



SLOVENSKI STANDARD SIST EN ISO 8362-2:2010

01-november-2010

Nadomešča:
SIST EN 28362-2:2000

Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 2. del: Zapirala za viale (ISO 8362-2:2008)

Injection containers and accessories - Part 2: Closures for injection vials (ISO 8362-2:2008)

Injektionsbehälter und Zubehör - Teil 2: Stopfen für Injektionsflaschen (ISO 8362-2:2008)

Réipients et accessoires pour produits injectables - Partie 2: Bouchons pour flacons (ISO 8362-2:2008) <https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

Ta slovenski standard je istoveten z: EN ISO 8362-2:2010

ICS:

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

SIST EN ISO 8362-2:2010

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 8362-2:2010

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

EUROPEAN STANDARD

EN ISO 8362-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2010

ICS 11.040.20

Supersedes EN 28362-2:1993

English Version

**Injection containers and accessories - Part 2: Closures for
injection vials (ISO 8362-2:2008)**Récipients et accessoires pour produits injectables - Partie
2: Bouchons pour flacons (ISO 8362-2:2008)Injektionsbehältnisse und Zubehör - Teil 2: Stopfen für
Injektionsflaschen (ISO 8362-2:2008)

This European Standard was approved by CEN on 5 August 2010.

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.

iTeh STANDARD PREVIEW

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.

[SIST EN ISO 8362-2:2010](https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010)

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG**Management Centre: Avenue Marnix 17, B-1000 Brussels**

Contents

Page

Foreword.....3

**iTeh STANDARD PREVIEW
(standards.iteh.ai)**

SIST EN ISO 8362-2:2010

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

Foreword

The text of ISO 8362-2:2008 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8362-2:2010.

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 March 2011, and conflicting national standards shall be withdrawn at the latest by March 2011.

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 28362-2:1993.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

Endorsement notice

The text of ISO 8362-2:2008 has been approved by CEN as a EN ISO 8362-2:2010 without any modification.

[SIST EN ISO 8362-2:2010](https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010)

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 8362-2:2010

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

INTERNATIONAL STANDARD

ISO
8362-2

Second edition
2008-10-15

Injection containers and accessories — Part 2: Closures for injection vials

Réipients et accessoires pour produits injectables —

Partie 2: Bouchons pour flacons

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 8362-2:2010](https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010)

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>



Reference number
ISO 8362-2:2008(E)

© ISO 2008

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 8362-2:2010](https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010)

<https://standards.iteh.ai/catalog/standards/sist/97ad845d-da16-45c3-bb60-ca16490d8bdc/sist-en-iso-8362-2-2010>

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2008

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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 8362-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8362-2:1988) which has been technically revised in order to align this part with ISO 8871-1, ISO 8871-4 and ISO 8871-5.

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*