

# SVENSK STANDARD

## SS-EN ISO 14160:2011

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**Sterilisering av medicintekniska produkter – Flytande kemiska steriliseringsmedia för medicintekniska produkter avsedda för engångsbruk innehållande vävnader från djur och derivat därav – Krav för karakterisering, utveckling, validering och rutinkontroll av steriliseringsprocesser för medicintekniska produkter (ISO 14160:2011)**

**Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2011)**

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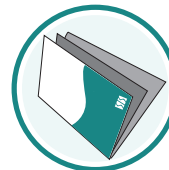
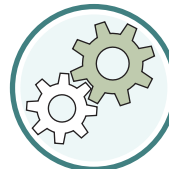
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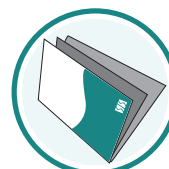
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Denna standard ersätter SS-EN ISO 14160, utgåva 1.

The European Standard EN ISO 14160:2011 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14160:2011.

This standard supersedes the Swedish Standard SS-EN ISO 14160, edition 1.

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EUROPEAN STANDARD

EN ISO 14160

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2011

ICS 11.080.01

Supersedes EN ISO 14160:1998

English Version

**Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2011)**

Stérilisation des produits de santé - Agents stérilisants chimiques liquides pour dispositifs médicaux non réutilisables utilisant des tissus animaux et leurs dérivés - Exigences pour la caractérisation, le développement, la validation et le contrôle de routine d'un procédé de stérilisation de dispositifs médicaux (ISO 14160:2011)

Sterilisation von Produkten für die Gesundheitsfürsorge - Flüssige chemische Sterilisiermittel für Medizinprodukte für den einmaligen Gebrauch, bei denen tierische Gewebe und deren Derivate verwendet werden - Anforderungen an die Charakterisierung, Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 14160:2011)

This European Standard was approved by CEN on 30 June 2011.

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## Foreword

This document (EN ISO 14160:2011) 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 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 January 2012, and conflicting national standards shall be withdrawn at the latest by January 2012.

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 ISO 14160:1998.

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 Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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### Endorsement notice

The text of ISO 14160:2011 has been approved by CEN as a EN ISO 14160:2011 without any modification.





## Introduction

A sterile medical device is one that is free of viable microorganisms. International standards, which specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one medical device in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a medical device.

Attention also has to be given to a number of factors, including the microbiological status (bioburden) of incoming raw materials and/or components and their subsequent storage, and to the control of the environment in which the product is manufactured, assembled and packaged (see also ISO 13485).

Requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained.

Animal tissues and their derivatives are used as constituents of certain medical devices to provide performance characteristics that present advantages over the characteristics provided by non-animal-based materials. The range and quantities of materials of animal origin in medical devices vary; such materials can comprise a major part of the device, can be a product coating or impregnation, or can be used in the manufacturing process for the medical device.

This International Standard describes requirements that, if met, will provide a liquid chemical sterilization process that has appropriate microbicidal activity for single-use medical devices containing materials of animal origin or their derivatives. The sterilizing agents used most frequently for medical devices are moist heat, dry heat, irradiation and ethylene oxide. While some devices containing animal tissues may be compatible with these commonly applied methods of sterilization (historically, for example, catgut sutures have been sterilized by irradiation), other devices, such as biological heart valves or tissue patches, are not compatible with conventional sterilization processes. It has been recognized that other sterilizing agents might have to be used in these exceptional circumstances. Liquid chemical sterilization is normally chosen over other sterilization processes in order that the medical devices present the desired physical properties of the tissue after sterilization. Sterilization by liquid chemicals of medical devices made in whole or in part from tissues of animal origin represents a special case in terms of establishing an effective sterilization process. In common with the other sterilization methods, the efficacy of a liquid chemical sterilization process needs to be demonstrated and recorded before it is adopted for routine use.

Liquid chemical sterilization requires determination of types of microorganisms comprising the bioburden and their resistance to the sterilization process in order to establish the appropriate reference microorganism, whether that be a recognized biological indicator or an isolate from the bioburden. Compliance with the requirements of this International Standard ensures that the microbicidal activity of the liquid chemical

sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on a product after sterilization. Specification of this probability is a matter for regulatory authorities and may vary among regions or countries (see, for example, EN 556-1 and ANSI/AAMI ST67).

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

- a) the source and harvesting conditions of the tissue;
- b) the microbiological status of incoming raw materials or components, or both;
- c) the routine control of any cleaning and disinfection procedures used on the product;
- d) the control of the environment in which the product is manufactured, assembled and packaged;
- e) the control of equipment and processes;
- f) the control of personnel and their hygiene;
- g) the manner and materials in which the product is packaged; and
- h) the conditions under which product is stored.

# **Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices**

## **1 Scope**

This International Standard specifies requirements for the characterization of a liquid chemical sterilizing agent and for the development, validation, process control and monitoring of sterilization by liquid chemical sterilizing agents of single-use medical devices comprising, in whole or in part, materials of animal origin.

This International Standard covers the control of risks arising from contamination with bacteria and fungi by application of a liquid chemical sterilization process. Risks associated with other microorganisms can be assessed using other methods (see Note 1).

This International Standard is not applicable to material of human origin.

This International Standard does not describe methods for the validation of the inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (see Note 2).

This International Standard does not describe methods for validation of the inactivation or elimination of protozoa and parasites.

The requirements for validation and routine control described in this International Standard are only applicable to the defined sterilization process of a medical device, which is performed after the manufacturing process, and do not take account of the lethal effects of other bioburden reduction steps (see Note 4).

This International Standard does not specify tests to establish the effects of any chosen sterilization process upon the fitness for use of the medical device (see Note 5).

This International Standard does not cover the level of residual sterilizing agent within medical devices (see Note 6).

This International Standard does not describe a quality management system for the control of all stages of manufacture (see Note 7).

NOTE 1 The prior application of risk management principles to medical devices utilizing animal tissues, as described in ISO 22442-1, is important.

NOTE 2 Liquid chemical sterilizing agents traditionally employed to sterilize animal tissues in medical devices might not be effective in inactivating the causative agents of TSE such as bovine spongiform encephalopathy (BSE), or scrapie. Satisfactory validation in accordance with this International Standard does not necessarily demonstrate inactivation of infective agents of this type. Risk controls related to sourcing, collection and handling of animal materials are described in ISO 22442-2.

NOTE 3 The validation of the inactivation, elimination, or elimination and inactivation of viruses and TSE agents is described in ISO 22442-3.