BS ISO 8536-6:2025

BSI Standards Publication

Infusion equipment for medical use

Part 6: Freeze drying closures for infusion bottles

Documents
Document Sharing Hub

Full document details: BS ISO 8536-6:2025

National foreword

This British Standard is the UK implementation of ISO 8536-6:2025. It supersedes BS ISO 8536-6:2016, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

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

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2025
Published by BSI Standards Limited 2025

ISBN 978 0 539 24633 9

ICS 11.040.20

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2025.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS ISO 8536-6:2025

International Standard

ISO 8536-6

Fourth edition
2025-03

Infusion equipment for medical use —

Part 6:
Freeze drying closures for infusion bottles

Matériel de perfusion à usage médical —

Partie 6: Bouchons à lyophilisation pour flacons de perfusion

Reference number
ISO 8536-6:2025(en)

© ISO 2025

Documents
Document Sharing Hub

Full document details: BS ISO 8536-6:2025

COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Documents
Document Sharing Hub
Full document details: BS ISO 8536-6:2025

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Shape and dimensions ... **2**
5 Designation ... **3**
6 Material ... **3**
7 Requirements ... **4**
7.1 General ... 4
7.2 Physical requirements ... 4
7.2.1 Hardness ... 4
7.2.2 Fragmentation (coring) ... 4
7.2.3 Spike penetration force ... 4
7.2.4 Spike retention/sealability ... 4
7.2.5 Resistance to ageing ... 4
7.2.6 Residual moisture ... 5
7.3 Chemical requirements ... 5
7.4 Biological requirements ... 5
8 Labelling ... **5**
Annex A (normative) **Determination of fragments** ... **6**
Annex B (normative) **Determination of spike penetration force** ... **8**
Annex C (normative) **Spike retention/sealability** ... **10**
Annex D (normative) **Closure piercing device** ... **12**
Annex E (informative) **Determination of residual moisture** ... **13**
Bibliography ... **16**

© ISO 2025 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 8536-6:2025

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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see http://www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at http://www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 http://www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 8536-6:2016), which has been technically revised.

The main changes are as follows:

— reference to [1] has been removed:

— reference to ISO 8536-7 has been added;

— information regarding fragment size and sterilization step have been clarified.

A list of all parts in the ISO 8536 series can be found on the ISO website.

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.

© ISO 2025 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 8536-6:2025

Introduction

Freeze drying closures are put on the top of infusion bottles after filling, leaving sufficient openings for the sublimation process and vacuum. At the end of the drying process, they can be fully inserted into the glass container by hydraulic or mechanical means in the vacuum chamber.

Freeze drying closures can pick up water during shipping, storage, washing and steam sterilization cycles, which is difficult to remove in a subsequent drying cycle. As a consequence, the freeze drying closures are usually loaded with residual moisture. Depending upon the mass of the freeze-dried product and the degree of its sensitivity to water, the residual moisture in the rubber material can spoil the freeze-dried preparation during storage.

These specific process requirements have been addressed in this document by specifying relevant requirements for freeze drying closures including a test method on determination of residual moisture.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, for example, ISO 15378[2] or GMP Guidelines as published by the European Community and the United States of America.

© ISO 2025 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 8536-6:2025

Documents
Document Sharing Hub