SLOVENSKI STANDARD
SIST EN ISO 8536-2:2000

01-januar-2000

Infuzijska oprema za uporabo v medicini - 2. del: Zapirala za infuzijske steklenice (ISO 8536-2:1999)

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:1999)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:1999)

Matériel de perfusion a usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:1999)

Ta slovenski standard je istoveten z: **EN ISO 8536-2:1999**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8536-2:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8536-2

February 1999

ICS 11.040.00

English version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:1999)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:1999)

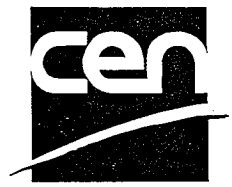
Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:1999)

This European Standard was approved by CEN on 9 January 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical use" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC "Non-active medical devices", the secretariat of which is held by BSI.

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 August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8536-2:1999 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 8536-2

First edition
1992-09-15

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 8536-2:1992(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland
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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.

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.

International Standard ISO 8536-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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*

— *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 an integral part of this part of ISO 8536.

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 test 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 standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8536 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1979, *Vulcanized rubbers — Determination of hardness (Hardness between 30 and 85 IRHD).*

ISO 2230:1973, *Vulcanized rubber — Guide to storage.*

ISO 2859-1:1989, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 8536-1:1991, *Infusion equipment for medical use — Part 1: Infusion glass bottles.*

ISO 8536-3:1992, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles.*

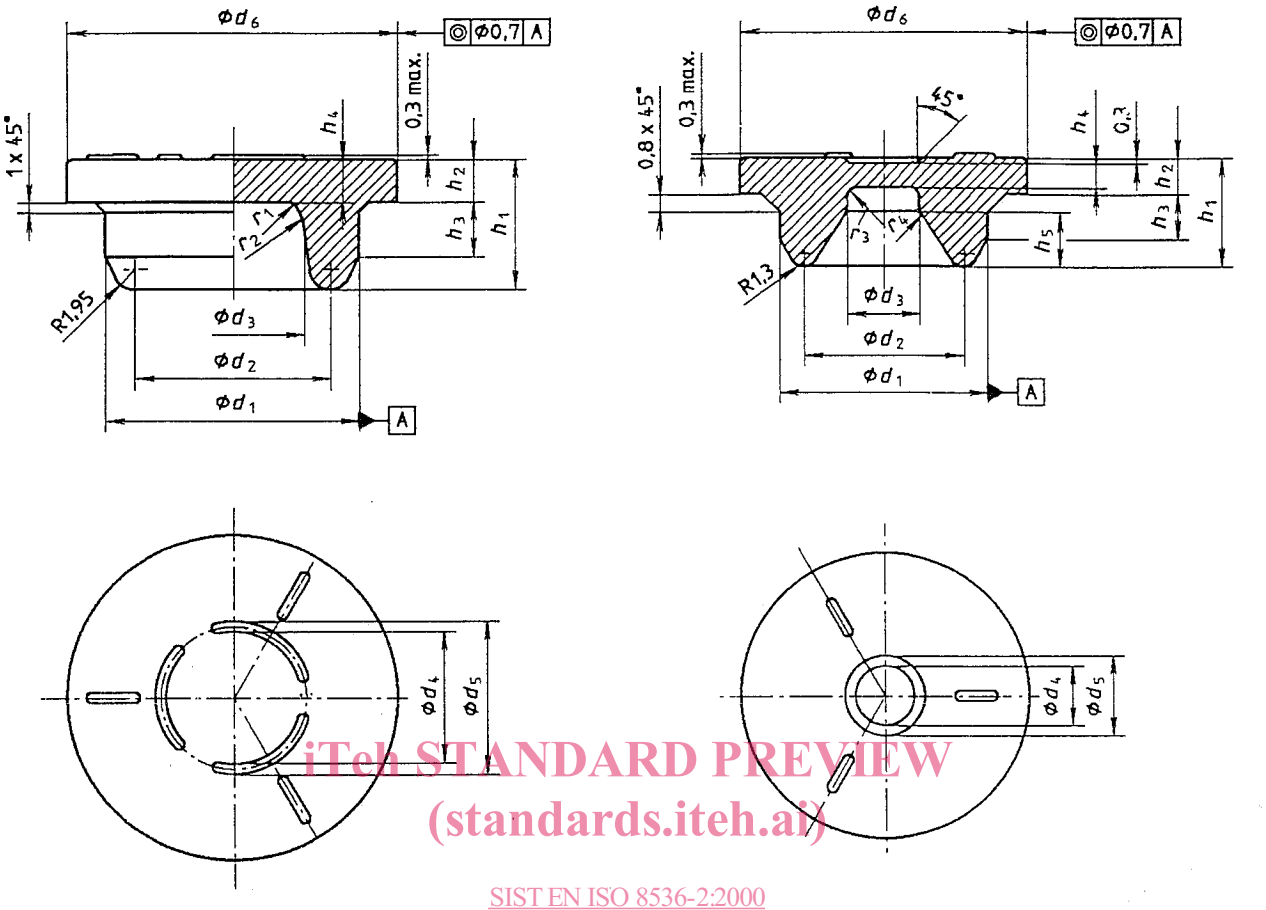
ISO 8871:1990, *Elastomeric parts for aqueous parenteral preparations.*

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 closure, types A and B.

Dimensions in millimetres



Type A Type B

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

Table 1 — Dimensions of infusion closures

Dimensions in millimetres

Type	Nominal size	d_1 ± 0,1	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 ± 0,3	h_5	r_1	r_2	r_3	r_4
A	32	23,6	18,2	13	13	14	30,8	12,2	4	5,1	4		1	5	—	—
B	28	19,6	15,5	6,9	6,1	7,1	27,1	10,2	3,4	4,2	2,5	5,1	—	—	1	1