



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 8362-2:2014**  
**01-september-2014**

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**Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 2. del: Zapirala za vialo (ISO/DIS 8362-2:2014)**

Injection containers and accessories - Part 2: Closures for injection (ISO/DIS 8362-2:2014)

Injektionsbehälter und Zubehör - Teil 2: Stopfen für Injektionsflaschen (ISO/DIS 8362-2:2014)

Réipients et accessoires pour produits injectables - Partie 2: Bouchons pour flacons (ISO/DIS 8362-2:2014)

**Ta slovenski standard je istoveten z: prEN ISO 8362-2**

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**oSIST prEN ISO 8362-2:2014**

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# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 8362-2

ISO/TC 76

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## Injection containers and accessories —

### Part 2: Closures for injection

*Réipients et accessoires pour produits injectables —*

*Partie 2: Bouchons pour flacons*

ICS: 11.040.20

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### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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## ISO/DIS 8362-2

### Foreword

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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 third edition cancels and replaces the second edition (ISO 8362-2:2008), which has been technically revised in order to include a new subclause 7.5 particulate contamination requirements.

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*