



SLOVENSKI STANDARD SIST EN ISO 13408-3:2011

01-oktober-2011

Nadomešča:
SIST EN 13824:2005

Aseptična proizvodnja izdelkov za zdravstveno nego - 3. del: Liofilizacija (ISO 13408-3:2006)

Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 3:
Gefriertrocknung (ISO 13408-3:2006)

(standards.iteh.ai)

Traitement aseptique des produits de santé - Partie 3: Lyophilisation (ISO 13408-3:2006)

[SIST EN ISO 13408-3:2011](https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-100000000000/sist-en-iso-13408-3-2011)

[https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-](https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-100000000000/sist-en-iso-13408-3-2011)

Ta slovenski standard je istoveten z: EN ISO 13408-3:2011

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
-----------	--	---

SIST EN ISO 13408-3:2011

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 13408-3:2011

<https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13408-3

June 2011

ICS 11.080.01

Supersedes EN 13824:2004

English Version

**Aseptic processing of health care products - Part 3:
Lyophilization (ISO 13408-3:2006)**

Traitement aseptique des produits de santé - Partie 3:
Lyophilisation (ISO 13408-3:2006)

Aseptische Herstellung von Produkten für die
Gesundheitsfürsorge - Teil 3: Gefriertrocknung (ISO 13408-
3:2006)

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.

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.

[SIST EN ISO 13408-3:2011](https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011)

<https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 13408-3:2011](https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011)

<https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011>

Foreword

The text of ISO 13408-3:2006 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 13408-3:2011 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 13408-3:2006 has been approved by CEN as a EN ISO 13408-3:2011 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	7	This relevant Essential Requirement is only partly addressed in this European Standard and only in conjunction with EN ISO 13408-1

SIST EN ISO 13408-3:2011

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	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	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	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	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.

INTERNATIONAL STANDARD

ISO
13408-3

First edition
2006-09-15

Aseptic processing of health care products —

Part 3: Lyophilization

*Traitement aseptique des produits de santé —
Partie 3: Lyophilisation*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 13408-3:2011

<https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011>



Reference number
ISO 13408-3:2006(E)

© ISO 2006

ISO 13408-3:2006(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 13408-3:2011](https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011)

<https://standards.iteh.ai/catalog/standards/sist/3b345bfe-a88b-4073-b97a-f40fa8cc025e/sist-en-iso-13408-3-2011>

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Quality system elements.....	1
4.1 General.....	1
4.2 Management responsibility	2
4.3 Design control.....	2
4.4 Measuring instruments and/or measuring systems	2
5 Product definition	2
6 Process definitions.....	2
7 User requirements	3
7.1 General.....	3
7.2 Equipment characterization.....	3
7.3 Product handling	4
7.4 Microbiological and particulate environmental monitoring	4
7.5 Cleaning and sterilization	4
7.6 Vent filter system	5
7.7 Lyophilizer leak test.....	5
8 Validation	5
8.1 General.....	5
8.2 Design qualification.....	6
8.3 Installation qualification.....	6
8.4 Operational qualification.....	6
8.5 Performance qualification.....	8
8.6 Process validation	8
8.7 Review and approval of validation.....	9
9 Routine monitoring and control	9
9.1 General.....	9
9.2 Operator training.....	9
9.3 Standard operating procedures	9
9.4 Requalification	10
9.5 Maintenance of equipment	10
9.6 Change control.....	10
Bibliography	11