

**Tervishoiutoodete aseptiline töötlemine. Osa 4:
Kohapeal puhastamise tehnoloogiad (ISO 13408-4:2005)**

Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 13408-4:2011 sisaldab Euroopa standardi EN ISO 13408-4:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 29.07.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 29.06.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 13408-4:2011 consists of the English text of the European standard EN ISO 13408-4:2011.</p> <p>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.</p> <p>Date of Availability of the European standard text 29.06.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)

Traitement aseptique des produits de santé - Partie 4:
Technologies de nettoyage sur place (ISO 13408-4:2005)

Aseptische Herstellung von Produkten für die
Gesundheitsfürsorge - Teil 4: Reinigung vor Ort (ISO
13408-4:2005)

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Foreword

The text of ISO 13408-4:2005 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 13408-4:2011 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of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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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 13408-4:2005 has been approved by CEN as a EN ISO 13408-4:2011 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.

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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

During the process of preparing ISO 13408-1 several items, e.g. filtration, lyophilization drying and sterilization-in-place technologies, were found to be in need of supplementary information that was too voluminous to be given in corresponding annexes.

This part of ISO 13408 includes requirements and guidance that are to be observed during clean-in-place processes. The purpose of this part of ISO 13408 is to achieve standardization in the field of validation and routine control of clean-in-place processes used in the manufacture of health care products.

Clean-in-place processes allow parts of the equipment or an entire process system to be cleaned without being dismantled, reducing the need for disassembling and connections under clean conditions. For example, tanks, vessels, freeze-dryers piping and other processing equipment used for manufacture may be cleaned in place.

The clean-in-place process is in most instances followed by sterilization-in-place process (described in ISO 13408-5). While clean-in-place and sterilization-in-place methods differ considerably in technology, the concept of *in situ* treatment is similar.

Design considerations of all systems are critical to ensure that clean-in-place technologies can be successfully applied to clean manufacturing equipment to the desired level of cleanliness.

Aseptic processing of health care products —

Part 4: Clean-in-place technologies

1 Scope

This part of ISO 13408 specifies the general requirements for clean-in-place (CIP) processes applied to product contact surfaces of equipment used in the manufacture of sterile health care products by aseptic processing and offers guidance on qualification, validation, operation and control.

This part of ISO 13408 is applicable to processes where cleaning agents are delivered to the internal surfaces of equipment designed to be compatible with CIP, which may come in contact with the product.

This part of ISO 13408 is not applicable to processes where equipment is dismantled and cleaned in a washer.

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 to particular 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, *Aseptic processing of health care products — Part 1: General requirements*

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 and the following apply.

3.1

cleaning agent

organic or inorganic chemical including water, detergent or mixture thereof, used as an aid in the cleaning process for cleaning equipment

3.2

clean-in-place

CIP

method of cleaning of the internal surfaces of parts of the equipment or an entire process system without or with minimal disassembly

NOTE CIP also includes the removal of remaining residual cleaning agent to an acceptable level which is defined based on the nature of the product and the process tolerance.