INTERNATIONAL STANDARD

ISO 8536-3

Third edition
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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

Reference number
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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8536-3 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8536-3:1999), which has been updated in Clause 2 (Normative references). In addition, the height and the tolerances of aluminium caps have been aligned with those given in ISO 8536-7.

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 infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

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

— *Part 8: Infusion equipment for use with pressure infusion apparatus*

— *Part 9: Fluid lines for use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for use with pressure infusion equipment*

— *Part 11: Infusion filters for use with pressure infusion equipment*

— *Part 12: Check valves*

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.

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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

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

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

ISO 8872, *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.

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

— an aluminium cap with centre hole, type A;

— a protective disc, E;

— a protective aluminium cap with complete tear-off tab, type F.

NOTE The width and the number of bridges for types C and F are a function of the intended resistance.