INTERNATIONAL STANDARD

ISO 8536-7

Second edition
1999-09-01

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-plastic

Reference number
ISO 8536-7:1999(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 8536-7 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.

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:—[1)], *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)

4 Dimensions and tolorances

4.1 Dimensions

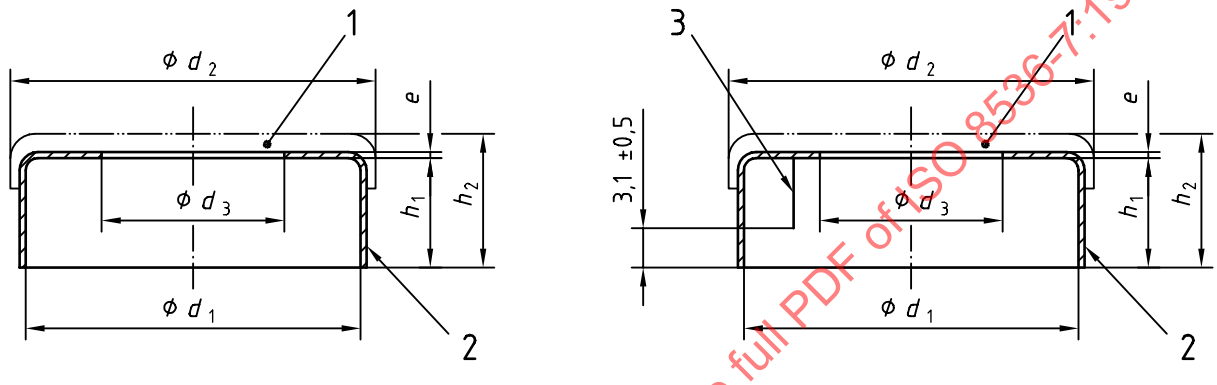
All cover versions (flat, ring-shaped or others) of caps shall meet the dimensions given in Figure 1 and Table 1.

NOTE The shape of the cap shown in Figure 1 is an example only.

4.2 Tolerances

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

Dimensions in millimetres



a) Type ZB

b) Type ZD

Key

1 Plastics component
2 Aluminium cap
3 Score line

Figure 1 — Configuration of cap

Table 1 — Dimensions of cap

Dimensions in millimetres

Nominal size	d_1 + 0,1 – 0,05	d_2[a]		d_3[b]		e[c]		h_1	h_2[d]	
		min.	max.	min.	max.	min.	max.	± 0,25	min.	max.
28	28,1	30,5	31,5	12	17	0,168	0,242	8,6 to 9,0	9	12
32	32,6	35,5	37	15	20			11,9	13	16

[a] 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.

[b] After plastics element removal.

[c] 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.

[d] 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.