NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 19973.1-2023

Sterilization of health care products--Microbiological methods - Part 1: Determination of a population of microorganisms on products

Issued on: March 17, 2023 **Implemented on: October 1, 2024**

Issued by: SAMR; SAC

Table of Contents

Foreword... 3
Introduction... 5
1 Scope... 7
2 Normative References... 7
3 Terms and Definitions... 8
4 General Requirements... 11
5 Selection of Products... 12
6 Methods of Determination and Microbial Characterization of Bioburden... 13
7 Validation of the Method for Determining Bioburden... 15
8 Routine Determination of Bioburden and Interpretation of Data... 16
9 Maintenance of the Method for Determining Bioburden... 17

Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for

Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 1 of GB/T 19973 Sterilization of Health Care Products - Microbiological

Methods. GB/T 19973 consists of the following parts.

--- Part 1.Determination of a Population of Microorganisms on Products;

--- Part 2.Tests of Sterility Performed in the Definition, Validation and Maintenance of a

Sterilization Process.

This Document replaced GB/T 19973.1-2015 Sterilization of Medical Devices -

Microbiological Methods - Part 1.Determination of a Population of Microorganisms on

Products. Compared with GB/T 19973.1-2015, the major technical changes of this Document

are as follows besides the structural adjustments and editorial modifications.

--- Added the term "bioburden spike" and its definition (see 3.6 of this Edition);

--- Add attention to the impact of changes in products and/or production processes on

bioburden determination methods (see 9.1 of this Edition).

This Document equivalently adopted ISO 11737-1.2018 Sterilization of Health Care Products

- Microbiological Methods - Part 1.Determination of a Population of Microorganisms on

Products.

This Document made the following minimum editorial modifications.

--- Incorporate the amendments to ISO 11737-1.2018/Amd.1.2021.The affected clauses are

marked with a double vertical line (||) in the outer margins.

--- Add the Pharmacopoeia of the People's Republic of China to the pharmacopoeia

examples (see A.4.3 of this Document).

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Sterilization

Techniques and Equipment of Standardization Administration of China (SAC/TC 200).

Drafting organizations of this Document. Suzhou ProSteri Medical Technology Co., Ltd.;

Hangzhou Endonom Medtech Co., Ltd.; Guangdong Medical Devices Quality Surveillance and

Test Institute; Johnson & Johnson Medical (Suzhou) Ltd.; Terumo Medical Products

Sterilization of Health Care Products - Microbiological

Methods - Part 1.Determination of a Population of

Microorganisms on Products

1 Scope

This Document 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.

NOTE 1.The nature and extent of microbial characterization is dependent on the intended use of

bioburden data.

NOTE 2.See Annex A for guidance on Clauses 1 to 9.

This document does not apply to the enumeration or identification of viral, prion or protozoan

contaminants. This includes the removal and detection of the causative agents of spongiform

encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob

disease.

NOTE 3.Guidance on inactivating viruses and prions can be found in ISO 22442-3, ICH Q5A(R1) and

ISO 13022.

This Document does not apply to the microbiological monitoring of the environment in which

health care products are manufactured.

2 Normative References

The provisions in following documents become the essential provisions of this Document

through reference in this Document. For the dated documents, only the versions with the dates

indicated are applicable to this Document; for the undated documents, only the latest version

(including all the amendments) is applicable to this Document.

ISO 13485 Medical devices - Quality management systems - requirements for regulatory

purposes

NOTE. YY/T 0287-2017 Medical devices - Quality management systems - Requirements for regulatory

purposes (ISO 13485.2016, IDT)

.....