and test methods;*

— *Part 10: Adhesive coated nonwoven materials of polyolefins — Requirements and test methods.*