

BS EN ISO 13408-1:2015



BSI Standards Publication

# Aseptic processing of health care products

Part 1: General requirements

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### National foreword

This British Standard is the UK implementation of EN ISO 13408-1:2015. It is identical to ISO 13408-1:2008, incorporating amendment 1:2013. It supersedes BS EN ISO 13408-1:2011+A1:2013 which is withdrawn.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  $\square_{A1}$   $\square_{A1}$ .

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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### Amendments issued since publication

Date	Text affected
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English Version

## Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)

Traitement aseptique des produits de santé - Partie 1:  
Exigences générales (ISO 13408-1:2008, y compris Amd  
1:2013)

Aseptische Herstellung von Produkten für die  
Gesundheitsfürsorge - Teil 1: Allgemeine Anforderungen  
(ISO 13408-1:2008, einschließlich Amd 1:2013)

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**