BS 6256:2021

BSI Standards Publication

Packaging for terminally-sterilized medical devices — Method for determination of methylene blue particulate penetration

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Published by BSI Standards Limited 2021

ISBN 978 0 5 9 12512 2

ICS 1.08 .30

The following BSI references relate to the work on this document:
Committee reference CH/198
Draft for comment 20/30408621 DC

Amendments/corrigenda issued since publication

Date	Text affected

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Summary of pages
This document comprises a front cover, and inside front cover, pages i to iv, pages 1 to 27, an inside back cover and a back cover.

Foreword

Publishing information

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 31 January 2021. It was prepared by 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 committee manager.

Supersession

This British Standard supersedes BS 6256:1989, incorporating amendment 1, which is withdrawn.

Information about this document

BS 6256:1989 specified requirements for materials, performance, marking and packaging for paper used in the manufacture of steam sterilization paper bags, pouches and reels. These requirements have been superseded by the adoption as British Standards of European Standards in the EN ISO 11607 series and EN 868 series (see Bibliography).

Annex C to BS 6256:1989 provided a test method for determination of methylene blue particulate penetration of packaging material. This test method is referenced in BS EN ISO 11607-1 but has not been incorporated into that standard nor into the BS EN 868 series. This British Standard contains only the test method from the 1989 edition of BS 6256 and retains the same BS identifier in order to maintain the integrity of the reference from BS EN 11607-1.

Annex C to BS 6256:1989 normatively referenced BS 2577:1955 and BS 3431:1961, which have been withdrawn. The necessary content of these standards has therefore been incorporated into this new edition.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its methods are expressed as a set of instructions, a description, or in sentences in which the principal auxiliary verb is “shall”.

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

The word “should” is used to express recommendations of this standard. The word “may” is used in the text to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word “can” is used to express possibility, e.g. a consequence of an action or an event.

Notes and commentaries are provided throughout the text of this standard. Notes give references and additional information that are important but do not form part of the recommendations. Commentaries give background information.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

Contractual and legal considerations

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

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

0 Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavour. The device components and the packaging system need to be combined to create a product that performs efficiently, safely, and effectively in the hands of the user. The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, intended sterilization methods(s), intended use, expiry date, transport and storage all influence the packaging system design and choice of materials. The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device.

BS EN ISO 11607-1 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs and sterilization methods.

BS EN ISO 11607-2 describes the validation requirements for forming, sealing and assembly processes.

BS EN 868 Parts 2 to 10 specify particular requirements for a range of commonly used materials. Compliance with BS EN 868 Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of BS EN ISO 11607-1.

BS EN 11607-1 requires that porous materials provide an adequate microbial barrier to microorganisms in order to provide integrity of the sterile barrier system and product safety. It continues by noting that there is no universally accepted method of demonstrating microbial barrier properties. Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates under a set of test conditions which specify the flow rate through the material, challenge to the sample and duration of the test. The microbial barrier properties of the material, under these specified test conditions, are determined by comparing the extent of bacterial or particulate penetration through the material with that of the original challenge. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. As validated microbial challenge methods for materials and sterile barrier systems become available, they will be considered for inclusion in future editions of BS EN ISO 11607-1.

BS EN ISO 11607-1:2009+A1:2014, Annex B lists standardized test methods and procedures that may be used to demonstrate compliance with the requirements of BS EN ISO 11607-1. The method described in this British Standard is listed as one of the possible methods of demonstrating microbial barrier properties. This method is based on a test method described in BS 2577 (withdrawn) that was developed to assess the protection afforded by respirator cannisters containing a filtering medium against particulate clouds.

1 Scope

This British Standard describes methods of demonstrating the performance of the microbial barrier of porous material used in a sterile barrier system by penetration of particles of methylene blue.

