Singapore Standards Council

SS ISO 14161 : 2018
ISO 14161:2009, IDT
(ICS 11.080.01)

SINGAPORE STANDARD

Sterilisation of health care products — Biological indicators — Guidance for the selection, use and interpretation of results

Published by
Enterprise Singapore

SS ISO 14161 : 2018
ISO 14161:2009, IDT
(ICS 11.080.01)

SINGAPORE STANDARD

Sterilisation of health care products — Biological indicators — Guidance for the selection, use and interpretation of results

ISBN 978-981-48-3550-3

This Singapore Standard was approved on 3 December 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

First published, 2019

The Biomedical and Health Standards Committee, appointed by the Standards Council, consists of the following members:

		Name	Capacity
Chairman	:	Dr Yong Chern Chet	*Individual Capacity*
Deputy Chairmen	:	Mr Vincent Cheung	*Individual Capacity*
		Ms Selina Seah	*Changi General Hospital*
		Ms Wong Woei Jiuang	*Health Sciences Authority*
Advisor	:	Ms Jacqueline Monteiro	*Individual Capacity*
Secretary	:	Mr Kevin Tan	*Singapore Manufacturing Federation – Standards Development Organisation*
Members	:	Mr Alec Chow Boon Kuan	*Medtronic International Ltd*
		Mr Chung Kwong Yuew	*Temasek Polytechnic (BioMedical Engineering Faculty)*
		Ms Heidi Goh	*Singapore Manufacturing Federation (Medical Technology Industry Group)*
		Prof James Goh	*Biomedical Engineering Society (Singapore)*
		Dr Lai Choon Sheen	*Eu Yan Sang International Ltd*
		Dr Christopher Lam	*Health Sciences Authority*
		Assoc Prof Leo Hwa Liang	*National University of Singapore*
		Dr Lin Jianhua	*TüV SüD PSB Pte Ltd*
		Dr Leonard Loh	*Nanyang Polytechnic*
		Assoc Prof Eddie Ng Yin Kwee	*Nanyang Technological University*
		Dr Ong Siew Hwa	*Acumen Research Laboratories Pte Ltd*
		Dr Padmanabhan Saravanan	*Temasek Polytechnic (Centre of Innovation for Complementary Health Products)*
		Mr Peh Ruey Feng	*Advent Access Pte Ltd*
		Ms Celine Tan	*Enterprise Singapore*
		Prof Tan Puay Hoon	*Singapore Health Services Pte Ltd*
		Ms Wang Dan	*Biosensors International Group*
		Dr Sidney Yee	*Diagnostics Development (DxD) Hub*
		Dr Zhou Zhihong	*Singapore Bioimaging Consortium*

The Technical Committee on Quality Management Systems, appointed by the Biomedical and Health Standards Committee, consists of representatives from the following organisations:

		Name	Capacity
Chairman	:	Ms Heidi Goh	*Individual Capacity*
Secretary	:	Mr Kevin Tan	*Singapore Manufacturing Federation – Standards Development Organisation*
Members	:	Ms Jasmine Chan	*Veredus Laboratories Pte Ltd*
		Mr Chin Kai Hwee	*Biosensors International Group*
		Ms Katherine Goh	*Singapore Accreditation Council*
		Dr Christopher Lam	*Health Sciences Authority*
		Mr Nishith Desai	*Medtronic International Ltd*
		Ms Grace Tan	*Edward Lifesciences (Singapore) Pte Ltd*

The National Mirror Working Group on ISO/TC 210, appointed by the Technical Committee to assist in the preparation of this standard, comprises the following experts who contribute in their individual capacity:

		Name
Convenor	:	Dr Margam Chandrasekaran
Secretary	:	Mr Kevin Tan
Members	:	Ms Heidi Goh
		Ms How Pei Sin
		Ms Audrey Lee
		Mr Liew Ee Bin
		Mr Narayanan Sethu
		Mr Caleb Ng
		Mr Paul Tan

The organisations in which the experts of the National Mirror Working Group are involved are:

Access-2-Healthcare
BioPharmaSpec UK Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
SysteMED Pte Ltd
TüV SüD PSB Pte Ltd
Wise Consultants and Services Pte Ltd

{blank page}

Contents

Page

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 210 appointed by the Technical Committee on Quality Management Systems under the direction of the Biomedical and Health Standards Committee.

This standard is identical with ISO 14161:2009, "Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results", published by the International Organization for Standardization.

Attention is drawn to the following:

1. Where appropriate, the words "International Standard" shall be replaced by "Singapore Standard"

2. The reference to International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
ISO/IEC 17025	SS ISO/IEC 17025
ISO 13485	SS ISO 13485
ISO 19011	SS ISO 19011
ISO 9000	SS ISO 9000
ISO 9001	SS ISO 9001
ISO 11737-1	SS ISO 11737-1
ISO 17665-1	SS ISO 17665-1

3. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations*

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 14161 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 14161:2000), which has been technically revised.

Introduction

This International Standard provides guidance regarding the selection, use and interpretation of results of biological indicators when used to develop, validate and monitor sterilization processes. The procedures described in this International Standard 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 International Standard is not to mandate 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 obviate misleading results.

In this International Standard, users will find guidance on selection of the correct biological indicator for their particular sterilization process and critical parameters as well as guidance on its appropriate use.

The user should select a biological indicator that is appropriate for the particular process to be used. 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 certified performance of a biological indicator can be adversely affected by the conditions of storage and transport prior to its use, by the use of the biological indicator or by the sterilizer process parameters. In addition, the incubation procedure used after exposure to the process, including outgrowth temperature and culture medium type, supplier and specific lot, can affect measured resistance as a function of recovery and growth. For these reasons, the recommendations of the biological indicator manufacturer for storage and use should be followed. After exposure, biological indicators should be aseptically transferred (if applicable) and incubated as specified by the biological indicator manufacturer.

It should be noted 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. Suitably trained personnel should conduct these studies.

Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results

1 Scope

This International Standard 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. This International Standard applies to biological indicators for which International Standards exist.

NOTE 1 See, for example, the ISO 11138 series.

NOTE 2 The general information provided in this International Standard can have useful application for processes and biological indicators not currently addressed by existing International Standards, e.g., new and developing sterilization processes.

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

This International Standard is not intended to apply to combination processes using, for example, washer disinfectors or flushing and steaming of pipelines.

This International Standard is not intended to apply to liquid sterilization processes.

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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11138-1:2006, S*terilization 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*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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*

ISO 18472:2006, *Sterilization of health care products — Biological and chemical indicators — Test equipment*