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 It supersedes BS EN ISO 13408-6:2011, which is withdrawn.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〈.

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.

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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Published by BSI Standards Limited 2013

ISBN 978 0 580 76266 6

ICS 11.080.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 October 2011.

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13408-6:2011+A1

March 2013

ICS 11.080.01

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)

This European Standard was approved by CEN on 10 June 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Ref. No. EN ISO 13408-6:2011: E

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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.

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 December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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

This document supersedes EN 13824:2004.

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 Directives.

For relationship with EU Directives, see informative Annexes ZA, ZB, or ZC, which are integral parts of this document.

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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.

This Amendment to the European Standard EN ISO 13408:2011 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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Endorsement notice

The text of ISO 13408-6:2005/Amd 1:2013 has been approved by CEN as EN ISO 13408-6:2011/A1:2013 without any modification.

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Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10	7	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

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Annex ZB
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10	8.3	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10	8.4	This relevant Essential Requirement is addressed in this International standard only in conjunction with ISO 13408-1

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Annex ZC
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EC

Clauses of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4,5,6,7,8,9,10	B.2.3	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10	B.2.4	This relevant Essential Requirement is addressed in this International standard only in conjunction with ISO 13408-1

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13408-6 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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*

〚A1〛 — *Part 7: Alternative processes for medical devices and combination products* 〚/A1〛

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