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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

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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.

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.

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*.

NOTE 2 *Geobacillus stearothermophilus* ATCC 7953 (NCTC 10007, DSM 22 and CIP 52.81), ATCC 12980 (equivalent to NRRL B-4419) have been found to be suitable[1)][1][2].

5.2 If a test organism other than *Geobacillus stearothermophilus* or *Bacillus subtilis* ATCC 35021 (5230) is used, the suitability of the resistance of that test organism shall be determined.

NOTE For processes at less than 121 °C, microorganisms such as *Bacillus subtilis* ATCC 35021 (5230) could be used, particularly in sterilization of heat-sensitive liquids.

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 moist heat 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 5 °C above the manufacturer's stated maximum exposure temperature,

b) sterilizing agent: dry saturated steam; if the biological indicator is intended for use in a moist heat process not using dry saturated steam, e.g. an air/steam mixture, the appropriate air steam mixture should be used and noted as an exception to this document,

c) maximum exposure temperature: as stated by the manufacturer; if not stated by the manufacturer, a temperature of 140 °C shall be used, and

d) exposure time: greater than or equal to 30 min.

NOTE These conditions have been selected to represent a realistic challenge to the carrier while remaining within the practical limits of a moist heat 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 $1,0 \times 10^5$.

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.

9.4 The resistance shall be expressed as the *D* value in minutes at 121 °C. Additional temperature(s) may be selected by the manufacturer. The *D* value of each batch/lot of biological indicators or inoculated carriers shall be stated in minutes to one decimal place at 121 °C.

9.5 Suspensions, inoculated carriers or biological indicators containing *Geobacillus stearothermophilus* spores shall have a D_{121} value of greater than or equal to 1,5 min when tested according to the conditions given in Annex A. Other microorganisms shall have *D* values supporting the application. The *z* value of the test organisms in the suspension, on the inoculated carrier or in the biological indicator shall be determined at not less than three temperatures, in the range of 110 °C to 138 °C. These data shall be used to calculate the *z* value, which shall be greater than or equal to 6 °C (see Annex B).

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

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

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

9.9 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 121 °C: survival time greater than or equal to 4,5 min and kill time less than or equal to 13,5 min.