SLOVENSKI STANDARD
SIST EN ISO 11737-2:2010

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Nadomešča:
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Sterilizacija medicinskih pripomočkov - Mikrobiološke metode - 2. del: Preskusi sterilnosti pri definiciji, validaciji in vzdrževanju sterilizacijskih postopkov (ISO 11737-2:2009)

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (ISO 11737-2:2009)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 2: Essais de stérilité pratiqués en cours de définition, validation et entretien d'un procédé de stérilisation (ISO 11737-2:2009)

Ta slovenski standard je istoveten z: **EN ISO 11737-2:2009**

ICS:

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

SIST EN ISO 11737-2:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-2

November 2009

ICS 07.100.10; 11.080.01

Supersedes EN ISO 11737-2:2000

English Version

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 2: Contrôles de stérilité pratiqués au moment de la définition, de la validation et de la maintenance d'un procédé de stérilisation (ISO 11737-2:2009)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11737-2:2009)

This European Standard was approved by CEN on 28 October 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 11737-2:2009: E

Contents

Page

Foreword

This document (EN ISO 11737-2:2009) 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 May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.

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 11737-2:2000.

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 Annexes ZA, ZB and ZC, 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11737-2:2009 has been approved by CEN as a EN ISO 11737-2:2009 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 European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4,5,6,7,8	7	This relevant Essential Requirement is only partly addressed in this European Standard

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 European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4,5,6,7,8	8.3	This relevant Essential Requirement is only partly addressed in this European Standard
4,5,6,7,8	8.4	This relevant Essential Requirement is only partly addressed in this European Standard

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 European Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4,5,6,7,8	B.2.3	This relevant Essential Requirement is only partly addressed in this European Standard
4,5,6,7,8	B.2.4	This relevant Essential Requirement is only partly addressed in this European Standard

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INTERNATIONAL STANDARD

ISO 11737-2

Second edition
2009-11-15

Sterilization of medical devices — Microbiological methods —

Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Stérilisation des dispositifs médicaux — Méthodes microbiologiques — Partie 2: Essais de stérilité pratiqués au moment de la définition, de la validation et de la maintenance d'un procédé de stérilisation

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Contents

Page

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 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 11737-2:1998) which has been technically revised.

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

— *Part 1: Determination of a population of microorganisms on products*

— *Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

