DRAFT AMENDMENT

ISO 11137-2:2013/DAM 1

ISO/TC **198**

Secretariat: **ANSI**

Voting begins on:
2021-02-01

Voting terminates on:
2021-04-26

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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

© ISO 2021

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2021 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2021 – All rights reserved

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

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}.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e927ef3/iso-11137-2-2013-damd-1

Add related content under Clause 9 so that it reads:

9 Method VDmax — 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.

© ISO 2021 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

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	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. 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.

© ISO 2021 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

© ISO 2021 – All rights reserved

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.

iTeh STANDARD PREVIEW

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.

(standards.iteh.ai)

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.

ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cff/iso-11137-2-2013-damd-1

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	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. 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.

© ISO 2021 – All rights reserved

Table ZB.1 *(continued)*

Essential Requirements (ERs) of Directive 93/42/EEC	Clauses of this EN	Qualifying remarks/Notes
8.4	4,5,6,7,8,9,10	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 ionising radiation is appropriate. Aspects of manufacture other than those related to sterilization by ionising radiation are not covered.

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 11137-2:2013/DAmd 1
https://standards.iteh.ai/catalog/standards/sist/fbe01d15-1329-4d07-b927-4b566e027cf1/iso-11137-2-2013-damd-1

© ISO 2021 – All rights reserved