INTERNATIONAL STANDARD

ISO 8536-7

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Infusion equipment for medical use —

Part 7:
Caps made of aluminium-plastics combinations for infusion bottles

Matériel de perfusion à usage médical —

Partie 7: Capsules en combinaison aluminium-plastique pour flacons de perfusion

Reference number
ISO 8536-7:1992(E)

Contents

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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 voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 8536-7 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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*

— *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*

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 materials in direct contact with the infusion solution.

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 bottles as specified in ISO 8536-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8536 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2768-1:1989, *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 8536-3:1992, *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 types

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.

4 Dimensions and tolerances

4.1 Dimensions

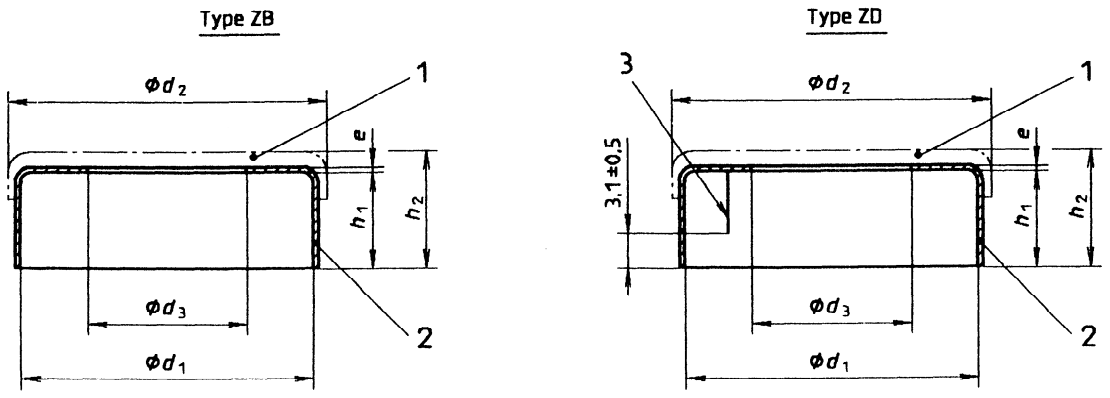
All cover versions (flat, ring-shaped or others) of caps shall meet the dimensions given in figure 1 and table 1.

NOTE 1 The configuration of the cap shown in figure 1 is informative only.

4.2 Tolerances

Cap tolerances shall be in accordance with ISO 2768-1 and ISO 2768-2.

Dimensions in millimetres



1 Plastics component
2 Aluminium cap in accordance with ISO 8536-3
3 Score line

Figure 1 — Configuration of cap

Table 1 — Dimensions of cap

Dimensions in millimetres

Nominal size	d_1 $^{+0,1}_{0}$	d_2 1) min.	d_2 1) max.	d_3 2) min.	d_3 2) max.	e 3) min.	e 3) max.	h_1 ± 0,25	h_2 4) min.	h_2 4) max.
28	27,9	30,5	31,5	12	17	0,168	0,242	9,2	9	12
32	32,6	35,5	37	15	20			11,9	13	16

1) The diameter d_2 shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,25 mm. The extreme limits are given without tolerance.

2) After plastics element removal.

3) The thickness e shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,022 mm. The extreme limits are given without tolerance.

4) The height h_2 shall be agreed between the manufacturer and user. It shall not differ from the nominal value by more than ± 0,4 mm. The extreme limits are given without tolerance.

5 Designation

Aluminium-plastics caps shall be designated according to type: the designation shall be 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 container.

For example a type ZD aluminium-plastics cap of nominal size 32 complying with the requirements laid down in 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 Forces required to remove tab

6.2.1 The maximum forces required to remove the tab shall comply with table 2.

Table 2 — Forces required to remove plastics component and tear off tab completely

Forces 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, subclauses 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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Descriptors: medical equipment, parenteral infusion equipment, containers, bottles, aluminium products, plastics products, caps (containers), classification, specifications, dimensions, designation, marking, packaging.

Price based on 3 pages