ICS 07.100.10, 11.080.01 SLOVENSKÁ TECHNICKÁ NORMA Júl 2018

STN	**Sterilizácia výrobkov na zdravotnú starostlivosť Mikrobiologické metódy Časť 1: Stanovenie populácie mikroorganizmov na výrobkoch (ISO 11737-1: 2018)**	**STN EN ISO 11737-1** 85 6534

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/18

Obsahuje: EN ISO 11737-1:2018, ISO 11737-1:2018

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 11737-1

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ICS 07.100.10; 11.080.01 Supersedes EN ISO 11737-1:2006

English Version

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)

Stérilisation des produits de santé - Méthodes microbiologiques - Partie 1: Détermination d'une population de micro-organismes sur des produits (ISO 11737-1:2018)

Sterilisation von Produkten für die Gesundheitsfürsorge - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO 11737-1:2018)

This European Standard was approved by CEN on 6 December 2017.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 11737-1:2018 E

EN ISO 11737-1:2018 (E)

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European foreword

This document (EN ISO 11737-1:2018) 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 July 2018, and conflicting national standards shall be withdrawn at the latest by July 2018.

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

This document supersedes EN ISO 11737-1:2006.

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(s), see informative Annex ZA, ZB, and ZC, which are integral parts of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, ZB or ZC, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	**Equivalent dated standard**	
	EN	**ISO**
ISO 10012	EN ISO 10012:2003	ISO 10012:2003
ISO 13485	EN ISO 13485:2016	ISO 13485:2016
ISO 15189	EN ISO 15189:2012	ISO 15189:2012
ISO/IEC 17025	EN ISO/IEC 17025:2017	ISO/IEC 17025:2017

NOTE 2 Many of the standards normatively referred to by ISO 11737-1 are undated. These referred standards also include normative references themselves to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11737-1:2018 has been approved by CEN as EN ISO 11737-1:2018 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 [OJ L 189] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023 to provide one voluntary means of conforming to essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 90/385/EEC [OJ L 189]

Essential Requirements (ERs) of Directive 90/385/EEC	Clauses of this EN	Qualifying remarks/Notes
7	4,5,6,7,8,9	This standard addresses the determination of the population of microorganisms on or in a medical device as part of the validation and routine control of a sterilization process. This relevant Essential Requirement is partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to sterilization are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products 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 [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements (ERs) of Directive 93/42/EEC	Clauses of this EN	Qualifying remarks/Notes
8.3	4,5,6,7,8,9	This standard addresses the determination of the population of microorganisms on or in a medical device as part of the validation and routine control of a sterilization process. This relevant Essential Requirement is partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to sterilization are not covered.

Essential Requirements (ERs) of Directive 93/42/EEC	Clauses of this EN	Qualifying remarks/Notes
8.4	4,5,6,7,8,9	This relevant Essential Requirement is only partly addressed in this European Standard. Aspects of manufacture other than those related to determination of the population of microorganisms are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products 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 [OJ L 331] aimed to be covered

This European standard has been prepared under a Commission's standardisation request, M/252, concerning the development of European standards relating to in vitro diagnostic medical devices, to provide one voluntary means of conforming to essential requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6, and 7 of the Directive.

NOTE 3 This Annex ZC is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.

Table ZC.1 — Correspondence between this European Standard and Annex I of Directive 98/79/EC [OJ L 331]

Essential Requirements (ERs) of Directive 98/79/EC	Clauses of this EN	Qualifying remarks/Notes
B.2.3	4,5,6,7,8,9	This standard addresses the determination of the population of microorganisms on or in a medical device as part of the validation and routine control of a sterilization process. This relevant Essential Requirement is partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to sterilization are not covered.

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Essential Requirements (ERs) of Directive 98/79/EC	Clauses of this EN	Qualifying remarks/Notes
B.2.4	4,5,6,7,8,9	This relevant Essential requirement is addressed only with regard to determination of the population of microorganisms for the validation and routine control of sterilization.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 11737-1

Third edition
2018-01

Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

Stérilisation des produits de santé — Méthodes microbiologiques —

Partie 1: Détermination d'une population de microorganismes sur des produits

Reference number
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

This third edition cancels and replaces the second edition (ISO 11737-1:2006), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11737-1:2006/Cor.1:2007.

The main changes compared to the previous edition are as follows:

— the term “bioburden spikes” has been introduced as a normal and consistent part of the bioburden, and examples of data have been provided;

— clarification has been added that package testing is not typically done except when it is an integral part of the product;

— more information has been provided on the most probable number (MPN) technique and its applications;

— details have been provided on ways to improve limit of detection (LOD) and correct use of the data;

— some discussion has been deleted of statistical methods for the evaluation of bioburden data where information was not typical or not required;

— a table has been added with criteria for selection of a bioburden recovery efficiency approach, the use of the correction factor (CF) has been explained, and the bioburden recovery efficiency value of < 50 % mentioned for technique modifications has been eliminated;

— more information has been provided on the application and performance of a bioburden method suitability test;

— a section has been added to detail rules for direct plate counts, estimated counts and counts beyond the ideal range;

— a table has been added to clarify where typical responsibilities reside for the manufacturer or the laboratory;

— the focus on a risk-based approach has been increased, including the purpose for which bioburden data will be used.

A list of all parts in the ISO 11737 series can be found on the ISO website.

Introduction

A sterile health care product is one that is free of viable microorganisms. International Standards that specify requirements for the validation and routine control of sterilization processes require, when it is necessary to supply a sterile health care product, that adventitious microbiological contamination of a health care product prior to sterilization be minimized. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize health care products 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 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 resistance of microorganisms and by the environment in which the microorganisms exist during treatment. It follows that the sterility of any one product in a population 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 product item.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular 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.

International Standards specifying procedures for the validation and routine control of the processes used for the sterilization of health care products have been prepared (see, for example, ISO 14937, ISO 11135, the ISO 11137 series, the ISO 17665 series and ISO 14160). However, it is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product is sterile and, in this respect, suitable for its intended use. Furthermore, for the effective validation and routine control of a sterilization process, it is important to be aware of the microbiological challenge that is presented in the process, in terms of number, characteristics and properties of microorganisms.

The term “bioburden” is used to describe the population of viable microorganisms present on or in a product and/or a sterile barrier system. A knowledge of bioburden can be used in a number of situations as part of the following:

— validation and requalification of sterilization processes;

— routine monitoring for control of manufacturing processes;

— monitoring of raw materials, components or packaging;

— assessment of the efficiency of cleaning processes;

— an overall environmental monitoring programme.

Bioburden is the sum of the microbial contributions from a number of sources, including raw materials, manufacturing of components, assembly processes, manufacturing environment, assembly/manufacturing aids (e.g. compressed gases, water, lubricants), cleaning processes and packaging of finished products. To control bioburden, attention should be given to the microbiological status of these sources.

It is not possible to enumerate bioburden exactly and, in practice, a determination of bioburden is made using a defined method. Definition of a single method for use in determining bioburden in all situations is not practicable because of the wide variety of designs and materials of construction of health care products. Nor is it possible to define a single technique to be used in all situations for the removal of

microorganisms in preparation for enumeration. Furthermore, the selection of culture conditions for enumeration of microorganisms will be influenced by the types of microorganism likely to be present on or in health care products.

This document specifies the requirements to be met for the determination of bioburden. In addition, it gives guidance in the annexes to provide explanations and methods that are deemed suitable to conform with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving conformity with the requirements of this document.

INTERNATIONAL STANDARD **ISO 11737-1:2018(E)**

Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

1 Scope

This document specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package.

NOTE 1 The nature and extent of microbial characterization is dependent on the intended use of bioburden data.

NOTE 2 See Annex A for guidance on Clauses 1 to 9.

This document does not apply to the enumeration or identification of viral, prion or protozoan contaminants. This includes the removal and detection of the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

NOTE 3 Guidance on inactivating viruses and prions can be found in ISO 22442-3, ICH Q5A(R1) and ISO 13022.

This document does not apply to the microbiological monitoring of the environment in which health care products are manufactured.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 15189, *Medical laboratories — Requirements for quality and competence*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

