



# SLOVENSKI STANDARD SIST EN ISO 8536-3:2000

01-januar-2000

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**Infuzijska oprema za uporabo v medicini - 3. del: Aluminijeve zaporke za infuzijske steklenice (ISO 8536-3:1999)**

Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles (ISO 8536-3:1999)

Infusionsgeräte zur medizinischen Verwendung - Teil 3: Aluminium-Bördelkappen für Infusionsflaschen (ISO 8536-3:1999)

Matériel de perfusion a usage médical - Partie 3: Capsules en aluminium pour flacons de perfusion (ISO 8536-3:1999)

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**Ta slovenski standard je istoveten z: EN ISO 8536-3:1999**

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**SIST EN ISO 8536-3:2000**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 8536-3

February 1999

ICS 11.040.20

English version

Infusion equipment for medical use - Part 3: Aluminium caps for  
infusion bottles (ISO 8536-3:1999)

Matériel de perfusion à usage médical - Partie 3: Capsules  
en aluminium pour flacons de perfusion (ISO 8536-3:1999)

Infusionsgeräte zur medizinischen Verwendung - Teil 3:  
Aluminium-Bördelkappen für Infusionsflaschen (ISO 8536-  
3:1999)

This European Standard was approved by CEN on 25 January 1999.

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.

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 Central Secretariat has the same status as the official versions.

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

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

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

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## Foreword

The text of the International Standard from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC "Non-active medical devices", the secretariat of which is held by BSI.

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 August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

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

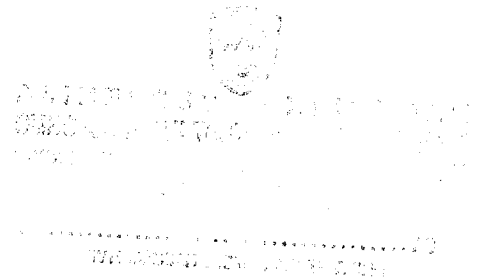
## Endorsement notice

The text of the International Standard ISO 8536-3:1999 has been approved by CEN as a European Standard without any modification.

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INTERNATIONAL  
STANDARD

**ISO**  
**8536-3**

Second edition  
1999-09-01

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**Infusion equipment for medical use —**

**Part 3:**

**Aluminium caps for infusion bottles**

*Matériel de perfusion à usage médical*

*Partie 3: Capsules en aluminium pour flacons de perfusion*

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Reference number  
ISO 8536-3:1999(E)

## ISO 8536-3:1999(E)

## 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 3.

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 part of ISO 8536 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8536-3 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 8536-3:1992), which has been technically revised.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- Part 1: *Infusion glass bottles*
- Part 2: *Closures for infusion bottles*
- Part 3: *Aluminium caps for infusion bottles*
- Part 4: *Infusion sets for single use, gravity feed*
- Part 5: *Burette-type infusion sets*
- Part 6: *Freeze-drying closures for infusion bottles*
- Part 7: *Caps made of aluminium-plastics combinations for infusion bottles*

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## Introduction

The materials from which infusion glass bottles (including elastomeric closures) are made are suitable primary packaging materials for storing infusion solutions until they are administered. However, in this part of ISO 8536, aluminium caps are not considered as primary packaging material in direct contact with the infusion solution.

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# Infusion equipment for medical use —

## Part 3: Aluminium caps for infusion bottles

### 1 Scope

This part of ISO 8536 specifies aluminium caps for infusion glass bottles which are in accordance with ISO 8536-1.

### 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8536 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 2768-1:—<sup>1)</sup>, *Geometrical product specifications (GPS) — General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*.

ISO 2768-2:1989, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*.

ISO 8536-1:1991, *Infusion equipment for medical use — Part 1: Infusion glass bottles*.

ISO 8872:1988, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*.

### 3 Dimensions and tolerances

#### 3.1 Dimensions

The dimensions of the caps shall be as shown in Figures 1 to 3, and as given in Table 1.

The shapes of the caps are shown only as typical examples.

The components of a two-piece tear-off cap are:

- an aluminium cap with centre hole, type A;
- a protective aluminium cap with complete tear-off tab, type F;

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1) To be published. (Revision of ISO 2768-1:1989)