

BS EN ISO 13408-6:2011+A1:2013



BSI Standards Publication

Aseptic processing of health care products

Part 6: Isolator systems

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National foreword

This British Standard is the UK implementation of EN ISO 13408-6:2011+A1:2013. It is identical to ISO 13408-6:2005, incorporating amendment 1:2013. It supersedes BS EN ISO 13408-6:2011, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization of medical devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Amendments/corrigenda issued since publication

Date	Text affected
30 June 2013	Implementation of ISO amendment 1:2013 with CEN endorsement A1:2013. Annexes ZA, ZB and ZC updated

English Version

Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)

Traitement aseptique des produits de santé - Partie 6:
Systèmes isolateurs (ISO 13408-6:2005)

Aseptische Herstellung von Produkten für die
Gesundheitsfürsorge - Teil 6: Isolatorensysteme (ISO
13408-6:2005)

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Foreword

The text of ISO 13408-6:2005 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13408-6:2011 by Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

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Endorsement notice

The text of ISO 13408-6:2005 has been approved by CEN as a EN ISO 13408-6:2011 without any modification.

Foreword to amendment A1

This document (EN ISO 13408-6:2011/A1:2013) 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” the secretariat of which is held by BSI.

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