SLS ISO 11737 PART 1: 2020
(ISO 11737-1: 2018)
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STERILIZATION OF HEALTH CARE PRODUCTS — MICROBIOLOGICAL METHODS — PART 1: DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard

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Sri Lanka Standard
STERILIZATION OF HEALTH CARE PRODUCTS — MICROBIOLOGICAL METHODS — PART 1: DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

NATIONAL FOREWORD

This Sri Lanka Standard was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2020-05-15.

In the context of corona virus crisis, it has been agreed to adopt the International Standard, **ISO 11737-1: 2018** Sterilization of health care products — Microbiological methods — Part 1: determination of a population of microorganisms on products.

This standard specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package. A sterile health care product is one that is free of viable microorganisms. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The text of the International Standard **ISO 11737-1:2018**, has been accepted for adoption as a Sri Lanka Standard. This Sri Lanka Standard is identical with **ISO 11737-1:2018**, Sterilization of health care products — Microbiological methods —Part 1: determination of a population of microorganisms on products, published by the International Organization of Standardization (ISO)

TERMINOLOGY AND CONVENTIONS

The text of the International Standard has been accepted as suitable for publication without deviation, as a Sri Lanka Standard. However certain terminology and conventions are not identical with those used in Sri Lanka Standards. Attention is therefore drawn to the following:

a) Wherever the words “International Standard” appear referring to this standard they should be interpreted as “Sri Lanka Standard”.

b) The comma has been used throughout as a decimal marker. In Sri Lanka Standards it is the current practice to use a full point on the baseline as the decimal marker.

c) Whenever page numbers are quoted, they are ISO page numbers.

INTERNATIONAL STANDARD

ISO 11737-1

Third edition
2018-01

Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

Stérilisation des produits de santé — Méthodes microbiologiques —

Partie 1: Détermination d'une population de microorganismes sur des produits

Reference number
ISO 11737-1:2018(E)

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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 11737-1:2006), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11737-1:2006/Cor.1:2007.

The main changes compared to the previous edition are as follows:

— the term “bioburden spikes” has been introduced as a normal and consistent part of the bioburden, and examples of data have been provided;

— clarification has been added that package testing is not typically done except when it is an integral part of the product;

— more information has been provided on the most probable number (MPN) technique and its applications;

— details have been provided on ways to improve limit of detection (LOD) and correct use of the data;

— some discussion has been deleted of statistical methods for the evaluation of bioburden data where information was not typical or not required;

— a table has been added with criteria for selection of a bioburden recovery efficiency approach, the use of the correction factor (CF) has been explained, and the bioburden recovery efficiency value of < 50 % mentioned for technique modifications has been eliminated;

— more information has been provided on the application and performance of a bioburden method suitability test;

— a section has been added to detail rules for direct plate counts, estimated counts and counts beyond the ideal range;

— a table has been added to clarify where typical responsibilities reside for the manufacturer or the laboratory;