INTERNATIONAL STANDARD

ISO 8536-1

Second edition
2000-06-15

Infusion equipment for medical use —

Part 1: Infusion glass bottles

Matériel de perfusion à usage médical —

Partie 1: Flacons en verre pour perfusion

Reference number
ISO 8536-1:2000(E)

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Contents

Page

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 8536-1 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 8536-1:1991), 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*

Introduction

Infusion bottles are suitable primary packaging materials for the storage of infusion solutions until they are administered to the patient. Due to the direct contact between infusion solution and the primary container components and in view of the extended storage periods, possible interactions must be avoided in order to guarantee the patient's safety. Adequate means to achieve this goal include the proper selection of the primary packaging materials, the choice of suitable package design and the availability of specific criteria and methods for testing of individual container systems.

Infusion equipment for medical use —

Part 1:
Infusion glass bottles

1 Scope

This part of ISO 8536 specifies the dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It is applicable only to infusion bottles for single use.

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 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification.*

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification.*

ISO 1101:—[1)], *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out.*

ISO 4802-1:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification.*

ISO 4802-2:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification.*

ISO 7458:1984, *Glass containers — Internal pressure resistance — Test methods.*

ISO 7459:1984, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods.*

3 Terms and definitions

For the purposes of this part of ISO 8536, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.

1) To be published. (Revision of ISO 1101:1983)

4 Dimensions and designation

4.1 Dimensions

The dimensions of the infusion glass bottle shall meet the requirements of Figure 1 and Tables 1 and 2.

4.2 Designation

4.2.1 General

An infusion glass bottle for medical use complying with the requirements laid down in this part of ISO 8536 is designated using the descriptor "Infusion bottle" followed by, in the order given, a reference to this part of ISO 8536, the model of the infusion bottle, the nominal capacity, the colour, and the hydrolytic resistance container class (see 7.1).

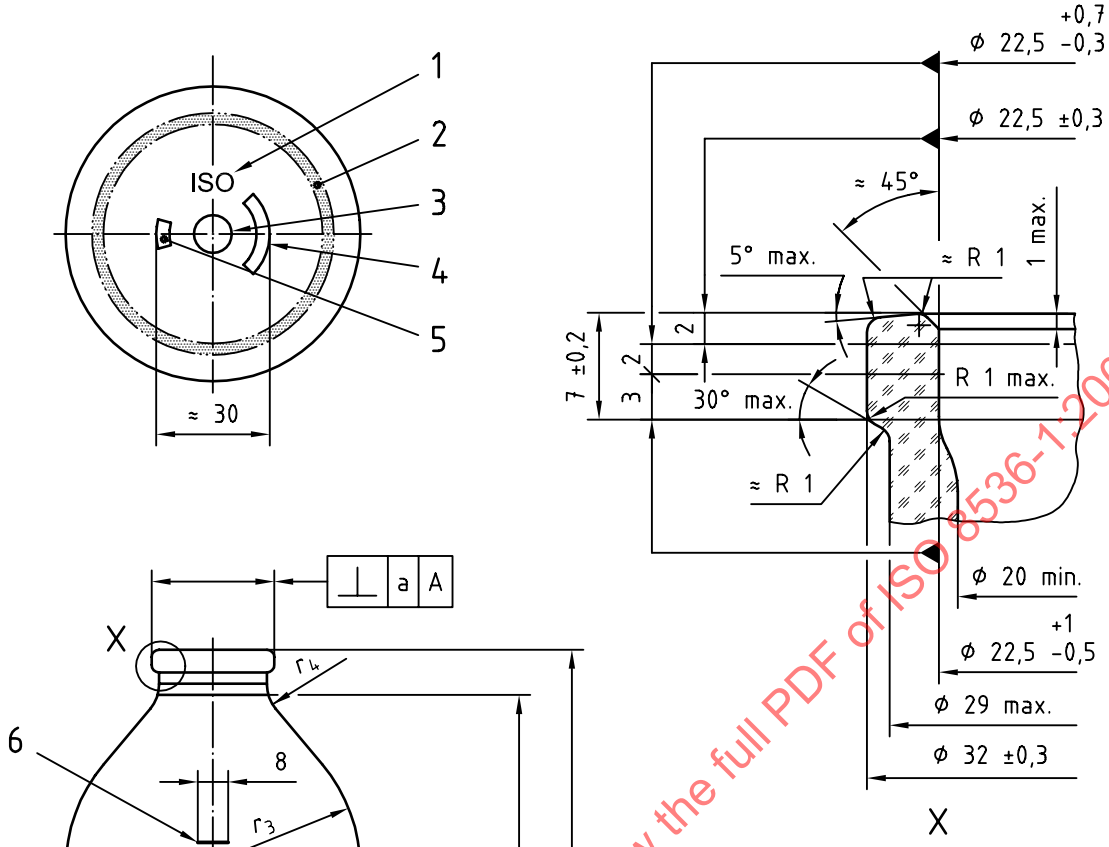
EXAMPLE An infusion bottle (model A) with a nominal capacity of 500 ml, made of colourless glass (cl) of hydrolytic resistance container class HC 2 complying with the requirements laid down in this part of ISO 8536 is designated as follows:

Infusion bottle ISO 8536-1 - A - 500 - cl - HC 2

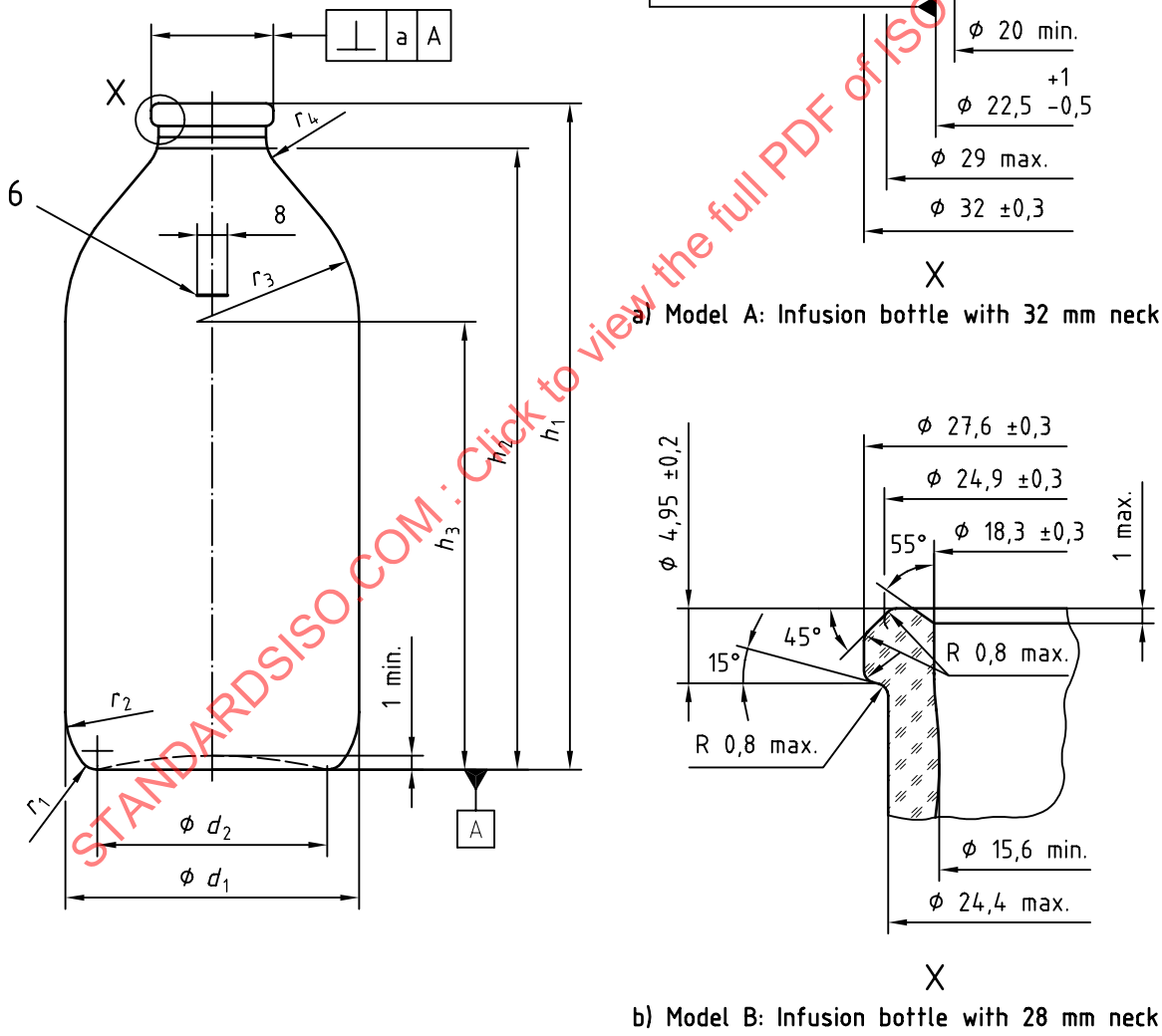
4.2.2 Location of designation marks

The designation marks on the bottom as specified in Figure 1, view Y, may be fixed also at the body of the bottle but not at the cylindrical part. The manufacturer's code can also be placed at the shoulder of the bottle. If marked at the lower bottom radius, r_2, or at the shoulder, r_3, the diameter at these places should not exceed the diameter d_1 of the bottle. The designation of hydrolytic resistance container class is abbreviated as given in 8.1.

Dimensions in millimetres



a) Model A: Infusion bottle with 32 mm neck finish



b) Model B: Infusion bottle with 28 mm neck finish

NOTE The marks (optional) or other markings in accordance with view Y may be placed on the bottom or at the bottom radius (r_2) of the infusion bottle. The drawing represents a typical example.

Key

1 ISO symbol
2 Bottom surface may be granular
3 Designation of hydrolytic resistance container class (see 8.1)
4 Manufacturer's code/designation of mould
5 Manufacturer's trade mark
6 Graduation mark

Figure 1 — Infusion glass bottle with two typical neck finishes