This is a free page sample. Access the full version online.

NSAI Standards

Irish Standard
I.S. EN ISO 11138-3:2017

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

© CEN 2017 No copying without NSAI permission except as permitted by copyright law.

This is a free page sample. Access the full version online.

I.S. EN ISO 11138-3:2017

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 11138-3:2017	2017-03-29

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2017-04-16	11.080.20
	NOTE: If blank see CEN/CENELEC cover page

NSAI	T +353 1 807 3800	Sales:
1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
Northwood, Santry	E standards@nsai.ie	F +353 1 857 6729
Dublin 9	W NSAI.ie	W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

National Foreword

I.S. EN ISO 11138-3:2017 is the adopted Irish version of the European Document EN ISO 11138-3:2017, Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

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

For relationships with other publications refer to the NSAI web store.

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 is a free page sample. Access the full version online.

This page is intentionally left blank

This is a free page sample. Access the full version online.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11138-3

March 2017

ICS 11.080.20

Supersedes EN ISO 11138-3:2009

English Version

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide (ISO 11138-3:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (ISO 11138-3:2017)

This European Standard was approved by CEN on 19 January 2017.

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, 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: Avenue Marnix 17, B-1000 Brussels

© 2017 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 11138-3:2017 E

This is a free page sample. Access the full version online.

Contents

Page

European foreword **3**

This is a free page sample. Access the full version online.

European foreword

This document (EN ISO 11138-3:2017) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices", the secretariat of which is held by DIN.

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 September 2017 and conflicting national standards shall be withdrawn at the latest by September 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11138-3:2009.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-3:2009:

— requirements on population and resistance (clause 9) revised;

— Annex A, in particular A.2.4 step 4 revised;

— informative Annex ZA respective relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered was deleted.

EN ISO 11138 consists of the following parts, under the general title *Sterilization of health care products — Biological indicators*:

— *Part 1: General requirements*

— *Part 2: Biological indicators for ethylene oxide sterilization processes*

— *Part 3: Biological indicators for moist heat sterilization processes*

— *Part 4: Biological indicators for dry heat sterilization processes*

Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11138-3:2017 has been approved by CEN as EN ISO 11138-3:2017 without any modification.

This is a free page sample. Access the full version online.

This page is intentionally left blank

This is a free page sample. Access the full version online.

INTERNATIONAL STANDARD

ISO 11138-3

Third edition
2017-03

Sterilization of health care products — Biological indicators —

Part 3: Biological indicators for moist heat sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide

Reference number
ISO 11138-3:2017(E)

© ISO 2017

This is a free page sample. Access the full version online.

COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, 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
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

This is a free page sample. Access the full version online.

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 General requirements **1**
5 Test organism **1**
6 Suspension **2**
7 Carrier and primary packaging **2**
8 Inoculated carriers and biological indicators **2**
9 Population and resistance **2**
Annex A (normative) **Method for determination of resistance to moist heat sterilization** **4**
Annex B (normative) **Calculation of *z* value and coefficient of determination, r^2** **5**
Bibliography **8**

© ISO 2017 – All rights reserved

This is a free page sample. Access the full version online.

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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This third edition cancels and replaces the second edition (ISO 11138-3:2006), which has been technically revised.

A list of all parts of ISO 11138 can be found on the ISO website.

© ISO 2017 – All rights reserved

This is a free page sample. Access the full version online.

Introduction

This document specifies production, labelling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes. This document gives specific requirements for those biological indicators intended for use in moist heat sterilization processes.

Moist heat as the sterilizing agent is defined in this document as dry saturated steam. While air-steam mixtures can be used in moist heat sterilization processes, the methods and performance requirements of this document might not be applicable for biological indicators used in such processes.

The ISO 11138 series represents the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing the standard. The intent is not to promote the use of biological indicators where such use is not advised, but to provide common requirements for the production of those biological indicators known to be in use today.

Standards exist providing requirements for the validation and control of moist heat sterilization (see ISO 17665 series).

NOTE It is possible that some countries or regions have published other standards covering requirements for sterilization or biological indicators.

Advice on selection, use and interpretation of results when using biological indicators can be found in ISO 14161.

© ISO 2017 – All rights reserved

This is a free page sample. Access the full version online.

This is a free page sample. Access the full version online.

Sterilization of health care products — Biological indicators —

Part 3: Biological indicators for moist heat sterilization processes

1 Scope

This document specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilization processes employing moist heat as the sterilizing agent.

NOTE 1 Requirements for validation and control of moist heat sterilization processes are provided by the ISO 17665 series.

NOTE 2 National or regional regulations can provide requirements for work place safety.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11138-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 General requirements

The requirements of ISO 11138-1 apply.

5 Test organism

5.1 The test organisms shall be spores of *Geobacillus stearothermophilus* or other strains of microorganism of demonstrated equivalent performance as required by this document.

NOTE 1 *Bacillus stearothermophilus* has been reclassified as *Geobacillus stearothermophilus*.

© ISO 2017 – All rights reserved

SAI GLOBAL

This is a free preview. Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation