SLOVENSKI STANDARD
SIST EN ISO 8536-1:2011

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Infuzijska oprema za uporabo v medicini - 1. del: Infuzijske steklenice (ISO 8536-1:2011)

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:2011)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:2011)

Matériel de perfusion à usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:2011)

Ta slovenski standard je istoveten z: **EN ISO 8536-1:2011**

ICS:

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

SIST EN ISO 8536-1:2011 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-1

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ICS 11.040.20

Supersedes EN ISO 8536-1:2008

English Version

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:2011)

Matériel de perfusion à usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:2011)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:2011)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 8536-1:2011) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing 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of an identical text or by endorsement, at the latest by March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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The text of ISO 8536-1:2011 has been approved by CEN as a EN ISO 8536-1:2011 without any modification.

INTERNATIONAL STANDARD

ISO 8536-1

Fourth edition
2011-09-01

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.

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

This fourth edition cancels and replaces the third edition (ISO 8536-1:2006), of which it constitutes a minor revision.

The principle changes to the third edition are the updating of normative references to ISO 4802-1 and ISO 4802-2, and the addition of a note at the start of Clause 8.

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*