



SLOVENSKI STANDARD
SIST EN 28362-3:2000

01-januar-2000

**Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 3. del:
Aluminijeve zaporke za viale (ISO 8362-3:1989)**

Injection containers for injectables and accessories - Part 3: Aluminium caps for injection vials (ISO 8362-3:1989)

Injektionsbehältnisse für Injektionspräparate und Zubehör - Teil 3: Aluminium-Bördelkappen für Injektionsflaschen (ISO 8362-3:1989)

Réipients et accessoires pour produits injectables - Partie 3: Capsules en aluminium pour flacons (ISO 8362-3:1989)

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Ta slovenski standard je istoveten z: EN 28362-3:1993

ICS:

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

EN 28362-3:1993

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 1993

UDC 615.473:621.790.26-034.71

Descriptors: Medical equipment, parenteral infusion equipment, injectable products, flasks, caps : containers, aluminium products, specifications, designation, dimensions

English version

**Injection containers for injectables and accessories
- Part 3: Aluminium caps for injection vials
(ISO 8362-3:1989)**

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Réipients et accessoires pour produits
injectables - Partie 3: Capsules en aluminium
pour flacons (ISO 8362-3:1989)

Injektionsbehältnisse für Injektionspräparate
und Zubehör - Teil 3: Aluminium-Bördelkappen
für Injektionsflaschen (ISO 8362-3:1989)

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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 8362-3:1989 "Injection containers for injectables and accessories - Part 3: Aluminium caps for injection vials" was submitted to the CEN Primary Questionnaire procedure.

Following the positive result of the CEN/CS Proposal, ISO 8362-3:1989 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 8362-3:1989 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 8872	Aluminium caps for transfusion, infusion and injection bottles - General requirements and test methods	EN 28872

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INTERNATIONAL STANDARD

ISO 8362-3

First edition
1989-11-15

Injection containers for injectables and accessories —

Part 3 : Aluminium caps for injection vials

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*Réipients et accessoires pour produits
injectables —*

Partie 3 : Capsules en aluminium pour flacons

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Reference number
ISO 8362-3 : 1989 (E)

ISO 8362-3 : 1989 (E)

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International Organization for Standardization

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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 8361-3 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*