

# **SLOVENSKI STANDARD**

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

**01-marec-2010**

**Nadomešča:**

**SIST EN ISO 8362-1:2005**

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**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)

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

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

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

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 8362-1**

December 2009

ICS 11.040.20

Supersedes EN ISO 8362-1:2004

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 Röhrglas (ISO 8362-1:2009)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

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# INTERNATIONAL STANDARD

**ISO**  
**8362-1**

Third edition  
2009-12-15

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## Injection containers and accessories — Part 1: Injection vials made of glass tubing

*Réipients et accessoires pour produits injectables —*

*Partie 1: Flacons en verre étiré*

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Reference number  
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## Foreword

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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.

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

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*