

**SLOVENSKI STANDARD**  
**SIST EN ISO 11737-1:2018/A1:2021**  
**01-september-2021**

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**Sterilizacija izdelkov za zdravstveno nego - Mikrobiološke metode - 1. del:  
Določevanje populacije mikroorganizmov na izdelku - Dopolnilo A1 (ISO 11737-  
1:2018/Amd 1:2021)**

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)

Sterilisation von Produkten für die Gesundheitsfürsorge - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten - Änderung 1 (ISO 11737-1:2018/Amd 1:2021)

Stérilisation des produits de santé - Méthodes microbiologiques - Partie 1: Détermination d'une population de microorganismes sur des produits - Amendement 1 (ISO 11737-1:2018/Amd 1:2021)

**Ta slovenski standard je istoveten z: EN ISO 11737-1:2018/A1:2021**

**ICS:**

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

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11737-1:2018/A1**

June 2021

ICS 07.100.10; 11.080.01

English Version

**Sterilization of health care products - Microbiological  
methods - Part 1: Determination of a population of  
microorganisms on products - Amendment 1 (ISO 11737-  
1:2018/Amd 1:2021)**

Stérilisation des produits de santé - Méthodes  
microbiologiques - Partie 1: Détermination d'une  
population de microorganismes sur des produits -  
Amendement 1 (ISO 11737-1:2018/Amd 1:2021)

Sterilisation von Produkten für die  
Gesundheitsfürsorge - Mikrobiologische Verfahren -  
Teil 1: Bestimmung der Population von  
Mikroorganismen auf Produkten - Änderung 1 (ISO  
11737-1:2018/Amd 1:2021)

This amendment A1 modifies the European Standard EN ISO 11737-1:2018; it was approved by CEN on 28 September 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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.

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



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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 11737-1:2018/A1:2021) 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 Amendment to the European Standard EN ISO 11737-1:2018 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

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 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) and Regulations, see informative Annex ZA and ZB, which are an integral part 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 or ZB, 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 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 The standards normatively referred to by ISO 11737-1:2018/Amd 1:2021 are undated. These referred standards also include normative references to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies.

**EN ISO 11737-1:2018/A1:2021 (E)**

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

**Endorsement notice**

The text of ISO 11737-1:2018/Amd1:2021 has been approved by CEN as EN ISO 11737-1:2018/A1:2021 without any modification.

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## Annex ZA (informative)

### Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

This document is an adoption of an International Standard. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the scope of this document can differ from the scope of the European Regulations that it supports. This document supports European regulatory requirements only to the extent of the scope of the European regulations for medical devices ((EU) 2017/745).

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, 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 Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

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 a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117]**

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8,9	This standard addresses the determination of bioburden in the validation and maintenance of a sterilization process for medical devices. It could also be applied in the development, validation and routine control of a process for attainment of a specific microbial state other than sterility.

## EN ISO 11737-1:2018/A1:2021 (E)

		This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to determination of bioburden in attainment of a specific microbial state are not covered.
11.4 first sentence only	4,5,6,7,8,9	<p>This standard addresses the determination of bioburden in the validation and maintenance of a sterilization process for medical devices.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related determination of bioburden in definition, validation and maintenance of a sterilization process are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.</p>
11.5	4,5,6,7,8,9	<p>This standard addresses the determination of bioburden in the validation and maintenance of a sterilization process for medical devices.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility are not covered. Aspects of manufacture other than those related to determination of bioburden in definition, validation and maintenance of a sterilization process 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 product(s) falling within the scope of this standard.



## Annex ZB (informative)

### Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [O] L 117].

This document is an adoption of an International Standard. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the scope of this document can differ from the scope of the European Regulations that it supports. This document supports European regulatory requirements only to the extent of the scope of the European regulations for in vitro diagnostic medical devices ((EU) 2017/746).

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, 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 Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

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 a General Safety and Performance 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 Regulation (EU) 2017/746 [O] L 117]**

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.2	4,5,6,7,8,9	This standard addresses the determination of bioburden in the validation and maintenance of a sterilization process for medical devices. It could also be applied to the development or validation of a process for attainment of a specific microbial state other than sterility. This relevant General Safety and

## EN ISO 11737-1:2018/A1:2021 (E)

		Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a sterility or another specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to determination of bioburden in attainment of a specific microbial state are not covered
11.3	4,5,6,7,8,9	<p>This standard addresses the determination of bioburden in the, validation and maintenance of a sterilization process for medical devices.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to determination of bioburden in definition, validation and maintenance of a sterilization process are not covered.</p>

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**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 product(s) falling within the scope of this standard.