Irish Standard
I.S. EN ISO 11138-3:2009

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)

I.S. EN ISO 11138-3:2009

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EUROPEAN STANDARD

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Supersedes EN ISO 11138-3:2006

English Version

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide (ISO 11138-3:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (ISO 11138-3:2006)

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Foreword

The text of ISO 11138-3:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11138-3:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 11138-3:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 11138-3:2006 has been approved by CEN as a EN ISO 11138-3:2009 without any modification.

I.S. EN ISO 11138-3:2009

INTERNATIONAL STANDARD

ISO 11138-3

Second edition
2006-07-01

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.

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, 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 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 — Biolgical 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.