DIN EN 868-2

ICS 11.080.30

Supersedes
DIN EN 868-2:2009-09

Packaging for terminally sterilized medical devices – Part 2: Sterilization wrap – Requirements and test methods; English version EN 868-2:2017, English translation of DIN EN 868-2:2017-05

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte –
Teil 2: Sterilisierverpackung –
Anforderungen und Prüfverfahren;
Englische Fassung EN 868-2:2017,
Englische Übersetzung von DIN EN 868-2:2017-05

Emballages des dispositifs médicaux stérilisés au stade terminal –
Partie 2: Enveloppe de stérilisation –
Exigences et méthodes d'essai;
Version anglaise EN 868-2:2017,
Traduction anglaise de DIN EN 868-2:2017-05

Document comprises 27 pages

Translation by DIN-Sprachendienst.

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 868-2:2017) has been prepared ty 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 Standards corresponding to the International Standards referred to in this document are as follows:

ISO 3689	DIN ISO 3689
ISO 3781	DIN ISO 3781
ISO 5725-2	DIN ISO 5725-2
ISO 8601	DIN ISO 8601

Amendments

This standard differs from DIN EN 868-2:2009-09 as follows:

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

   1) terms of EN ISO 11607 have been adopted without additional elements, i.e. the terms “sterile field” and “surgical drape” which are covered by the EN 13795 series have been deleted;

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

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

   4) the test methods with regard to information on statement of precision and bias, repeatability and reproducibility have been linked to those in EN ISO 11607-1:2009 + A1:2014, Table B.1;

b) the test method on fluorescence is in accordance with ISO 2470-2; the test method according to Annex B has been deleted;

c) the following test methods have been updated by a statement on repeatability and reproducibility:

   1) method for the determination of water repellency according to Annex C;

   2) method for the determination of pore size according to Annex D;

d) informative data on repeatability and reproducibility for test methods has been provided for the determination of water repellency according to Annex C as well as for the method for the determination of pore size according to Annex D, the chloride content and the sulphate content;

e) the Bibliography has been updated.

Previous editions

DIN 58953-5: 1982-11, 1987-05
DIN EN 868-2: 1999-08, 2009-09

National Annex NA
(informative)

Bibliography

DIN ISO 3689, *Paper and board — Determination of bursting strength after immersion in water*

DIN ISO 3781, *Paper and board — Determination of tensile strength after immersion in water*

DIN ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

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

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