INTERNATIONAL STANDARD

ISO 11138-2

Third edition
2017-03

Sterilization of health care products — Biological indicators —

Part 2: Biological indicators for ethylene oxide sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques — Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène

Reference number
ISO 11138-2:2017(E)

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Contents

Page

Foreword

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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 11138-2:2006), which has been technically revised.

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

Introduction

ISO 11138-1 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 ethylene oxide sterilization 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 rather to provide common requirements for the production of those biological indicators that are known to be in use today.

Standards exist providing requirements for the validation and control of ethylene oxide sterilization (see ISO 11135 and ISO 14937).

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.

Sterilization of health care products — Biological indicators —

Part 2: Biological indicators for ethylene oxide 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 sterilizers and sterilization processes employing ethylene oxide gas as the sterilizing agent, either as pure ethylene oxide gas or mixtures of this gas with diluent gases, at sterilizing temperatures within the range of 29 °C to 65 °C.

NOTE 1 Requirements for validation and control of ethylene oxide sterilization processes are provided by ISO 11135 and ISO 14937.

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 https://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 *Bacillus atrophaeus, Bacillus subtilis* or other strains of microorganisms of demonstrated equivalent performance as required by this document.

NOTE 1 Some strains of *Bacillus subtilis* have been reclassified as *Bacillus atrophaeus*.

NOTE 2 *Bacillus atrophaeus* ATCC 9372, NCTC 10073, NCIMB 8058, DSM 2277, NRRL B-4418 and CIP 77.18 have been found to be suitable[1)].

5.2 If a test organism other than *Bacillus atrophaeus* is used, the suitability of the resistance of that test organism shall be determined.

6 Suspension

The requirements of ISO 11138-1 apply.

7 Carrier and primary packaging

7.1 The suitability of the carrier and primary packaging materials for biological indicators for use in ethylene oxide sterilization processes shall be demonstrated in accordance with the requirements of ISO 11138-1:2017, 5.2 and Annex B.

7.2 The exposure conditions to determine compliance shall be

a) minimum exposure temperature: greater than or equal to 55 °C,

b) sterilizing agent: ethylene oxide gas at a concentration not less than 800 mg/l in air at greater than or equal to 70 % RH,

c) maximum exposure temperature: as stated by the biological indicator manufacturer, and

d) exposure time: greater than or equal to 6h.

NOTE These conditions have been selected to represent a realistic challenge to the carrier while remaining within the practical limits of an ethylene oxide sterilization process.

8 Inoculated carriers and biological indicators

The requirements of ISO 11138-1 apply.

9 Population and resistance

9.1 The manufacturer shall state the resistance characteristics in accordance with ISO 11138-1:2017, 6.4.

9.2 The viable count shall be stated with increments less than or equal to $0{,}1 \times 10^n$ per unit (e.g. per ml of suspension, per inoculated carrier or per biological indicator).

9.3 For inoculated carriers and biological indicators, the viable count shall be greater than or equal to $1{,}0 \times 10^6$.

9.4 The resistance shall be expressed as the *D* value in minutes, at 54 °C. The *D* value of each batch/lot of biological indicators or inoculated carriers shall be stated in minutes, to one decimal place at 54 °C.

9.5 Suspensions, inoculated carriers or biological indicators containing *Bacillus atrophaeus* spores shall have a *D* value of not less than 2,5 min at 54 °C when tested according to the conditions in Annex A using test gas mixtures (see Annex B). Other microorganisms shall have *D* values supporting the application.

1) These are examples of suitable products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

9.6 Suspensions, inoculated carriers or biological indicators containing *Bacillus atrophaeus* spores shall have a *D* value of not less than 2,0 min at 54 °C when tested according to the conditions in Annex A using a test gas consisting of 100 % EO (see Annex B). Other microorganisms shall have *D* values supporting the application.

9.7 The resistance characteristics specified in this document and any other parts of ISO 11138 shall be defined using the specific critical variables associated with the referenced sterilization process.

9.8 *D* values are determined according to methods given in ISO 11138-1:2017, Annex C and Annex D.

9.9 Determination of *D* value and survival-kill response characteristics require the use of a resistometer applying the reference resistometer process parameters (see Annex A).

9.10 The survival-kill window can be calculated using the formulae in ISO 11138-1:2017, Annex E.

NOTE This information can be of value to the user when comparing different batches from the same manufacturer.

EXAMPLE Using the formulae in ISO 11138-1:2017, Annex E with the minimum population and minimum *D* value requirements specified in this document, the survival-kill response characteristics are:

— at 54 °C, 2,5 *D* value; survival time greater than or equal to 10 min and kill time less than or equal to 25 min;

— at 54 °C, 2,0 *D* value; survival time greater than or equal to 8 min and kill time less than or equal to 20 min.