



SLOVENSKI STANDARD SIST EN ISO 8536-1:2008

01-julij-2008

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SIST EN ISO 8536-1:2003

SIST EN ISO 8536-1:2003/AC:2005

Infuzijska oprema za uporabo v medicini - 1. del: Infuzijske steklenice (ISO 8536-1:2006)

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:2006)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:2006)

Matériel de perfusion à usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:2006)

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Ta slovenski standard je istoveten z: EN ISO 8536-1:2008

ICS:

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

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English Version

Infusion equipment for medical use - Part 1: Infusion glass
bottles (ISO 8536-1:2006)

Matériel de perfusion à usage médical - Partie 1: Flacons
en verre pour perfusion (ISO 8536-1:2006)

Infusionsgeräte zur medizinischen Verwendung - Teil 1:
Infusionsflaschen aus Glas (ISO 8536-1:2006)

This European Standard was approved by CEN on 7 March 2008.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

The text of ISO 8536-1:2006 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 8536-1:2008 by Technical Committee CEN/SS S02 “Transfusion equipment” the secretariat of which is held by CMC.

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 2008, and conflicting national standards shall be withdrawn at the latest by September 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8536-1:2003.

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

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Endorsement notice

The text of ISO 8536-1:2006 has been approved by CEN as a EN ISO 8536-1:2008 without any modification.
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**Infusion equipment for medical use —
Part 1:
Infusion glass bottles**

Matériel de perfusion à usage médical —

Partie 1: Flacons en verre pour 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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition (ISO 8536-1:2000) and amendment ISO 8536-1:2000/Amd.1:2004, of which it constitutes a minor revision.

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 infusion sets for single use, gravity feed*
- Part 6: *Freeze drying closures for infusion bottles*
- Part 7: *Caps made of aluminium-plastics combinations for infusion bottles*
- Part 8: *Infusion equipment for use with pressure infusion apparatus*
- Part 9: *Fluid lines for use with pressure infusion equipment*
- Part 10: *Accessories for fluid lines for use with pressure infusion equipment*
- Part 11: *Infusion filters for use with pressure infusion equipment*
- Part 12: *Check valves*