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Sterilization of health care products — Biological indicators —

Part 7: Guidance for the selection, use and interpretation of results

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 7: Directives générales pour la sélection, l'utilisation et l'interprétation des résultats

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This first edition cancels and replaces ISO 14161:2009, which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides guidance regarding the selection, use and interpretation of results of biological indicators used to develop, validate and monitor sterilization processes. The procedures described in this document are of a general nature and do not, of themselves, constitute a comprehensive development, validation or monitoring programme with regard to the sterilization of health care products. The intent of this document is not to stipulate the use of biological indicators in a process but, if they are used, to provide guidance for their proper selection and use in order to avoid misleading results.

In this document, users will find guidance on selection of the correct biological indicator for their particular sterilization process (see the ISO 11138 series) and critical parameters as well as guidance on its appropriate use.

The selection of an appropriate biological indicator for the particular process used is critical. There is a wide variety of sterilization processes in common use, and biological indicator manufacturers are not able to foresee all possible uses of their product. Manufacturers, therefore, label biological indicators according to their intended use. It is the responsibility of the users of biological indicators to select, use, recover and interpret the results as appropriate for the particular sterilization process used.

The performance of a biological indicator can be adversely affected by the conditions of storage and transport prior to its use, by inappropriate/non-indicated use of the biological indicator or by the sterilizer process parameters. In addition, the incubation procedure used after exposure to the process, including incubation temperature and culture medium type, supplier and specific batch, can affect measured resistance as a function of recovery and growth. For these reasons, the recommendations of the biological indicator manufacturer for transportation, storage and use should be followed. After exposure, the aseptic transfer (if applicable) and incubation of biological indicators as specified by the biological indicator manufacturer is critical for obtaining correct results.

It is important to note that biological indicators are not intended to indicate that the products in the load being sterilized are sterile. Biological indicators are utilized to test the effectiveness of a given sterilization process and the equipment used, by assessing microbial lethality according to the concept of sterility assurance level. Suitable training is necessary for personnel conducting these studies.

NOTE The general information provided in this document can have useful application for processes and biological indicators not currently addressed by existing International Standards, e.g. new and developing sterilization processes.

Sterilization of health care products — Biological indicators —

Part 7: Guidance for the selection, use and interpretation of results

1 Scope

This document provides guidance for the selection, use and interpretation of results from application of biological indicators when used in the development, validation and routine monitoring of sterilization processes.

It does not consider those processes that rely solely on physical removal of microorganisms, e.g. filtration.

It is not applicable to combination processes using, for example, washer-disinfectors or flushing and steaming of pipelines.

It does not specify requirements for the selection and use of biological indicators intended to monitor vaporised hydrogen peroxide processes for isolator and room biodecontamination processes at atmospheric pressure.

It is not applicable to liquid immersion sterilization processes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aseptic technique
conditions and procedures used to minimize the risk of the introduction of microbial contamination

[SOURCE: ISO 11139:2018, 3.16]

3.2
bioburden
population of viable microorganisms on or in a product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]