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DIN EN ISO 13408-3

ICS 11.080.01

Supersedes: see below

Aseptic processing of health care products – Part 3: Lyophilization (ISO 13408-3:2006) English translation of DIN EN ISO 13408-3:2011-09

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge – Teil 3: Gefriertrocknung (ISO 13408-3:2006) Englische Übersetzung von DIN EN ISO 13408-3:2011-09

Traitement aseptique des produits de santé – Partie 3: Lyophilisation (ISO 13408-3:2006) Traduction anglaise de DIN EN ISO 13408-3:2011-09

Together with DIN EN ISO 13408-1:2011-09, DIN EN ISO 13408-2:2011-09, DIN EN ISO 13408-4:2011-09, DIN EN ISO 13408-5:2011-09 and DIN EN ISO 13408-6:2011-09 supersedes DIN EN 13824:2005-02

Document comprises 22 pages

Translation by DIN-Sprachendienst.

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

National foreword

This standard has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” (Secretariat: ANSI, United States) 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 the *Normenausschuss Medizin* (Medical Standards Committee), Working Committee NA 063-01-12 AA *Aseptische Herstellung*.

ISO 13408 consists of the following parts, under the general title *Aseptic processing of health care products*:

— *Part 1: General requirements*

— *Part 2: Filtration*

— *Part 3: Lyophilization*

— *Part 4: Clean-in-place technologies*

— *Part 5: Sterilization in place*

— *Part 6: Isolator systems*

The following parts are in preparation:

— *Part 7: Alternative processes for atypical medical devices and combination products*

— *Part 8: Cell based health care products*

Parts 1 to 6 of the DIN EN ISO 13408 series supersede DIN EN 13824, *Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements.*

The DIN Standards corresponding to the International Standards referred to in this standard are as follows:

ISO 9000	DIN EN ISO 9000
ISO 9001	DIN EN ISO 9001
ISO 13408-1	DIN EN ISO 13408-1
ISO 13408-4	DIN EN ISO 13408-4
ISO 13408-5	DIN EN ISO 13408-5
ISO 13485	DIN EN ISO 13485

Amendments

This standard differs from DIN EN 13824:2005-02 as follows:

a) the specifications relating to lyophilization have been updated and rendered more precise.

Previous editions

DIN EN 13824: 2005-02

National Annex NA
(informative)

Bibliography

DIN EN ISO 9000, *Quality management systems — Fundamentals and vocabulary*

DIN EN ISO 9001, *Quality management systems — Requirements*

DIN EN ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

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

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