PD ISO/TS 22456:2021

BSI Standards Publication

Sterilization of healthcare products — Microbiological methods — Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

bsi.

National foreword

This Published Document is the UK implementation of ISO/TS 22456:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2021

ISBN 978 0 539 02803 4

ICS 07.100.10; 11.080.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 March 2021.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 22456:2021

TECHNICAL SPECIFICATION

ISO/TS 22456

First edition
2021-03-19

Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

Reference number
ISO/TS 22456:2021(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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.*

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

The sources and types of some microorganisms, as well as the test methods used to evaluate biologics and tissue-based products, can be unique relative to other health care products, such as plastic and metal medical devices. This document provides guidance to address issues that are applicable to the microbiological testing of biologics and tissue-based products, where this testing constitutes bioburden testing or a test of sterility performed in relation to product sterilization. Except where otherwise indicated in this document, the requirements in ISO 11737-1:2018 and ISO 11737-2:2019 apply.

TECHNICAL SPECIFICATION **ISO/TS 22456:2021**

Sterilization of healthcare products — Microbiological methods — Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

1 Scope

1.1 Inclusions

1.1.1 This document provides guidance for bioburden testing and tests of sterility for biologics and tissue-based products, where this testing is in relation to product sterilization.

NOTE This document is intended to be used in conjunction with ISO 11737-1 and ISO 11737-2.

1.1.2 Guidance in this document can be applicable to biologics and tissue-based products that are not sterile but are microbiologically controlled.

1.2 Exclusions

1.2.1 This document does not include guidance for validation requirements for testing, eliminating and/or inactivating viruses and prions or sterilization of tissue-based products.

NOTE Guidance on inactivating viruses and prions can be found in ISO 22442-3.

1.2.2 This document does not include guidance for containment or biosafety issues for biologics and tissue-based products.

1.2.3 This document does not include guidance for testing biologics and tissue-based products for specific infectious agents as listed in relevant national or international guidance (e.g. viruses/protozoa/parasites, intracellular microorganisms or mycoplasma screening).

1.2.4 This document does not include guidance for the acceptance criteria for biologics and tissue-based products during procurement or tissue to be processed and/or released for use.

1.2.5 This document does not include guidance for the testing associated with procurement and screening of biologics and tissue-based products.

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 11737-1:2018, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2:2019, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

