SLOVENSKI STANDARD
SIST EN ISO 8362-1:2010

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Nadomešča:
SIST EN ISO 8362-1:2005

Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 1. del: Viale iz cevnega stekla (ISO 8362-1:2009)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 8362-1:2009**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8362-1:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8362-1

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Supersedes EN ISO 8362-1:2004

English Version

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

Récipients 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)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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of an identical text or by endorsement, at the latest by June 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.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

INTERNATIONAL STANDARD

ISO 8362-1

Third edition
2009-12-15

Injection containers and accessories —

Part 1: Injection vials made of glass tubing

Récipients et accessoires pour produits injectables —

Partie 1: Flacons en verre étiré

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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.

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*