
Sterilizacija izdelkov za zdravstveno nego - Sevanje - 1. del: Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke - Dopolnilo A2: Revizija točke 4.3.4 in 11.2 (ISO 11137-1:2006/Amd 2:2018)

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)

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Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte - Änderung 2 (ISO 11137-1:2006/Amd 2:2018)

<https://standards.iteh.ai/catalog/standards/sist/86d09389-a22d-4026-9475-72a1f7b57ac7/sist-en-iso-11137-1-2015-a2-2020>

Stérilisation des produits de santé - Irradiation - Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux - Amendement 2: Révision de 4.3.4 et de 11.2 (ISO 11137-1:2006/Amd 2:2018)

Ta slovenski standard je istoveten z: EN ISO 11137-1:2015/A2:2019

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
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SIST EN ISO 11137-1:2015/A2:2020 **en**

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EUROPEAN STANDARD

EN ISO 11137-1:2015/A2

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English Version

**Sterilization of health care products - Radiation - Part 1:
Requirements for development, validation and routine
control of a sterilization process for medical devices -
Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-
1:2006/Amd 2:2018)**

Stérilisation des produits de santé - Irradiation - Partie
1: Exigences relatives à la mise au point, à la validation
et au contrôle de routine d'un procédé de stérilisation
pour les dispositifs médicaux - Amendement 2:
Révision de 4.3.4 et de 11.2 (ISO 11137-1:2006/Amd
2:2018)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen
an die Entwicklung, Validierung und Lenkung der
Anwendung eines Sterilisationsverfahrens für
Medizinprodukte - Änderung 2 (ISO 11137-
1:2006/Amd 2:2018)

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This amendment A2 modifies the European Standard EN ISO 11137-1:2015; it was approved by CEN on 4 November 2019.

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.

<https://standards.iteh.ai/catalog/standards/sist/86d09389-a22d-4026-9475-72a1f7b57ac7/sist-en-iso-11137-1-2015-a2-2020>

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.

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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 11137-1:2015/A2:2019) 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 11137-1:2015 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 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 modifies EN ISO 11137-1:2006/Amd 1:2013 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 relationship with EU Directive(s) and Regulation(s), see informative Annex ZA, ZB, ZC, ZD and ZE, 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, ZB, ZC, ZD or ZE, 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 10012-1	EN ISO 10012:2003	ISO 10012:2003
ISO 11137-2	EN ISO 11137-2:2015	ISO 11137-2:2013
ISO 11737-1	EN ISO 11737-1:2006	ISO 11737-1:2006
ISO 11737-2:2009	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 13485:2003	EN ISO 13485:2016	ISO 13485:2016

NOTE Some standards normatively referred to by EN ISO 11137-1/Amd 2:2019 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 11137-1:2015/A2:2019 (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 11137-1:2006/Amd 2:2018 has been approved by CEN as EN ISO 11137-1:2015/A2:2019 without any modification.

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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/BC/CEN/89/9 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.

EN ISO 11137-1:2015/A2:2019 (E)

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	4,5,6,7,8,9,10,11,12	<p>This standard provides requirements for the development, validation and routine control of a sterilization process using radiation for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This Essential Requirement is addressed only with regard to devices for which sterilization by irradiation is appropriate.</p> <p>This relevant Essential 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 to sterilization by radiation 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/BC/CEN/89/9 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.

EN ISO 11137-1:2015/A2:2019 (E)

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	4,5,6,7,8,9,10,11,12	<p>This standard provides requirements for the development, validation and routine control of a sterilization process radiation for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This Essential Requirement is addressed only with regard to devices for which sterilization by irradiation is appropriate.</p> <p>This relevant Essential 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 to sterilization by radiation are not covered.</p>
8.4	4,5,6,7,8,9,10,11,12	<p>This relevant Essential Requirement is only partly addressed in this European Standard. This Essential Requirement is addressed only with regard to devices for which sterilization by irradiation is appropriate. Aspects of manufacture other than those related to sterilization by radiation 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 [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.