DIN EN ISO 13408-2

ICS 11.080.01

Supersedes
DIN EN ISO 13408-2:2011-09

Aseptic processing of health care products – Part 2: Sterilizing filtration (ISO 13408-2:2018); English version EN ISO 13408-2:2018, English translation of DIN EN ISO 13408-2:2018-06

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge – Teil 2: Sterilfiltration (ISO 13408-2:2018); Englische Fassung EN ISO 13408-2:2018, Englische Übersetzung von DIN EN ISO 13408-2:2018-06

Traitement aseptique des produits de santé – Partie 2: Filtration stérilisante (ISO 13408-2:2018); Version anglaise EN ISO 13408-2:2018, Traduction anglaise de DIN EN ISO 13408-2:2018-06

Document comprises 48 pages

Translation by DIN-Sprachendienst.

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

A comma is used as the decimal marker.

National foreword

This document (EN ISO 13408-2:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" (Secretariat: BSI, United Kingdom).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-01-12 AA "Aseptic processing".

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

ISO 10993-12:2012	DIN EN ISO 10993-12:2012-10
ISO 11135	DIN EN ISO 11135
ISO 11137-1	DIN EN ISO 11137-1
ISO 11139	DIN EN ISO 11139[*)]
ISO 13408-1:2008	DIN EN ISO 13408-1:2011-09
ISO 13408-1:2008/Amd. 1:2013	DIN EN ISO 13408-1:2015-12
ISO 13408-3	DIN EN ISO 13408-3
ISO 13408-4	DIN EN ISO 13408-4
ISO 13408-5	DIN EN ISO 13408-5
ISO 13408-6	DIN EN ISO 13408-6
ISO 13408-7	DIN EN ISO 13408-7
ISO 13485	DIN EN ISO 13485
ISO 11737-1	DIN EN ISO 11737-1
ISO 17665-1	DIN EN ISO 17665-1

Amendments

This standard differs from DIN EN ISO 13408-2:2011-09 as follows:

a) the structure of the standard has been adapted to ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*;

b) risk management has been included;

c) the informative Annex A has been extended to provide guidance on the application of this document;

d) the standard has been editorially revised.

Previous editions

DIN EN 13824: 2005-02
DIN EN ISO 13408-2: 2011-09

[*)] Stage at the time of publication: draft standard.

National Annex NA
(informative)

Bibliography

DIN EN ISO 10993-12:2012-10, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2012)*

DIN EN ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11139[*)], *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

DIN EN ISO 13408-1:2011-09, *Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008)*

DIN EN ISO 13408-1:2015-12, *Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)*

DIN EN ISO 13408-3, *Aseptic processing of health care products — Part 3: Lyophilization*

DIN EN ISO 13408-4, *Aseptic processing of health care products — Part 4: Clean-in-place technologies*

DIN EN ISO 13408-5, *Aseptic processing of health care products — Part 5: Sterilization in place*

DIN EN ISO 13408-6, *Aseptic processing of health care products — Part 6: Isolator systems*

DIN EN ISO 13408-7, *Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products*

DIN EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

DIN EN ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

DIN EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 13408-2

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English Version

Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)

Traitement aseptique des produits de santé - Partie 2: Filtration stérilisante (ISO 13408-2:2018)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 2: Sterilfiltration (ISO 13408-2:2018)

This European Standard was approved by CEN on 2 January 2018.

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