

**Tervishoiutoodete aseptiline töötlemine. Osa 6:  
Isolaatorsüsteemid (ISO 13408-6:2005)**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 13408-6:2011 sisaldab Euroopa standardi EN ISO 13408-6:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.07.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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This Estonian standard EVS-EN ISO 13408-6:2011 consists of the English text of the European standard EN ISO 13408-6:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 29.07.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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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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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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

## 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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

### 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

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

## 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

**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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## 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:—<sup>1)</sup>, *Aseptic processing of health care products — Part 4: Clean-in-place technologies*

ISO 13408-5:—<sup>1)</sup>, *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

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1) To be published.