

BS EN ISO 8362-5:2016



BSI Standards Publication

Injection containers and accessories

Part 5: Freeze drying closures for injection vials

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National foreword

This British Standard is the UK implementation of EN ISO 8362-5:2016.

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 secretary.

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

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Amendments/corrigenda issued since publication

Date	Text affected
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English Version

Injection containers and accessories - Part 5: Freeze drying closures for injection vials (ISO 8362-5:2016)

Réipients et accessoires pour produits injectables -
Partie 5: Bouchons à lyophilisation pour flacons
d'injection (ISO 8362-5:2016)

Injektionsbehältnisse und Zubehör - Teil 5:
Gefriertrocknungsstopfen für Injektionsflaschen (ISO
8362-5:2016)

This European Standard was approved by CEN on 2 January 2016.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 8362-5:2016) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by September 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 8362-5:2016 has been approved by CEN as EN ISO 8362-5:2016 without any modification.

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8362-5:2008), which has been technically revised to include a new [7.5](#).

ISO 8362 consists of the following parts, under the general title *Injection containers and accessories*:

- *Part 1: Injection vials made of glass tubing*
- *Part 2: Closures for injection vials*
- *Part 3: Aluminium caps for injection vials*
- *Part 4: Injection vials made of moulded glass*
- *Part 5: Freeze drying closures for injection vials*
- *Part 6: Caps made of aluminium-plastics combinations for injection vials*
- *Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*