# SLOVENSKI STANDARD
# SIST EN ISO 8362-4:2011

**01-december-2011**

**Nadomešča:**
**SIST EN ISO 8362-4:2005**

---

**Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 4. del: Viale iz litega stekla (ISO 8362-4:2011)**

Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)

Injektionsbehältnisse und Zubehör - Teil 4: Injektionsflaschen aus Hüttenglas (ISO 8362-4:2011)



Récipients et accessoires pour produits injectables - Partie 4: Flacons en verre moulé (ISO 8362-4:2011)



**Ta slovenski standard je istoveten z:** **EN ISO 8362-4:2011**

---

**ICS:**

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

**SIST EN ISO 8362-4:2011** **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 8362-4

September 2011

ICS 11.040.20

Supersedes EN ISO 8362-4:2004

English Version

# Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)

Récipients et accessoires pour produits injectables - Partie 4: Flacons en verre moulé (ISO 8362-4:2011)

Injektionsbehältnisse und Zubehör - Teil 4: Injektionsflaschen aus Hüttenglas (ISO 8362-4:2011)

This European Standard was approved by CEN on 31 August 2011.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.



CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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 United Kingdom.



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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Contents

Page

# Foreword

This document (EN ISO 8362-4:2011) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing 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 March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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 8362-4:2004.

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, Croatia, 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.



**Endorsement notice**

The text of ISO 8362-4:2011 has been approved by CEN as a EN ISO 8362-4:2011 without any modification.

INTERNATIONAL STANDARD

**ISO 8362-4**

Third edition
2011-09-01

# Injection containers and accessories —

## Part 4: Injection vials made of moulded glass

*Récipients et accessoires pour produits injectables —*

*Partie 4: Flacons en verre moulé*



Reference number
ISO 8362-4:2011(E)



ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

 

# 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.

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 8362-4 was prepared by Technical Committee 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 8362-4:2003), of which it constitutes a minor revision.

The principle changes to the second edition are the updating of normative references to ISO 4802-1 and ISO 4802-2, and the revision of Figure 2 and Table 2.



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*