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Infusionsutrustning för medicinskt bruk – Del 2: Försegling av infusionsflaskor (ISO 8536-2:2010)

Infusion equipment for medical use – Part 2: Closures for infusion bottles (ISO 8536-2:2010)

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Europastandarden EN ISO 8536-2:2010 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8536-2:2010.

Denna standard ersätter SS-EN ISO 8536-2, utgåva 1 och SS-EN ISO 8536-2/AC:2005, utgåva 1.

The European Standard EN ISO 8536-2:2010 has the status of a Swedish Standard. This document contains the official English version of EN ISO 8536-2:2010.

This standard supersedes the Swedish Standard SS-EN ISO 8536-2, edition 1 and SS-EN ISO 8536-2/AC:2005, edition 1.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-2

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Supersedes EN ISO 8536-2:2002

English Version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2010)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:2010)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:2010)

This European Standard was approved by CEN on 18 February 2010.

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Ref. No. EN ISO 8536-2:2010: E

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Foreword

This document (EN ISO 8536-2:2010) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2010, and conflicting national standards shall be withdrawn at the latest by September 2010.

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Endorsement notice

The text of ISO 8536-2:2010 has been approved by CEN as a EN ISO 8536-2:2010 without any modification.

Introduction

The purpose of this part of ISO 8536 is to specify the shape and dimensions of and the requirements for elastomeric closures intended for infusion bottles. In order to provide seal integrity of the container closure systems the dimensions of the elastomeric closures have to be compatible with the dimensions of the infusion bottles and the caps as specified in corresponding parts of ISO 8536.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practice (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, e.g. ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.

Infusion equipment for medical use —

Part 2:
Closures for infusion bottles

1 Scope

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

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this part of ISO 8536 are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can strongly be affected by the nature and performance of the primary packaging.

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

ISO 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 3302-2, *Rubber — Tolerances for products — Part 2: Geometrical tolerances*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

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, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

3 Shape and dimensions

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

Dimensions in millimetres

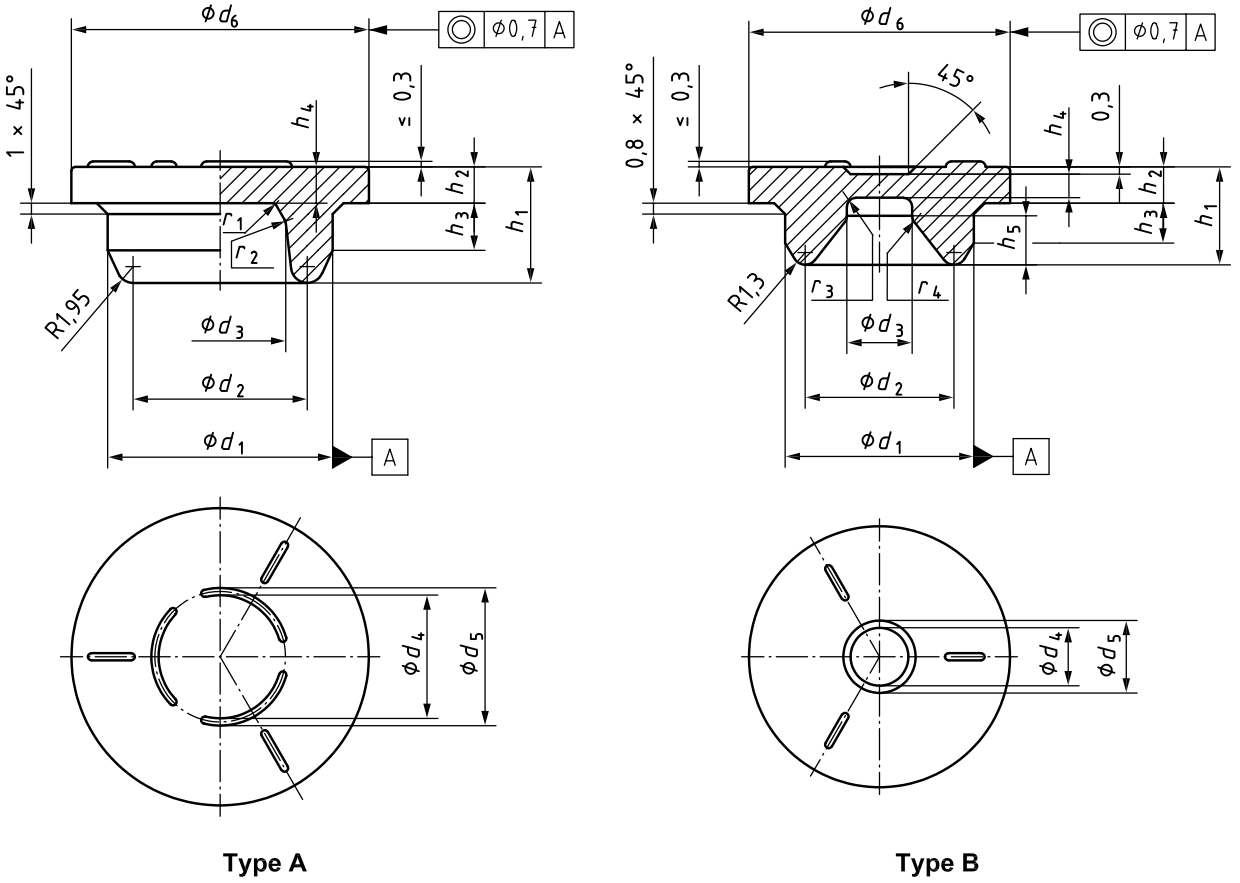

Figure 1 — Dimensions and configuration of type A and type B closures

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 If not otherwise specified, general dimensional tolerances shall be in accordance with ISO 3302-1 and ISO 3302-2.

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

3.4 The diameter, d_4, which defines the piercing area shall not exceed d_3. Marks and indentations may be placed in the piercing area. The height of the marks shall not exceed 0,3 mm.

NOTE The spacers in Figure 1 for type A and type B closures are shown for illustrative purposes only and do not form part of the requirements of this part of ISO 8536.

3.5 All edges of the closure may be rounded.

4 Designation

Closures can be designated according to their type, see 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

5 Material

The elastomeric material used shall meet the requirements specified in Clause 6.

The elastomeric material shall withstand two sterilization cycles when autoclaving in saturated steam at (121 ± 2) °C for 30 min without exceeding the specified limits and without the impairment of its performance characteristics under the conditions of normal use. In case of other sterilization methods, e. g. irradiation, the suitability of the material shall be evaluated.

NOTE For use with infusion solutions, resistance to two steam sterilization cycles may not be needed because only terminal sterilization is applied.

Closures shall be made of elastomeric formulation originally tested and approved by the end-user. The closure manufacturer shall ensure the conformance of each delivery with the type sample and the compliance with previously agreed functional parameters and compendium requirements.

6 Requirements

6.1 General

The requirements specified in 6.2 to 6.4 represent minimum requirements which refer to the condition of the elastomeric closures on receipt by the user.

6.2 Physical requirements

6.2.1 Hardness

The hardness agreed between manufacturer and user shall not differ from the nominal value by more than ± 5 Shore A when tested in accordance with ISO 7619-1 on a special test specimen. Alternatively, the hardness can be tested on the closures according to ISO 48. If tested according to ISO 48, the microhardness shall not differ by more than ± 5 IRHD from the type sample.

6.2.2 Fragmentation

When tested for fragmentation in accordance with Annex A, not more than 20 fragments of diameter ⩾ 50 µm per 10 piercings shall be observed.