SLOVENSKI STANDARD
SIST EN ISO 8536-2:2003

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Infuzijska oprema za uporabo v medicini - 2. del: Zapirala za infuzijske steklenice (ISO 8536-2:2001)

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2001)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:2001)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:2001)

Ta slovenski standard je istoveten z: **EN ISO 8536-2:2002**

ICS:

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

SIST EN ISO 8536-2:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-2

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ICS 11.040.20

Supersedes EN ISO 8536-2:1999

English version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2001)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:2001)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:2001)

This European Standard was approved by CEN on 30 August 2002.

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 Management Centre 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 Management Centre 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

The text of ISO 8536-2:2001 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8536-2:2002 by the Technical Board of CEN.

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 March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.

This document supersedes EN ISO 8536-2:1999.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 8536-2:2001 has been approved by CEN as EN ISO 8536-2:2002 without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA
(normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO 868	1985	Plastics and ebonite - Determination of indentation hardness by means of a durometer (Shore hardness)	EN ISO 868	1997
ISO 8536-1	1999	Infusion equipment for medical use - Part 1: Infusion glass bottles	EN ISO 8536-1	1999
ISO 8536-3	1999	Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles	EN ISO 8536-3	1999

INTERNATIONAL STANDARD

ISO 8536-2

Second edition
2001-06-15

Infusion equipment for medical use —

Part 2: Closures for infusion bottles

Matériel de perfusion à usage médical —

Partie 2: Bouchons pour flacons de perfusion

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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 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 8536-2 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 8536-2:1992), 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*

Annexes A, B, C and D form a normative part of this part of ISO 8536.

Introduction

The materials from which injection containers (including elastomeric closures) are made are suitable primary packaging materials for storing injectable products until they are administered.