

MEDITSIINISEADMETE STERILISEERIMINE.
MIKROBIOLOOGILISED MEETODID. OSA 2:
STERILISEERIMISPROTSESSIDE MÄÄRATLEMISEL,
VALIDEERIMISEL JA HOOLDAMISEL TEOSTATUD
STERIILSUSTESTID

Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11737-2:2020 sisaldab Euroopa standardi EN ISO 11737-2:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11737-2:2020 consists of the English text of the European standard EN ISO 11737-2:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.05.2020.	Date of Availability of the European standard is 13.05.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 07.100.10, 11.080.01

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Sterilization of health care products - Microbiological
methods - Part 2: Tests of sterility performed in the
definition, validation and maintenance of a sterilization
process (ISO 11737-2:2019)**

Stérilisation des produits de santé - 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
11737-2:2019)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Mikrobiologische Verfahren -
Teil 2: Prüfungen der Sterilität bei der Definition,
Validierung und Aufrechterhaltung eines
Sterilisationsverfahrens (ISO 11737-2:2019)

This European Standard was approved by CEN on 29 April 2020.

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.

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

European foreword

This document (EN ISO 11737-2:2020) 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 November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

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 11737-2:2009, with a revised European Foreword and European Annexes ZA, ZB and ZC, and additional European Annexes ZD and ZE.

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 the relationship with EU Directive(s) see informative Annex ZA, ZB, ZC, ZD and ZE which are an integral part 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, 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 11737-2:2019 has been approved by CEN as EN ISO 11737-2:2020 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 [O] 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 [O] 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 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	<p>This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices.</p> <p>This relevant Essential Requirement is only 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 the use of a test of sterility in the definition, validation or 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 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 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	<p>This standard addresses the performance of tests of sterility in the definition, validation and maintenance of a sterilization process for medical devices.</p> <p>This relevant Essential Requirement is only 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 the use of a test of sterility in definition, validation or maintenance of a sterilization process are not covered.</p>
8.4	4,5,6,7,8	<p>This relevant Essential Requirement is addressed only in regards to the use of a test of sterility in the definition, validation or maintenance of a sterilization process for the device. Aspects of manufacture other than those related to the use of a test of sterility in the definition, validation or 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 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 [O] 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 [O] 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 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.