



**SLOVENSKI STANDARD**  
**SIST EN ISO 11137-2:2015/oprA1:2021**  
**01-marec-2021**

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**Sterilizacija izdelkov za zdravstveno nego - Sevanje - 2. del: Določanje odmerka sterilizacije - Dopolnilo A1 (ISO 11137-2:2013/DAMd 1:2021)**

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 (ISO 11137-2:2013/DAMd 1:2021)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 2: Festlegung der Sterilisationsdosis - ÄNDERUNG 1 (ISO 11137 2:2013/DAM 1:2021)

Stérilisation des produits de santé - Irradiation - Partie 2: Établissement de la dose stérilisante - Amendement 1 (ISO 11137-2:2013/DAMd 1:2021)

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**Ta slovenski standard je istoveten z: EN ISO 11137-2:2015/prA1**

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**ICS:**

11.080.01 Sterilizacija in dezinfekcija na splošno Sterilization and disinfection in general

**SIST EN ISO 11137-2:2015/oprA1:2021 en,fr,de**

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# DRAFT AMENDMENT

## ISO 11137-2:2013/DAM 1

ISO/TC 198

Secretariat: ANSI

Voting begins on:  
2021-02-01Voting terminates on:  
2021-04-26

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### Sterilization of health care products — Radiation —

#### Part 2: Establishing the sterilization dose

#### AMENDMENT 1

*Stérilisation des produits de santé — Irradiation —**Partie 2: Établissement de la dose stérilisante**AMENDEMENT 1*

ICS: 11.080.01

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**ISO/CEN PARALLEL PROCESSING**



Reference number  
ISO 11137-2:2013/DAM 1:2021(E)

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Published in Switzerland

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Amendment 1 to ISO 11137-2:2013 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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# Sterilization of health care products — Radiation —

## Part 2: Establishing the sterilization dose

### AMENDMENT 1

Add a new 6.4:

**6.4** If a sterilization dose of 17,5, 20, 22,5, 27,5, 30, 32,5 or 35 kGy is established in accordance with ISO/TS 13004, it shall be substantiated by one of the following methods:

- a) Method  $VD_{max}^{SD}$  of ISO/TS 13004;
- b) Method 1 (see Clause 7), subject to the derived sterilization dose taking a value less than or equal to the selected sterilization dose and achieving maximally an SAL of  $10^{-6}$ ;
- c) Method 2 (see Clause 8), subject to the derived sterilization dose taking a value less than or equal to the selected sterilization dose and achieving an SAL of  $10^{-6}$ ; or
- d) a method providing equivalent assurance to that of a), b) or c) above in achieving maximally an SAL of  $10^{-6}$ .

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[Add related content under Clause 9 so that it reads:](https://standards.iteh.ai/catalog/standards/sist/6a5c5edf-3fe9-41da-a749-c16d801185/cit/en-iso-11137-2-2015-oprA1-2021)

#### **9 Method $VD_{max}$ — Substantiation of 25 kGy or 15 kGy as the sterilization dose**

Rationale and methods for substantiation of sterilization doses of 15 and 25 kGy using Method  $VD_{max}$  are provided below. Rationale and methods for substantiation of sterilization doses of 17,5, 20, 22,5, 27,5, 30, 32,5 or 35 kGy using Method  $VD_{max}$  are provided in ISO/TS 13004.

## Annex ZA (informative)

### Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, 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 Directive 90/385/EEC**

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 ionising radiation. This Essential Requirement is addressed only with regard to devices for which sterilization by ionising radiation is appropriate and only in conjunction with EN ISO 11137-1.</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 ionising 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.**

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## Annex ZB (informative)

### Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN/CENELC by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, 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 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 ZB.1 — Correspondence between this European Standard and EU Directive 93/42/EEC**

Essential Requirements (ERs) of Directive 93/42/EEC	Clauses of this EN	Qualifying remarks/Notes
8.3	4,5,6,7,8,9,10	<p>This standard provides requirements for the development, validation and routine control of a sterilization process ionising radiation for medical devices . This Essential Requirement is addressed only with regard to devices for which sterilization by ionising radiation is appropriate and only in conjunction with EN ISO 11137-1.</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 ionising radiation are not covered.</p>