SLOVENSKI STANDARD
SIST EN ISO 11737-2:2001

01-november-2001

Sterilizacija medicinskih pripomoļ kov - Mikrobiologķke metode - 2. del: Preskusi sterilnosti pri validaciji sterilizacijskih postopkov (ISO 11737-2:1998)

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2:1998)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Sterilitätsprüfungen bei der Validierung eines Sterilisationsverfahrens (ISO 11737-2:1998)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 2: Essais de stérilité pratiqués en cours de validation d'un procédé de stérilisation (ISO 11737-2:1998)

Ta slovenski standard je istoveten z: **EN ISO 11737-2:2000**

ICS:

07.100.10	Medicinska mikrobiologija	Medical microbiology
11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11737-2:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-2

February 2000

ICS 07.100.10; 11.080

English version

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2:1998)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 2: Essais de stérilité pratiqués en cours de validation d'un procédé de stérilisation (ISO 11737-2:1998)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Sterilitätsprüfungen bei der Validierung eines Sterilisationsverfahrens (ISO 11737-2:1998)

This European Standard was approved by CEN on 17 December 1999.

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

Foreword

The text of the International Standard from Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) has been taken over as an European Standard 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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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 11737-2:21998 has been approved by CEN as a European Standard without any modification.

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

EN ISO 11737-2:200

INTERNATIONAL STANDARD

ISO 11737-2

First edition
1998-07-01

Sterilization of medical devices — Microbiological methods —

Part 2: Tests of sterility performed in the validation of a sterilization process

Stérilisation des dispositifs médicaux — Méthodes microbiologiques

Partie 2: Essais de stérilité pratiqués en cours de validation d'un procédé de stérilisation

Reference number
ISO 11737-2:1998(E)

Contents

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 11737-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11737 consists of the following parts, under the general title *Sterilization of medical devices — Microbiological methods*:

— *Part 1: Estimation of the population of microorganisms on product*

— *Part 2: Tests of sterility performed in the validation of a sterilization process*

Annex A of this International Standard is for information only.

Introduction

A sterile product item is one which is free of viable microorganisms. The International Standards for sterilization of medical devices require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a medical device from all sources be minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with the requirements for quality systems for medical devices may, 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 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 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 the existence of a non-sterile item in that population.

Requirements for the quality system for the design/development, production, installation and servicing of medical devices are given in ISO 9001 and ISO 9002 in conjunction with ISO 13485 and ISO 13488, respectively.

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.

International Standards specifying procedures for the validation and routine control of the processes used for sterilization of medical devices have been prepared (see ISO 11134, 11135 and 11137). An element of this validation may consist of exposing medical devices to the sterilizing agent when the extent of treatment has been reduced relative to that which will be used in routine processing in order to provide a knowledge of the resistance to the agent of the microbial contamination as it occurs naturally on medical devices. Subsequent to this exposure, medical devices are subjected individually to tests of sterility as described in this part of ISO 11737. An example of the use of such a test is in establishing a sterilizing dose for sterilization by radiation and for demonstrating the continued validity of this sterilization dose (see ISO 11137, Annex B).

Annex A of this part of ISO 11737 gives guidance on the techniques used and on practical aspects of the requirements.

Sterilization of medical devices — Microbiological methods —

Part 2:
Tests of sterility performed in the validation of a sterilization process

1 Scope

1.1 This part of ISO 11737 specifies the general criteria for tests of sterility on medical devices which have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process. These tests are intended to be performed when validating a sterilization process.

1.2 This part of ISO 11737 is not applicable to:

a) sterility testing for routine release of product that has been subjected to a sterilization process;

b) performance of a pharmacopoeial test for sterility; or

NOTE 1 The performance of a) or b) above is not a requirement of ISO 11134, 11135 or 11137.

c) culturing of biological indicators, including inoculated products.

NOTE 2 Methods of culturing biological indicators are described in ISO 11138.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11737. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11737 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9001:1994, *Quality Systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

3 Terms and definitions

For the purposes of this part of ISO 11737, the following terms and definitions apply.

3.1
aerobic organism
microorganisms that utilize oxygen as the final electron acceptor during metabolism and which will only grow in the presence of oxygen

3.2
anaerobic organism
microorganisms that do not utilize oxygen as the final electron acceptor during metabolism and which will only grow in the absence of oxygen

3.3
bacteriostasis/fungistasis test
test performed with selected microorganisms to demonstrate the presence of substances that inhibit the multiplication of these microorganisms

3.4
culture conditions
stated combination of conditions, including the growth medium with the period and temperature of incubation, used to promote growth and multiplication of microorganisms

3.5
facultative organism
microorganism capable of both aerobic and anaerobic metabolism

3.6
false negative
result of a test of sterility in which a true positive is interpreted as negative

3.7
false positive
result of a test of sterility in which a true negative is interpreted as a positive

3.8
growth promotion test
test performed to demonstrate that a given medium will support microbial growth

3.9
product
generic term used to describe raw materials, intermediate products, subassemblies and finished medical devices

3.10
product unit
medical device, collection of products or components within a primary package

3.11
sample item portion
SIP
defined portion of a product unit that is tested

3.12
test of sterility
test performed to establish the presence or absence of viable microorganisms on product units (or portions thereof) when subjected to defined culture conditions

4 General

4.1 Documentation

4.1.1 Documented instructions detailing the testing technique to be employed and the use and operation of relevant equipment shall be available. These documented instructions shall be approved and controlled as specified in ISO 9001 or ISO 9002.

4.1.2 The documented instructions required by this part of ISO 11737 shall be implemented effectively.