BS EN ISO 13408-6:2021

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 13408-6:2021. It is identical to ISO 13408-6:2021. It supersedes BS EN ISO 13408-6:2011+A1:2013, which is withdrawn.

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 committee manager.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association and is intended to support essential requirements of the EU legislation detailed in the European foreword. Annex ZA/ZZ describes how the publication relates to the legislation.

For the Great Britain market (England, Scotland and Wales), if the UK Government has designated this publication for conformity with UKCA marking legislation and has not amended the essential requirements of that legislation, Annex ZA/ZZ and any references to EU law in the publication should be read in accordance with the designation as applying to UK legislation in the same way as to EU law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. References to EU legislation are therefore still valid.

More information on legislation can be found at www.gov.uk.

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Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13408-6

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English Version

Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)

Traitement aseptique des produits de santé - Partie 6: Systèmes isolateurs (ISO 13408-6:2021)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 6: Isolatorensysteme (ISO 13408-6:2021)

This European Standard was approved by CEN on 7 June 2020.

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European foreword

This document (EN ISO 13408-6:2021) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 13408-6:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZA, ZB, ZC, ZD and ZE which are an integral parts of this document.

This document is an adoption of an International Standard. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the scope of this document can differ from the scope of the European Regulations that it supports. This document supports European regulatory requirements only to the extent of the scope of the European regulations for medical devices and in vitro diagnostic medical devices. For relationship with EU Directive(s) and Regulations, see informative Annex ZA, ZB, and ZC, and additional Annexes ZD and ZE which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annexes ZA, ZB, ZC, ZD and ZE’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — – Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 11139	EN ISO 11139:2018	ISO 11139:2018
ISO 13408-1:2008	EN ISO 13408-1:2015	ISO 13408-1:2008
ISO 13408-4	EN ISO 13408-4:2011	ISO 13408-4:2005
ISO 13408-7	EN ISO 13408-7:2015	ISO 13408-7:2012
ISO 14644-1:2015	EN ISO 14644-1:2015	ISO 14644-1:2015
ISO 14644-7	EN ISO 14644-7:2004	ISO 14644-7:2004
ISO 18362:2016	No equivalent	ISO 18362:2016
ISO/IEC/IEEE 90003	No equivalent	ISO/IEC/IEEE 90003:2018

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