

## 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

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\*) 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<sup>\*</sup>), *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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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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