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**Infusion equipment for medical use —**

**Part 7:**

Caps made of aluminium-plastics combinations  
for infusion bottles

**iTeh STANDARD PREVIEW**

*Matériel de perfusion à usage médical*

*Partie 7: Capsules en combinaison aluminium-plastic*

ISO 8536-7:1999

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## Foreword

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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 8536-7 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 8536-7:1992), 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, caps of aluminium-plastics combinations are not considered as primary packaging materials in direct contact with the infusion solution.

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# Infusion equipment for medical use —

## Part 7:

### Caps made of aluminium-plastics combinations for infusion bottles

#### 1 Scope

This part of ISO 8536 specifies caps made of aluminium-plastics combinations intended for use on 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>, *Geometric 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 8536-3:1999, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles.*

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

ISO 10985:1992, *Caps made of aluminium-plastics combinations for infusion bottles and injection vials — Requirements and test methods.*

#### 3 Classification of type

Caps shall be classified as follows:

- Type ZB: Aluminium cap with central opening, and plastics component;
- Type ZD: Aluminium cap with complete tear-off tab, and plastics component.

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



## 5 Designation

Aluminium-plastics caps shall be designated according to type.

The designation is expressed as the word "cap", the number and part of this International Standard, followed by the type letters, followed by the nominal size of the cap.

EXAMPLE A type ZD aluminium-plastics cap of nominal size 32 complying with the requirements of this part of ISO 8536 is designated:

**Cap ISO 8536-7 - ZD - 32**

## 6 Requirements

### 6.1 General requirements

6.1.1 The requirements for aluminium caps shall be in accordance with ISO 8536-3.

6.1.2 The requirements for plastics components, and the combination between the plastics component and the aluminium cap, shall be in accordance with ISO 10985.

6.1.3 Construction elements which penetrate into the interior space of the aluminium cap shall not interfere with the sealing process.

### 6.2 Force required to remove tab

6.2.1 The maximum force required to remove the tab shall comply with Table 2.

**Table 2 — Force required to remove plastics component and tear-off tab completely**

Force in newtons

Nominal size	Force to remove plastics component max.	Force to tear off tab completely max.
28	40	30
32	60	40

6.2.2 For incoming control, a minimum value for the tear-off tab removal force shall be agreed between the supplier and user. The infusion caps shall also withstand a sterilization process in accordance with ISO 8872:1988, 5.1 and 5.2 b).

## 7 Packaging

Packaging shall comply with the requirements of ISO 8872.

## 8 Marking

Marking shall be in accordance with ISO 8872 and the designation shall be as specified in clause 5.

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