Tervishoiutoodete aseptiline töötlemine. Osa 5: Kohapeal steriliseerimine (ISO 13408-5:2006)

Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 13408-5:2011 sisaldab Euroopa standardi EN ISO 13408-5:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13408-5:2011 consists of the English text of the European standard EN ISO 13408-5:2011.
Standard on kinnitatud Eesti Standardikeskuse 29.07.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	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.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 29.06.2011.	Date of Availability of the European standard text 29.06.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.080.01

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13408-5

June 2011

ICS 11.080.01

Supersedes EN 13824:2004

English Version

Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)

Traitement aseptique des produits de santé - Partie 5: Stérilisation sur place (ISO 13408-5:2006)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 5: Sterilisation vor Ort (ISO 13408-5:2006)

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

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Ref. No. EN ISO 13408-5:2011: E

Foreword

The text of ISO 13408-5:2006 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 13408-5:2011 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of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.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 13408-5:2006 has been approved by CEN as a EN ISO 13408-5:2011 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

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

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

Sterilization in place is, in most instances, preceded by cleaning in place which is described in ISO 13408-4. While methods of cleaning in place and sterilization in place differ considerably in technology, the concept of *in situ* treatment is similar.

The most important issue to consider in establishing sterilization-in-place technology is the design of the system(s) to ensure that they be able to successfully sterilize manufacturing equipment to the desired level of sterility assurance.

Aseptic processing of health care products —
Part 5:
Sterilization in place

1 Scope

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

NOTE SIP can be achieved by using steam or other gaseous or liquid sterilizing agents. Specific guidance on steam sterilization in place, which is the most common method used, is given in Annex A.

1.2 This part of ISO 13408 applies to processes where sterilizing agents are delivered to the internal surfaces of equipment that can come in contact with the product.

1.3 This part of ISO 13408 does not apply to processes where equipment is dismantled and delivered to a sterilizer.

1.4 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 national or regional jurisdictions.

1.5 This part of ISO 13408 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See also ISO 22442-1, ISO 22442-2 and ISO 22442-3.

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 11138 (all parts), *Sterilization of health care products — Biological indicators*

ISO 11140 (all parts), *Sterilization of health care products — Chemical indicators*

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

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

ISO 14161, *Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

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
dead leg
location which, by design, does not permit adequate accessibility of the sterilizing agent

3.2
design qualification
verification that the proposed specification for the facility, equipment or system is suitable for the intended use

[ISO/TS 11139:2006, definition 2.12]

3.3
material safety data sheet
MSDS
document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

[ISO/TS 11139:2006, definition 2.23]

3.4
process parameter
specified value for a process variable

NOTE The specification for a sterilization process includes the process parameters and their tolerances.

[ISO/TS 11139:2006, definition 2.34]

3.5
process variable
condition within a sterilization process, changes in which alter microbicidal effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[ISO/TS 11139:2006, definition 2.35]

3.6
sterilization in place
SIP
method of sterilization of the internal surfaces of parts of the equipment or an entire process system *in situ*, without disassembly, using appropriate sterilizing agents

NOTE The term “Steam in place” is used in ISO 13408-1, Clause 19, and this term is sometimes abbreviated as SIP. However, in this part of ISO 13408, “SIP” is used with a wider meaning and includes not only steam in place, but all kinds of sterilization used for the sterilization “in place” or “in situ”. In this part of ISO 13408, “Steam sterilization in place” is referred to as “Steam SIP”.