

Injection containers and accessories

Part 1: Injection vials made of glass tubing (ISO 8362-1:2009)

ICS 11.040.20

National foreword

This British Standard is the UK implementation of EN ISO 8362-1:2009+A1:2015. It supersedes BS EN ISO 8362-1:2009 which is withdrawn.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 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	Comments
31 January 2016	Implementation of ISO amendment 1:2015 with CEN endorsement A1:2015: Table 1 updated

English Version

Injection containers and accessories - Part 1: Injection vials
made of glass tubing (ISO 8362-1:2009)

Réipients et accessoires pour produits injectables - Partie
1: Flacons en verre étiré (ISO 8362-1:2009)

Injektionsbehältnisse und Zubehör - Teil 1:
Injektionsflaschen aus Röhrenglas (ISO 8362-1:2009)

This European Standard was approved by CEN on 21 December 2009.

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Foreword

This document (EN ISO 8362-1:2009) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use".

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of an identical text or by endorsement, at the latest by June 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.

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.

This document supersedes EN ISO 8362-1:2004.

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Endorsement notice

The text of ISO 8362-1:2009 has been approved by CEN as a EN ISO 8362-1:2009 without any modification.

Foreword to amendment A1

This document (EN ISO 8362-1:2009/A1:2015) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use".

This Amendment to the European Standard EN ISO 8362-1:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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Endorsement notice

The text of ISO 8362-1:2009/Amd 1:2015 has been approved by CEN as EN ISO 8362-1:2009/A1:2015 without any modification.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 8362-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8362-1:2003), which has undergone minor revision by including further types of neck finishes for injection vials [model B – neck finish with blow back (European style) and model C – neck finish with blow back (American style)].

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*