SLOVENSKI STANDARD
SIST EN ISO 13408-6:2011/A1:2013

01-junij-2013

Aseptična proizvodnja izdelkov za zdravstveno nego - 6. del: Sistemi izolatorjev - Dopolnilo A1 (ISO 13408-6:2005/Amd 1:2013)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 13408-6:2011/A1:2013**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 13408-6:2011/A1:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13408-6:2011/A1

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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)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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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.

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 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 Annex ZA, B, C, which is an integral part 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

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	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered

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	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10	8.4	This relevant Essential Requirement is addressed in this International standard only in conjunction with 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	In conjunction with EN ISO 13408-1, this relevant Essential Requirement is only partly addressed in this International Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10	B.2.4	This relevant Essential Requirement is addressed in this International standard only in conjunction with 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

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AMENDMENT 1
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Aseptic processing of health care products —

Part 6: Isolator systems

AMENDMENT 1

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs

AMENDEMENT 1

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