SLOVENSKI STANDARD
SIST EN ISO 8536-1:2000

01-januar-2000

Infuzijska oprema za uporabo v medicini - 1. del: Infuzijske steklenice (ISO 8536-1:1999)

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:1999)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:1999)

Matériel de perfusion a usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:1999)

Ta slovenski standard je istoveten z: EN ISO 8536-1:1999

ICS:

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

SIST EN ISO 8536-1:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8536-1

February 1999

ICS 11.040.00

English version

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:1999)

Matériel de perfusion à usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:1999)

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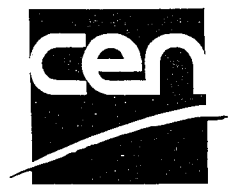
This European Standard was approved by CEN on 9 January 1999.

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 8536-1:1999 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 8536-1

First edition
1991-08-15

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 8536-1:1991(E)

Contents

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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 8536-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

ISO 8536-1 is a revision, in part, of ISO 1135:1977; this first edition of ISO 8536-1 together with the other parts of ISO 8536 and of ISO 1135 will cancel and replace ISO 1135:1977.

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: Infusion caps made of aluminium-plastics combinations*

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 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 dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It applies only to infusion bottles for single use.

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 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 1101:1983, *Technical drawings — Geometrical tolerancing — Tolerances of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings.*

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 Definitions

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

4 Dimensions and designation

4.1 Dimensions

The dimensions of the infusion glass bottle shall meet the requirements of figure 1 and table 1.

4.2 Designation marks

The designation marks on the bottom as specified in figure 1, view Y may be fixed also at the bottom 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.