



BSI Standards Publication

## **Sterilization of health care products - Microbiological methods**

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Part 1: Determination of a population of microorganisms on products

## National foreword

This British Standard is the UK implementation of EN ISO 11737-1:2018. It is identical to ISO 11737-1:2018. It supersedes BS EN ISO 11737-1:2006, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

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### Amendments/corrigenda issued since publication

Date	Text affected
31 May 2018	Implementation of CEN correction notice 14 March 2018: European Foreword has been updated and Annexes ZA, ZB and ZC have been added
30 June 2018	Implementation of CEN correction notice 18 April 2018: Z Annexes updated

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

# EN ISO 11737-1

January 2018

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  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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	<p>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.</p> <p>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.</p>

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	<p>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.</p> <p>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.</p>