American National Standard

ANSI/AAMI/ ISO 11138-3: 2017/(R)2024

Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes

AAMI
Advancing Safety in Health Technology

American National Standard **ANSI/AAMI/ISO 11138-3:2017/(R)2024**
(Revision of ANSI/AAMI/ISO 11138-3:2006/(R)2015

Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes

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Abstract: 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.

Keywords: carrier, organism, resistance, packaging, value

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International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Biological Indicators Working Group

The adoption of ISO 11138-3:2017 as an American National Standard was initiated by the AAMI Biological Indicators Working Group of the AAMI Sterilization Standards Committee. U.S. representatives from the AAMI Biological Indicators Working Group played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Biological Indicators Working Group** had the following members:

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NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO 11138-3:2017

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

ISO 11138-3:2017 was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for an international standard specifying general production, labelling, test methods and performance requirements for the manufacture of biological indicators (including inoculated carriers and suspensions) intended for use in assessing the performance of sterilizers and sterilization processes employing moist heat as the sterilizing agent. Biological indicators are fundamental in the measurement of the sterilization process in that they are required for the demonstration of Sterility Assurance Levels as part of validation studies and also play a key role in the routine release of sterilization loads.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group (TAG) for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). The U.S. TAG for ISO/TC 198 made considerable contributions to this standard and supports the requirements for biological indicators specified in this document.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of the final Draft International Standard (FDIS) of ISO 11138-3:2017, the AAMI Biological Indicator Working Group decided to adopt this document verbatim as a revision of ANSI/AAMI 11138-3:2006/(R)2015, *Sterilization of health care products-Biological indicators—Part 3: Biological indicators for moist heat sterilization processes.*

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The ISO 11138:2017 biological indicator standards series consists of the following parts:

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

ISO 11138-2, *Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4, *Sterilization of health care products—Biological indicators—Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5, *Sterilization of health care products—Biological indicators—Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

NOTE Beginning with the ISO foreword on page viii, this American National Standard is identical to ISO 11138-3:2017.

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*.

