SVENSK STANDARD
SS-EN ISO 13408-1:2011/A1:2013

Fastställd/Approved: 2013-05-13
Publicerad/Published: 2013-05-20
Utgåva/Edition: 1
Språk/Language: engelska/English
ICS: 11.080.01; 11.080.20; 11.120.01

Aseptisk behandling av medicintekniska produkter – Del 1: Allmänna krav (ISO 13408-1:2008/Amd 1:2013)

Aseptic processing of health care products – Part 1: General requirements (ISO 13408-1:2008/Amd 1:2013)

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka
Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet
Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence
As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work
We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception
With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00

Europastandarden EN ISO 13408-1:2011/A1:2013 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 13408-1:2011/A1:2013.

The European Standard EN ISO 13408-1:2011/A1:2013 has the status of a Swedish Standard. This document contains the official version of EN ISO 13408-1:2011/A1:2013.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Sterilisering av medicintekniska produkter, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13408-1:2011/A1

May 2013

ICS 11.080.01

English Version

Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008/Amd 1:2013)

Traitement aseptique des produits de santé - Partie 1: Exigences générales (ISO 13408-1:2008/Amd 1:2013)

Aseptische Herstellung von Produkten für die Gesundheitsfürsorge - Teil 1: Allgemeine Anforderungen (ISO 13408-1:2008/Amd 1:2013)

This amendment A1 modifies the European Standard EN ISO 13408-1:2011; it was approved by CEN on 18 April 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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 13408-1:2011/A1:2013: E

Foreword

This document (EN ISO 13408-1:2011/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 November 2013, and conflicting national standards shall be withdrawn at the latest by November 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 and C, 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, 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 13408-1:2008/Amd 1:2013 has been approved by CEN as EN ISO 13408-1:2011/A1:2013 without any modification.

Aseptic processing of health care products —

Part 1:
General requirements

AMENDMENT 1

Page vi, Introduction

In the second paragraph, replace the second sentence with the following:

> ISO/TC 198 has prepared standards for terminal sterilization of health care products by irradiation (ISO 11137 series), by moist heat (ISO 17665 series), by dry heat (ISO 20857), by ethylene oxide (ISO 11135) and by liquid chemical sterilants (ISO 14160).

Page vii, Introduction

At the end of the last sentence of the penultimate paragraph, add the word "component" so that it reads:

> "... of which process simulation studies are an essential component."

Page 1, Normative references

Delete the following reference:

> ISO 9001, *Quality management systems — Requirements*

Page 2, Normative references

Delete footnote 1 and renumber footnote 2 accordingly.

Page 3, 3.7

Delete the following:

> [ISO 13408-6:2005, definition 3.1]

Page 4, 3.14

Correct the spelling of the term to read "depyrogenation".

Page 5, 3.24

Replace the note with the following:

NOTE The required grade of cleanliness of the indirect support zone depends on the aseptic processing technologies and activities performed.

Page 7, 4.1.1

In the first sentence, replace "over all activities affecting aseptic processing" with "over all activities affecting aseptic processing (e.g. ISO 9001 and/or ISO 13485)".

Delete the second sentence.

Page 7, 4.3.2

Replace the text with the following:

The accuracy and tolerance of all measuring instruments shall be adequate for the parameters to be measured.

Page 8, 5.2.1.2

At the end of the subclause, insert the following note:

NOTE Assessment of risk to condone poor or improper practice during aseptic processing is not appropriate.

Page 10, 5.2.4.4

Replace item a) with the following:

a) microbiological quality of the product at defined stages during the manufacturing process, alert and action levels shall be established;

Page 10, 6.1.2

Replace the second sentence of the note with the following:

Where highly potent, cytotoxic or radioactive health care products are to be processed, protection of personnel and the environment is considered an ancillary element of aseptic processing design.

Page 36, Table 1, fifth column

In the first, third and fifth rows, replace "restart validation" with "repeat initial performance qualification" to be in line with the title of Table 1.

Page 36, Table 2, fourth column

In the first, third and fifth rows, replace "revalidation" with "repeat initial performance qualification" to be in line with the title of Table 1.