SLOVENSKI STANDARD
SIST EN ISO 14160:2000

01-januar-2000

Sterilizacija medicinskih pripomoļkov za enkratno uporabo, ki vsebujejo materiale ģivalskega izvora - Validacija in redni nadzor sterilizacije s tekoļimi kemijskimi sredstvi za sterilizacijo (ISO 14160:1998)

Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants (ISO 14160:1998)

Sterilisation von Medizinprodukten für den einmaligen Gebrauch mit Bestandteilen tierischer Herkunft - Validierung und Routineüberwachung der Sterilisation mit flüssigen chemischen Sterilisiermitteln (ISO 14160:1998)

Stérilisation des dispositifs médicaux non réutilisables contenant des matieres d'origine animale - Validation et contrôle de routine de la stérilisation par agents stérilisants chimiques liquides (ISO 14160:1998)

Ta slovenski standard je istoveten z: **EN ISO 14160:1998**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 14160:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14160

March 1998

ICS 11.080

Descriptors: see ISO document

English version

Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants (ISO 14160: 1998)

Stérilisation des dispositifs médicaux non réutilisables contenant des matières d'origine animale - Validation et contrôle de routine de la stérilisation par agents stérilisants chimiques liquides (ISO 14160:1998)

Sterilisation von Medizinprodukten für den einmaligen Gebrauch mit Bestandteilen tierischer Herkunft - Validierung und Routineüberwachung der Sterilisation mit flüssigen chemischen Sterilisiermitteln (ISO 14160:1998)

This European Standard was approved by CEN on 13 February 1998.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 14160:1998 E

Foreword

The text of the International Standard ISO 14160:1998 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 month of September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

This European Standard 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(s).

For relationship with EU Directive(s), see informative Annex ZB, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14160:1998 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 9001	1994	Quality systems - Model for quality assurance in design, development, production, installation and servicing	EN ISO 9001	1994
ISO 9002	1994	Quality systems - Model for quality assurance in production, installation and servicing	EN ISO 9002	1994

Annex ZB (informative)

Clauses of this European Standard addressing esential requirements or other provisions of EU directives.

This Europrean standard 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 93/42/EWG.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this international standard as detailed in table ZB.1 are likely to support requirements of the Directive 93/42/EWG.

Compliance with the clauses if this international standard provides one means of conforming with the specific essential requirements if the Directive concerned and associated EFTA regulations.

Table ZB.1

Clauses/sub-clauses of this standard	Corresponding ERs of Directive 93/42/EWG	Comments
4, 5, 6, 7	8.4	

INTERNATIONAL STANDARD

ISO 14160

First edition
1998-03-15

Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid sterilants

Stérilisation des dispositifs médicaux non réutilisables contenant des matières d'origine animale — Validation et contrôle de routine de la stérilisation par agents stérilisants chimiques liquides

Reference number
ISO 14160:1998(E)

Contents

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X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

International Standard ISO 14160 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Annexes A, B and C of this International Standard are for information only.

Introduction

A sterile product item is one which is free of viable microorganisms. International Standards require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a medical device from all sources prior to sterilization be minimized by all practical means. Even so, product items produced under defined manufacturing conditions in accordance with the requirements for quality systems for medical devices (see ISO 13485 and ISO 13488) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are non-sterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the non-sterile items into sterile ones.

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

Generic requirements for the quality system for the design/development, production, installation and servicing are given in the ISO 9000 family of standards and in ISO 13485 and ISO 13488. The ISO 9000 series of standards designates certain processes used in manufacture as "special" if the results cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, sterilization processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

It is important to be aware that the exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and in this respect suitable for its intended use. Attention has also to be given to a number of factors, including the microbiological status (bioburden) of incoming raw materials and/or components, their subsequent storage, and to the control of the environment in which the product is manufactured, assembled and packaged.

The agents for sterilization 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 (for example catgut sutures are usually 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 sterilants have been widely used in such instances and, in common with the other sterilization methods, the efficacy of the process needs to be demonstrated and recorded before it is adopted for routine use.

This International Standard contains requirements for the validation and routine monitoring of sterilization of single-use medical devices containing materials of animal origin by exposure to liquid chemical sterilants; guidance on the application of this International Standard is given in annex A. Manufacturing processes for medical devices containing animal tissues frequently include exposure to chemical agents which can in themselves reduce significantly the bioburden on the medical device. Following the manufacturing process, a medical device is exposed to a defined sterilization process; the requirements for validation and routine control described in this International Standard apply only to this defined sterilization process and do not take account of the lethal effects of other bioburden reduction steps.

NOTE — The guidance given in annex A is not obligatory and it is not provided as a check list for auditors.