



SLOVENSKI STANDARD

SIST EN 28362-2:2000

01-januar-2000

Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 2. del: Zapirala za viale (ISO 8362-2:1988)

Injection containers for injectables and accessories - Part 2: Closures for injection vials (ISO 8362-2:1988)

Injektionsbehälter für Injektionspräparate und Zubehör - Teil 2: Stopfen für Injektionsflaschen (ISO 8362-2:1988)

Réipients et accessoires pour produits injectables - Partie 2: Bouchons pour flacons injectables (ISO 8362-2:1988)

[SIST EN 28362-2:2000](https://standards.iteh.ai/catalog/standards/sist/f7449b7c-9535-46e5-a7ac-0a32595ae320/sist-en-28362-2-2000)

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Ta slovenski standard je istoveten z: EN 28362-2:1993

ICS:

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

EN 28362-2:1993

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 1993

UDC 615.473.014.87-036

Descriptors: Medical equipment, parenteral infusion equipment, injectable products, flasks, stoppers, rubber products, specifications, tests, marking

English version

**Injection containers for injectables and accessories
- Part 2: Closures for injection vials
(ISO 8362-2:1988)**

Réipients et accessoires pour produits
injectables - Partie 2: Bouchons pour flacons
injectables (ISO 8362-2:1988)

Injektionsbehältnisse für Injektionspräparate
und Zubehör - Teil 2: Stopfen für
Injektionsflaschen (ISO 8362-2:1988)

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This European Standard was approved by CEN on 1993-04-14. 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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

In 1990, the International Standard ISO 8362-2:1988 "Injection containers for injectables and accessories - Part 2: Closures for injection vials" was submitted to the CEN Primary Questionnaire procedure.

Following the positive result of the CEN/CS Proposal, ISO 8362-2:1988 was submitted to the Formal Vote.

The result of the Formal Vote was positive.

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 October 1993, and conflicting national standards shall be withdrawn at the latest by October 1993.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

Endorsement notice

The text of the International Standard ISO 8362-2:1988 was approved by CEN as a European Standard without any modification.

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NOTE: The European references to international publications are given in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

<u>Publication</u>	<u>Title</u>	<u>EN/HD</u>
ISO 48	Vulcanized rubbers - Determination of hardness (Hardness between 30 and 85 IRHD)	
ISO 2859-1	Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection	
ISO 3302	Rubber - Dimensional tolerances for use with products	
ISO 3696	Water for analytical laboratory use - Specification and test methods	
ISO 7864	Sterile hypodermic needles for single use	
ISO 7886	Sterile hypodermic syringes for single use	
ISO 8362-1	Injection containers for injectables and accessories - Part 1: Injection vials made of glass tubing	EN 28362-1
ISO 8362-4	Injection containers for injectables and accessories - Part 4: Injection vials made of moulded glass	EN 28362-4
ISO 8871	Elastomeric parts for aqueous parenteral preparations	EN 28871

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INTERNATIONAL STANDARD

ISO
8362-2

First edition
1988-12-15



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Injection containers for injectables and accessories —

Part 2 : Closures for injection vials

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Réipients et accessoires pour produits injectables —

Partie 2: Bouchons pour flacons

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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

ISO 8362 consists of the following parts, under the general title *Injection containers for injectables 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*

Annexes A, B and C form an integral part of this part of ISO 8362.