
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 stérilisateur à la vapeur d'eau conformes à l'EN 285 - Exigences et méthodes d'essai

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

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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.

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

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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.*