American National Standard

ANSI/AAMI/ISO 11138-3:2006/(R)2010

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

AAMI
Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News.* The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News.*

American National Standard

ANSI/AAMI/ISO 11138-3:2006/(R)2010
(Revision of ANSI/AAMI ST19:1999)

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

Approved 9 December 2005 by
Association for the Advancement of Medical Instrumentation

Approved 4 May 2006 and Reaffirmed 22 April 2010 by
American National Standards Institute, Inc.

Abstract: Provides specific requirements for test organisms and biological indicators intended for use in assessing the performance of sterilizers employing moist heat as the sterilizing agent at sterilizing temperatures in excess of 100 °C.

Keywords: carrier, organism, resistance, packaging, value

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:200x[2]	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations

International designation	U.S. designation	Equivalency
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO/TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:200x[1]	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1] In production
[2] Final approval pending

Committee representation

Association for the Advancement of Medical Instrumentation
Biological Indicators Working Group

The adoption of ISO 11138-3:2006 as an American National Standard was initiated by the AAMI Biological Indicators Working Group of the AAMI Sterilization Standards Committee. The AAMI Biological Indicators Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Biological Indicators Working Group (U.S. Sub-TAG for ISO/TC 198/WG 4) 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.

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Background of AAMI adoption of ISO 11138-3:2006

As indicated in the foreword to the main body of this document (page xi), 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 11138-3:2006 was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for an international standard for specifying the test organisms and performance requirements for biological indicators (including inoculated carriers and suspensions) used in assessing the performance of sterilization processes employing moist heat as the sterilizing agent.

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 11138-3:2006, the AAMI Biological Indicator Working Group decided to adopt this document verbatim as a revision of ANSI/AAMI ST19:1999, *Sterilization of health care products-Biological indicators — Part 3: Biological indicators for moist heat.* (The AAMI Biological Indicator Working Group previously developed deviations to ISO 11138-3:1995 to create ANSI/AAMI ST19:1999).

The ISO 11138:2006 biological indicator standards series was developed as the result of the joint revision of the ISO 11138:1994-1995 series of biological indicator standards (Parts 1-3) and the EN 866:1997-2000 series of biological indicator standards (Parts 1-8). The revised ISO 11138:2006 series of standards consist 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*

Major changes that were made to the predicate ISO and CEN series during the revision process which are incorporated into the revised ISO 11138:2006 series of standards include:

a) Elimination of EN 866-4:1999, *Biological systems for testing sterilizers and sterilization processes — Part 4: Particular systems for use in irradiation sterilizers*. (Radiation biological indicators can demonstrate ISO 11138:2006 compliance by complying with the provisions of ISO 11138-1:2006 even though there is no specific subpart for irradiation).

b) Elimination of EN 866-7:1999 and EN 866-8:1999*, Biological systems for testing sterilizers and sterilization processes — Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers* and *Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers*.

c) Inclusion of specific information pertaining to self-contained biological indicators in ISO 11138-1:2006.

d) Inclusion of a table with consolidated labeling requirements in ISO 11138-1:2006.

e) Provision for use of biological indicators deviating from the specified minimum population and/or resistance criteria providing all other requirements of ISO 11138:2006 are met and the deviation is clearly indicated in the product labeling.

f) Allowance for the calculation of D value by either the Holcomb-Spearman-Karber, Limited Holcomb-Spearman-Karber or Stumbo-Murphy-Cochran procedures as indicated in Annex D, 11138-1:2006.

g) Allowance for the use of dual species biological indicators with appropriate documentation.

h) Removal of the performance requirements for resistometers in ISO 11138:2006 Parts 2-4 (resistometer performance requirements are contained in ISO 18472:2006).

i) Removal of the $\log_{10}$ population $\times$ D value $\geq$ 10 requirement in ISO 11138-3:2006 (moist heat) and 11138-4:2006 (dry heat).

j) Provision for use of a liquid (rather than vapor phase) test method for characterization of biological indicators used in the low temperature steam and formaldehyde process in ISO 11138-5:2006.

The primary differences between ANSI/AAMI/ISO 11138-3:2006 and ANSI/AAMI ST19:1999 are indicated in h) and i) above as well as the changes pertaining to ANSI/AAMI/ISO 11138-1:2006, i.e., c), d), and e) above.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page xi, this American National Standard is identical to ISO 11138-3:2006.

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.

ISO 11138-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11138-3:1995), which has been technically revised.

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*

Introduction

ISO 11138-1 specifies production, labeling, 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 part of ISO 11138 gives specific requirements for those biological indicators intended for use in moist heat sterilization processes.

The intent of providing requirements in the ISO 11138 series of International Standards is to provide general requirements and requirements for test methods. This series of International Standards 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).

NOTE Some countries or regions may have published 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 part of ISO 11138 provides specific 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.

Moist heat as the sterilizing agent is defined in this part of ISO 11138 as dry saturated steam. While air-steam mixtures may be used in moist heat sterilization processes, the methods and performance requirements of this part of ISO 11138 might not be applicable for biological indicators used in such processes.

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

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

2 Normative references

The following referenced documents are indispensable for the application 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 11138-1:2006, *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.

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 part of ISO 11138.

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.

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 11138-1:2006, 5.2 and Annex B.

7.2 The exposure conditions for establishing compliance shall be:

a) minimum exposure temperature: ≥ 5 °C above the manufacturer's stated maximum 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 part of ISO 11138;

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

d) exposure time: ≥ 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 11138-1:2006, 6.4.

9.2 The viable count shall be stated with increments $\leq 0.1 \times 10^n$ 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 $\geq 1.0 \times 10^5$.

9.4 The resistance shall be expressed as the D value in minutes at 121 °C. 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 $\geq$ 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 130 °C. These data shall be used to calculate the z value, which shall be $\geq$ 6 °C (see Annex B).

9.6 The resistance of a biological indicator may also be indicated by the term F_{BIO} value (see 11138-1:2006, 3.7).

The resistance characteristics specified in this part of ISO 11138 and any other part of ISO 11138 apply to the specific test conditions stated in the standards.

9.7 D values are determined according to methods given in Annexes C and D of ISO 11138-1:2006.

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

9.9 The survival-kill window can be calculated using the formulae in ISO 11138-1:2006, Annex E.

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

EXAMPLE

Using the formulae in ISO 11138-1:2006, Annex E with the minimum population and minimum D value requirements specified in this part of ISO 11138, the survival-kill response characteristics are:

— at 121 °C: survival time $\geq$ 4.5 min and kill time $\leq$ 13.5 min.

Annex A
(normative)

Method for determination of resistance to moist heat sterilization

A.1 General

This method requires the use of a test apparatus referred to as a resistometer in this part of ISO 11138. The specifications of the resistometer process parameters for moist heat sterilization processes are provided in ISO 18472.

Specific requirements related to the test method are provided in A.2.

A.2 Method

A.2.1 Load the test samples on to suitable sample holders.

A.2.2 Pre-heat the resistometer chamber to the required operating temperature, e.g. 121 °C ± 0.5 °C.

A.2.3 Place the loaded sample holders in the chamber, close the chamber and initiate the process cycle.

A.2.4 Carry out the following sequence of operations:

— Step 1: Evacuate the chamber to a set point of 4.5 kPa ± 1 kPa within 2 min.

— Step 2: Admit steam to the chamber to obtain the required temperature and pressure within 10 s. For the 0 minute exposure time, no steam shall be admitted.

— Step 3: Maintain these conditions for the required exposure time.

— Step 4: At the end of the exposure period, evacuate the chamber to 10 kPa or less within 1 min. The time taken to achieve a temperature of less than 100 °C shall be less than 5 s. Then admit filtered air to ambient pressure.

— Step 5: At the end of the above process, remove the samples from the chamber, and cool down rapidly. Transfer the samples to the growth medium and incubate (see 11138-1:2006, Clause 7).

A.2.5 The transfer period should be documented and the same time period should be used for all tests.

A.3 Determination of resistance

Resistance characteristics shall be determined according to methods given in Annexes C, D, and E of ISO 11138-1:2006.

Annex B
(normative)

Calculation of z value and correlation coefficient, r^2

B.1 Using all the data obtained from either Annex C or D of ISO 11138-1:2006, plot the $\log_{10}$ of the D value against exposure temperature in degrees Celsius. The z value is equal to the negative reciprocal of the slope of the best-fit rectilinear curve as determined by regression analysis.

NOTE See 9.5 for requirements regarding calculation of z value and correlation coefficient, r^2.

B.2 The slope of the best-fit rectilinear curve is calculated using the following formula:

$$m = \frac{(nG) - (AB)}{(nC) - (A^2)}$$

where

m is the slope of the best-fit rectilinear curve;

n is the number of D value/temperature pairs;

$G = \sum[t(\log_{10} y)]$;

$A = \sum(t)$;

$B = \sum(\log_{10} y)$;

$C = \sum(t^2)$.

The data required for the calculation are given in Table B.1.

Table B.1 — Examples of data collected for regression analysis

D **value** (min) = y	**Exposure temperature** (°C) = t	$\log_{10} y$	t^2	$t(\log_{10} y)$	$(\log_{10} y)^2$
y_1	t_1	$\log_{10} y_1$	$(t_1)^2$	$t_1(\log_{10} y_1)$	$(\log_{10} y_1)^2$
y_2	t_2	$\log_{10} y_2$	$(t_2)^2$	$t_2(\log_{10} y_2)$	$(\log_{10} y_2)^2$
y_3	t_3	$\log_{10} y_3$	$(t_3)^2$	$t_3(\log_{10} y_3)$	$(\log_{10} y_3)^2$
y_n	t_n	$\log_{10} y_n$	$(t_n)^2$	$t_n(\log_{10} y_n)$	$(\log_{10} y_n)^2$
	$A = \sum_{i=1}^{i=n} t_i$	$B = \sum_{i=1}^{i=n} \log_{10} y_i$	$C = \sum_{i=1}^{i=n} (t_i)^2$	$G = \sum_{i=1}^{i=n} \left[t_i (\log_{10} y_i) \right]$	$E = \sum_{i=1}^{i=n} (\log_{10} y_i)^2$
Assigned variable	A	B	C	G	E

B.3 Table B.2 shows example calculations for the slope of the best-fit rectilinear curve.

Table B.2 — Examples of calculations for slope

D **value** (min) = y	**Exposure temperature** (°C) = t	$\log_{10} y$	t^2	$t(\log_{10} y)$	$(\log_{10} y)^2$
$y_1 = 2.0$	$t_1 = 121$	$\log_{10} y_1 = 0.3010$	$(t_1)^2 = 14{,}641$	$t_1(\log_{10} y_1) = 36.4210$	$(\log_{10} y_1)^2 = 0.0906$
$y_2 = 1.1$	$t_2 = 124$	$\log_{10} y_2 = 0.0414$	$(t_2)^2 = 15{,}376$	$t_2(\log_{10} y_2) = 5.1336$	$(\log_{10} y_2)^2 = 0.0017$
$y_3 = 0.4$	$t_3 = 129$	$\log_{10} y_3 = -0.3979$	$(t_3)^2 = 16{,}641$	$t_3(\log_{10} y_3) = -51.3291$	$(\log_{10} y_3)^2 = 0.1583$
	$A = \sum_{i=1}^{i=3} t_i$	$B = \sum_{i=1}^{i=3} \log_{10} y_i$	$C = \sum_{i=1}^{i=3} (t_i)^2$	$G = \sum_{i=1}^{i=3} \left[t_i (\log_{10} y_i) \right]$	$E = \sum_{i=1}^{i=5} (\log_{10} y_i)^2$
Assigned variable	$A = 374$	$B = -0.0555$	$C = 46658$	$G = -9.7745$	$E = 0.2506$

$$m = \frac{(nG) - (AB)}{(nC) - (A^2)}$$

$$m = \frac{\left[(3)(-9.7745)\right] - \left[(374)(-0.0555)\right]}{\left[(3)(46{,}658)\right] - (374^2)}$$

$$m = \frac{(-29.3235) - (-20.7570)}{(139{,}974) - (139{,}876)}$$

$$m = \frac{-8.5665}{98}$$

$$m = -0.0874$$

B.4 The z value is equal to the negative reciprocal of the slope obtained and is calculated using the following formula:

$$z \text{ value} = -1\left(\frac{1}{m}\right)$$

using the above calculated slope, the resulting z value is:

$$z = -1\left(\frac{1}{-0.0874}\right) = 11.4416 \text{ °C rounded to one decimal point}$$

z = 11.4 °C

B.5 The correlation coefficient, r^2, for the linearity of the z value curve is calculated using the following formula:

$$r^2 = \frac{\left\{(G) - \left[(A)(B/n)\right]\right\}^2}{\left[(C) - \left(A^2/n\right)\right]\left[(E) - \left(B^2/n\right)\right]}$$

where all variables are as defined in B.2 and $E = \sum(\log_{10} y)^2$.

B.6 Example calculations for the correlation coefficient for the linearity of the z value curve are given below.

Using the values from Table B.2,

$$r^2 = \frac{\left\{(-9.7745) - \left[(374)(-0.0555/3)\right]\right\}^2}{\left[(46{,}658) - \left(374^2/3\right)\right]\left[(0.2506) - \left(-0.0555^2/3\right)\right]}$$

$$r^2 = \frac{\left[(-9.7745) - \left[(-6.9190)\right]\right]^2}{\left[(46{,}658) - (46{,}625.3333)\right]\left[(0.2506) - (0.0010)\right]}$$

$$r^2 = \frac{(-2.8555)^2}{(32.6667)(0.2496)}$$

$$r^2 = \frac{8.1539}{8.1536}$$

$$r^2 = 1.0000$$

Bibliography

[1] ISO 14161, *Sterilization of health care products — Biological indicators — Guidance for the selection, use, and interpretation of results*

[2] ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*