
**Sterilization of health care products —
Biological indicators —**

**Part 1:
General requirements**

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 1: Exigences générales

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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 11138-1:2006), which has been technically revised.

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

Introduction

This document specifies general requirements for 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. Other parts of ISO 11138 provide additional specific requirements for biological indicators for defined sterilization processes.

A graphic description of a biological indicator and its components is presented in [Table F.1](#). The presentation includes the two types of biological indicators which are covered by ISO 11138 (all parts). This shows that inoculated carriers can be presented directly to the sterilizing agent without prior packaging, or included in a primary package that permits access by the sterilizing agent.

The resistance characteristics depend on the type of test organism, its numbers, the method of preparation, the substrate upon which it is inoculated, environmental conditions during inoculation and drying and the effects of the primary package. Advice on selection, use and interpretation of results of biological indicators can be found in ISO 14161.

For any individual sterilization process, including those covered in relevant parts of ISO 11138, the resistance of the biological indicator will also depend on its microenvironment during testing. In theory, this could lead to an infinite variation in the preparation of biological indicators. Moreover, a sterilization process could be manipulated in infinite variety to suit each possible set of conditions to which products could be exposed. It has, therefore, been a routine practice to manufacture biological indicators that, when exposed to a set of conditions in a defined sterilization process, provide resistance characteristics expressed as *D* values and, where relevant, *z* values. Such values are set out in the relevant parts of ISO 11138.

The ISO 11138 series represents the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing this document.

Biological indicators for specific sterilization processes not covered by reference test conditions in relevant parts of ISO 11138 should comply with the general requirements in this document, including the resistance testing procedures. Such biological indicators might not be well enough described, or might be used for novel sterilization processes, or might be represented by isolated bioburden microorganisms. If microorganisms other than risk group 1 (WHO 2004) are included in these biological indicators, appropriate safety measures (e.g. containment) are necessary.

Standards exist providing requirements for the validation and control of sterilization processes (see Bibliography).

NOTE It is possible that some countries or regions have published other standards covering requirements for sterilization or biological indicators (see Bibliography).

