INTERNATIONAL STANDARD

ISO 8536-2

Second edition
2001-06-15

Infusion equipment for medical use —

Part 2: Closures for infusion bottles

Matériel de perfusion à usage médical —

Partie 2: Bouchons pour flacons de perfusion

Reference number
ISO 8536-2:2001(E)

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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.

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 8536-2 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 8536-2:1992), 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*

Annexes A, B, C and D form a normative part of this part of ISO 8536.

Introduction

The materials from which injection containers (including elastomeric closures) are made are suitable primary packaging materials for storing injectable products until they are administered.

Infusion equipment for medical use —

Part 2:
Closures for infusion bottles

1 Scope

This part of ISO 8536 specifies the design, dimensions, material, performance requirements and testing of closures for infusion bottles as specified in ISO 8536-1.

Closures described herein are intended for single use only.

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 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD).*

ISO 868, *Plastics and ebonite — Determination of indentation hardness by means of a durometer (Shore hardness).*

ISO 2230, *Vulcanized rubber — Guide to storage.*

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

ISO 8536-3, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles.*

ISO 8871-1:—[1)], *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates.*

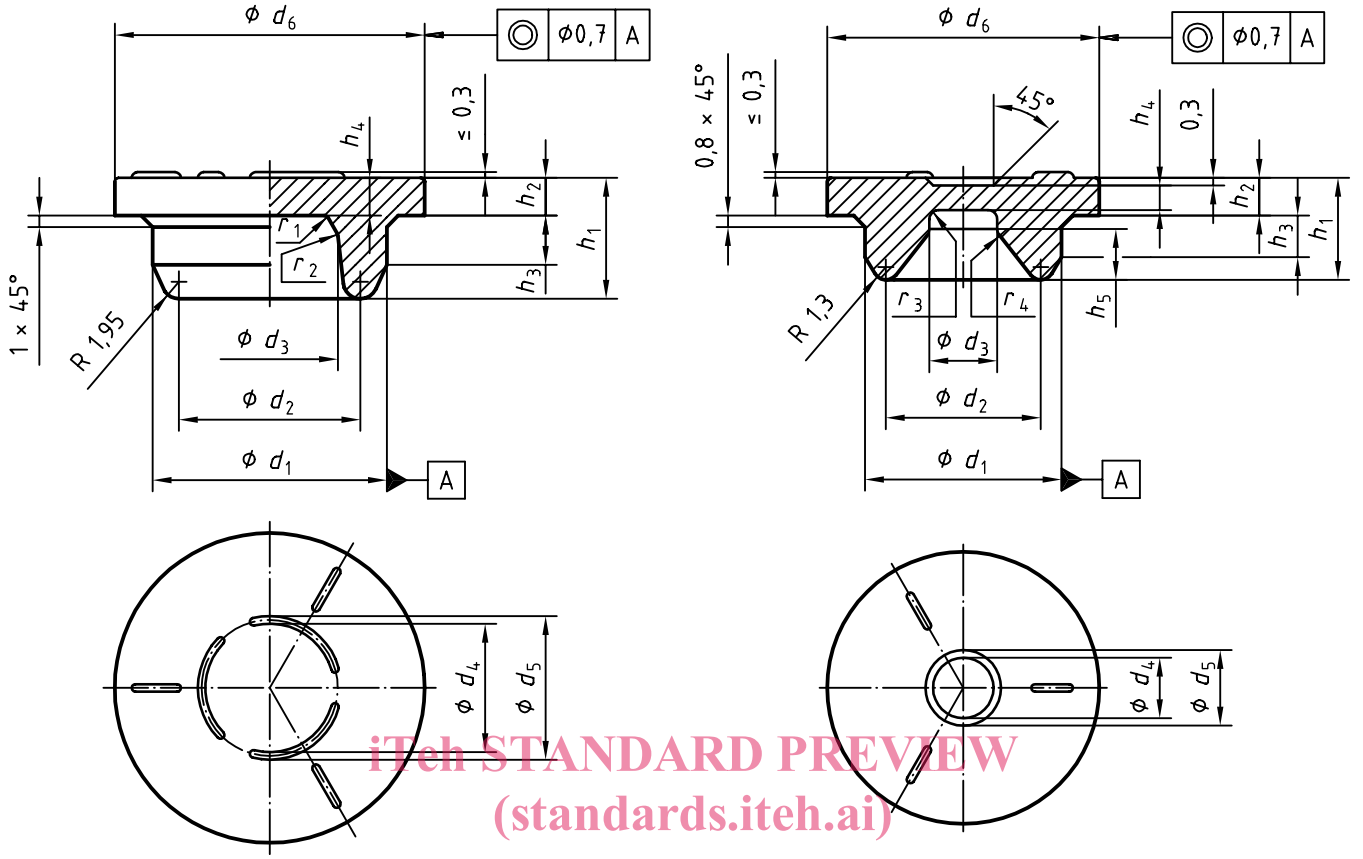
3 Dimensions and designation

3.1 Dimensions

The dimensions of closures shall be as shown in Figure 1 and as given in Table 1. Figure 1 illustrates two typical designs of closures, type A and type B.

1) To be published.

Dimensions in millimetres



Type A **Type B**

Figure 1 — Dimensions and configuration of type A and type B closures

Table 1 — Dimensions of infusion closures

Dimensions in millimetres

Type	Nominal size	d_1 ± 0,2	d_2 max.	d_3 min.	d_4 min.	d_5 max.	d_6 ± 0,3	h_1 ± 0,4	h_2 ± 0,3	h_3	h_4[a] ± 0,3	h_5
A	32	23,6	18,2	13	13	14	30,8	12,2	4	5,1	4	—
B	28	19,6	15,5	6,9	6,1	7,1	27,1	10,2	3,4	4,2	2,5	5,1

[a] Indentations may reduce the piercing thickness.

3.2 Designation

Closures are designated according to type: the two types, A and B, are illustrated in Figure 1. The designation is expressed as the number of this part of ISO 8536 followed by the nominal size of the infusion bottle followed by the type letter.

EXAMPLE A type A closure for infusion bottles of nominal size 32 mm complying with the requirements laid down in this part of ISO 8536 is designated as follows:

Infusion closure ISO 8536-2 - 32 - A

4 Material

The closure shall be made of self-sealing elastomeric material and shall withstand sterilization by autoclaving in saturated steam at (121 ± 2) °C for 1 h without impairment of its function under the conditions of normal use.

5 Physical requirements

5.1 General

The physical test procedures, described in annexes A, B and C, serve exclusively as comparative type tests of different elastomeric materials and do not enable conclusions to be drawn on the serviceability of closures to be applied. The reason for this is that, in practice, a multitude of different plastic spikes are on the market which do not meet the requirements of the reference steel spike in annex D.

5.2 Performance

5.2.1 In order to facilitate the production process, the flange of the closure may have a slightly conical shape (max. 0,8 mm related to the diameter). The trimming edge of the flange shall comply with the acceptable tolerances specified for the diameter of the flange.

5.2.2 All edges of the closure may be rounded.

5.2.3 Sprues, bleeders and injection points shall not be present in the sealing area.

5.2.4 On the inside diameter, d_3, there may be marks or indentations; on the outside, d_4, there may be spacers, of which the height should not exceed 0,3 mm.

5.3 Hardness

The hardness shall be agreed between manufacturer and user. The hardness shall not differ from the nominal value by more than ± 5 IRHD when tested in accordance with ISO 48 or ± 5 Shore A when tested in accordance with ISO 868.

NOTE The manufacturer should provide suitable test plates upon request.

5.4 Fragmentation

When tested for fragmentation in accordance with annex A, not more than 20 fragments of diameter equal to or greater than 50 µm per ten piercings shall be observed.

5.5 Spike penetration force

When tested for penetrability in accordance with annex B, the force needed to penetrate the closure shall not exceed 80 N, and the average value shall be less than 75 N. No closure shall be pushed into the bottle during piercing.

