Irish Standard
I.S. EN ISO 11137-1:2015

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)

I.S. EN ISO 11137-1:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:	*Published:*
EN ISO 11137-1:2015	2015-06-10

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2015-07-02	11.080.01
	NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 11137-1:2015 is the adopted Irish version of the European Document EN ISO 11137-1:2015, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11137-1

June 2015

ICS 11.080.01

Supersedes EN ISO 11137-1:2006

English Version

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)

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 (ISO 11137-1:2006, y compris Amd 1:2013)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11137-1:2006, einschließlich Amd 1:2013)

This European Standard was approved by CEN on 20 May 2015.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, 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: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11137-1:2015 E

Contents

Page

Annex ZC
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic 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 98/79/EC on in vitro diagnostic 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 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 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 ZC.1 — Correspondence between this European Standard and Directive 98/79/EC

Clauses of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	B.2.3	Only a sterilization process using ionizing radiation is considered by this standard. 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 are not covered.

4,5,6,7,8,9,10,11,12	B.2.4	This relevant Essential requirement is addressed only with regard to: - sterilization, not covering other special microbiological state - devices for which sterilization by radiation is appropriate

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

INTERNATIONAL STANDARD

ISO 11137-1

First edition
2006-04-15

AMENDMENT 1
2013-07-15

Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

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 1

Reference number
ISO 11137-1:2006/Amd.1:2013(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

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

Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

Page 2, Normative references

Replace the reference to ISO 11137-2:2006 with the following:

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

Page 6, Terms and definitions

Replace entry 3.29 with the following:

3.29
processing category
collection of different product or product families that can be sterilized together

NOTE Processing categories can be based on, for instance, composition, density or dose requirements.

Replace entry 3.31 with the following:

3.31
product family
group of product possessing characteristics that allow them to be sterilized using given defined process conditions

NOTE Bioburden on members of a product family destined for radiation sterilization has to comprise similar numbers and types of microorganisms.

Page 11, 6.2.5

Add the following item to the list:

m) the means of ceasing irradiation if failure of the target cooling system occurs.

Page 12, 7.4

Replace the reference “ISO 11137-2:2006, Clause 4” with “ISO 11137-2”.

Page 12, 8.2.2, NOTE to a)

Replace the reference “6.1 of ISO 11137-2:2006” with “ISO 11137-2”.

Page 12, 8.2.2, NOTE to b)

Replace the reference "6.2 of ISO 11137-2:2006" with "ISO 11137-2".

Page 17, 12.1.1 a)

Replace a) with:

a) determinations of bioburden to monitor the number of microorganisms present on product in relation to a specified bioburden limit, and

Page 18, 12.1.2.5

Replace the first paragraph up to and including b) 1) with the following:

If the outcome of determinations of bioburden exceeds the specified bioburden limit, an investigation in accordance with ISO 11737-1 shall be performed. If the outcome of the investigation indicates that the bioburden determination is a true result, procedures specified in 4.4 shall be implemented and a sterilization dose audit shall be performed immediately. Depending on the outcome of the sterilization dose audit, a) or b) below shall be followed.

a) If the sterilization dose audit is unsuccessful, action shall be taken in accordance with 12.1.3.5.

b) If the outcome of the sterilization dose audit is successful and the bioburden continues to exceed the specified bioburden limit, sterilization shall continue using the dose used prior to the sterilization dose audit. Also

1) if the sterilization dose has been established using Method 1 (see ISO 11137-2), a three-month interval for the sterilization dose audit shall be used until either the bioburden is returned to the specified bioburden limit or the sterilization dose is re-established;

Page 19, 12.1.3.1

Replace b) 1) with the following:

1) the specified bioburden limit;

Page 19, 12.1.3.2

Replace b) 1) with the following:

1) bioburden determinations performed at least every three months or every month in the case of product of average bioburden less than 1,5 for which the sterilization dose has been set using Method 1 or a sterilization dose of 15 kGy has been selected and substantiated and

Page 20, 12.1.3.5

Replace the reference "ISO 11137-2:2006, Clause 10" with "ISO 11137-2".

Add "and" at the end of b).

