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DIN EN 868-5:2009-09

Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods; English version EN 868-5:2018, English translation of DIN EN 868-5:2019-03

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte –
Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien und Kunststoff-Verbundfolie –
Anforderungen und Prüfverfahren;
Englische Fassung EN 868-5:2018,
Englische Übersetzung von DIN EN 868-5:2019-03

Emballages des dispositifs médicaux stérilisés au stade terminal –
Partie 5: Sachets et gaines scellables constitués d'une face matière poreuse et d'une face film plastique –
Exigences et méthodes d'essai;
Version anglaise EN 868-5:2018,
Traduction anglaise de DIN EN 868-5:2019-03

Document comprises 23 pages

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In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (EN 868-5:2018) has been prepared by Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-04 AA "Sterile supply".

The DIN document corresponding to the international document referred to in this document is as follows:

ISO 8601 DIN ISO 8601

Amendments

This standard differs from DIN EN 868-5:2009-09 as follows:

a) normative references have been updated;

b) references to ASTM standards have been added;

c) this European Standard has been amended to be in line with the standards series EN ISO 11607; in particular, the following changes have been made:

   1) the requirements according to EN ISO 11607-1 have been declared general requirements for this standard;

   2) the significance and limits of the requirements of this document have been specified with regard to requirements according to EN ISO 11607-1;

d) different performance requirements and marking requirements have been clarified;

e) the method for the determination of the strength of the seal for pouches and reel material according to Annex D has been amended;

f) the method for the determination of peel characteristics of paper/plastic laminate products according to Annex E has been amended;

g) the Bibliography has been updated.

Previous editions

DIN 58953-4: 1982-11, 1987-01
DIN EN 868-5: 1999-08, 2002-01, 2009-09

National Annex NA
(informative)

Bibliography

DIN ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

EUROPEAN STANDARD

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EN 868-5

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Supersedes EN 868-5:2009

English Version

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This European Standard was approved by CEN on 20 August 2018.

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