



NSAI
Standards

Irish Standard
I.S. EN ISO 13408-6:2011

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

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I.S. EN ISO 13408-6:2011

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English Version

Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005/Amd 1:2013)

Traitement aseptique des produits de santé - Partie 6:
Systèmes isolateurs (ISO 13408-6:2005/Amd 1:2013)

Aseptische Herstellung von Produkten für die
Gesundheitsfürsorge - Teil 6: Isolatorenssysteme (ISO
13408-6:2005/Amd 1:2013)

This amendment A1 modifies the European Standard EN ISO 13408-6:2011; it was approved by CEN on 7 March 2013.

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Contents

Page

Foreword.....	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices	4
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	5
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.....	6

Foreword

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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.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.

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: Isolatorenssysteme (ISO
13408-6:2005)

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

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Contents	Page
Foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices	4
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	5
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices	6

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.

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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.

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	This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with EN ISO 13408-1

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

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	This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with EN ISO 13408-1
4,5,6,7,8,9,10	8.4	This relevant Essential Requirement is addressed in this European standard only in conjunction with EN 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	This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with EN ISO 13408-1
4,5,6,7,8,9,10	B.2.4	This relevant Essential Requirement is addressed in this European standard only in conjunction with EN ISO 13408-1

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INTERNATIONAL STANDARD

ISO
13408-6

First edition
2005-06-15

Aseptic processing of health care products —

Part 6: Isolator systems

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs



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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Quality system elements.....	3
4.1 General.....	3
4.2 Management responsibility	3
4.3 Design control.....	3
4.4 Measuring instruments and measuring systems	3
5 Design of isolator systems	4
5.1 General.....	4
5.2 Types of isolators	4
5.3 Materials of construction	4
5.4 Air-handling system	4
5.5 Operator interface.....	5
5.6 Ancillary equipment.....	6
6 Facility requirements.....	6
6.1 Surrounding room classification	6
6.2 Process utilities	7
7 User requirements	7
7.1 Product/process application	7
7.2 Ergonomics	7
7.3 Cleaning.....	7
7.4 Bio-decontamination	8
8 Validation.....	10
8.1 General.....	10
8.2 Design qualification.....	11
8.3 Installation qualification.....	11
8.4 Operational qualification.....	12
8.5 Performance qualification.....	13
8.6 Review and approval of validation.....	14
8.7 Requalification	14
9 Routine monitoring and control	14
9.1 Procedures	14
9.2 System integrity	14
9.3 Bio-decontamination process monitoring	15
9.4 Environmental monitoring	15
9.5 Change control.....	15
9.6 Maintenance and calibration	15
10 Personnel training	15
Bibliography	17

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.

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

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*

Introduction

Health care products that are labelled “sterile” are prepared by using appropriate and validated methods. When a health care product is intended to be sterile and cannot be terminally sterilized, aseptic processing provides an alternative. This applies to the aseptic preparation and filling of solutions, suspensions, emulsions, and solids, as well as to the aseptic handling, transfer and filling of those products which cannot be terminally sterilized.

Aseptic processing is an exacting and demanding discipline. It is essential that manufacturers make use of qualified/validated systems, adequately trained personnel, controlled environments and well-documented systematic processes to assure a sterile finished product.

Aseptic processing of health care products —

Part 6: Isolator systems

1 Scope

This part of ISO 13408 specifies the requirements for isolator systems used for aseptic processing and offers guidance on qualification, bio-decontamination, validation, operation and control of isolator systems used for aseptic processing of health care products.

This part of ISO 13408 is focused on the use of isolator systems to maintain aseptic conditions; this may include applications for hazardous materials.

This part of ISO 13408 does not supersede or replace national regulatory requirements, such as Good Manufacturing Practices (GMPs) and/or compendial requirements that pertain in particular to national or regional jurisdictions.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13408-1:1998, *Aseptic processing of health care products — Part 1: General requirements*

ISO 13408-4:—¹⁾, *Aseptic processing of health care products — Part 4: Clean-in-place technologies*

ISO 13408-5:—¹⁾, *Aseptic processing of health care products — Part 5: Sterilization in place*

ISO 14644-7:2004, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

ISO/IEC 90003, *Software engineering — Guidelines for the application of ISO 9001:2000 to computer software*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13408-1:1998 and the following apply.

3.1

bio-decontamination

removal of microbiological contamination or its reduction to an acceptable level

1) To be published.

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