Singapore Standards Council

SS ISO 11137-3 : 2018
ISO 11137-3 : 2017, IDT
(ICS 11.080.01)

SINGAPORE STANDARD

Sterilisation of health care products — Radiation

– Part 3 : Guidance on dosimetric aspects of development, validation and routine control

Published by
Enterprise Singapore

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Sterilisation of health care products — Radiation

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ISBN 978-981-48-3547-3

This Singapore Standard was approved on 9 November 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

First published, 2019

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Singapore Manufacturing Federation (Medical Technology Industry Group)
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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 11137-3:2017, "Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control", published by the International Organization for Standardization.

Attention is drawn to the following:

1. The references to International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
ISO 11137-1	SS ISO 11137-1
ISO 13485	SS ISO 13485
ISO 14971	SS ISO 14971
ISO/IEC 17025	SS ISO/IEC 17025

2. 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 also 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.

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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).

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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 second edition cancels and replaces the first edition (ISO 11137-3:2006), which has been technically revised.

A list of all parts in the ISO 11137 series can be found on the ISO website.

Introduction

An integral part of radiation sterilization is the ability to measure dose. Dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or an International Standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental considerations on dosimeter response is known and taken into account. Process parameters are established and applied based on dose measurements. This document provides guidance on the use of dose measurements (dosimetry) during all stages in the development, validation and routine control of the radiation sterilization process.

Requirements in regard to dosimetry are given in ISO 11137-1 and ISO 11137-2 and ISO/TS 13004. This document gives guidance to these requirements. The guidance given is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control

1 Scope

This document gives guidance on meeting the requirements in ISO 11137-1 and ISO 11137-2 and in ISO/TS 13004 relating to dosimetry and its use in development, validation and routine control of a radiation sterilization process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of a selected sterilization dose: Method* VD_{max}^{SD}

ISO 13485**,** *Medical devices — Quality management systems — Requirements for regulatory purposes*