

# SLOVENSKI STANDARD

## SIST EN ISO 8536-2:2010

01-junij-2010

Nadomešča:

SIST EN ISO 8536-2:2003

SIST EN ISO 8536-2:2003/AC:2005

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**Infuzijska oprema za uporabo v medicini - 2. del: Zapirala za infuzijske steklenice  
(ISO 8536-2:2010)**

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2010)

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Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen  
(ISO 8536-2:2010)

[SIST EN ISO 8536-2:2010](https://standards.iteh.ai/catalog/standards/sist/659d4c26-30d3-40d6-9ed2-e89aac600b29/sist-en-iso-8536-2-2010)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion  
(ISO 8536-2:2010)

**Ta slovenski standard je istoveten z: EN ISO 8536-2:2010**

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**SIST EN ISO 8536-2:2010**

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EUROPEAN STANDARD

**EN ISO 8536-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2010

ICS 11.040.20

Supersedes EN ISO 8536-2:2002

English Version

**Infusion equipment for medical use - Part 2: Closures for  
infusion bottles (ISO 8536-2:2010)**Matériel de perfusion à usage médical - Partie 2: Bouchons  
pour flacons de perfusion (ISO 8536-2:2010)Infusionsgeräte zur medizinischen Verwendung - Teil 2:  
Stopfen für Infusionsflaschen (ISO 8536-2:2010)

This European Standard was approved by CEN on 18 February 2010.

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.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG**Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## Foreword

This document (EN ISO 8536-2:2010) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection 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 September 2010, and conflicting national standards shall be withdrawn at the latest by September 2010.

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 8536-2:2002.

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, Croatia, 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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# INTERNATIONAL STANDARD

**ISO**  
**8536-2**

Third edition  
2010-03-15

Corrected version  
2010-05-15

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## 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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Reference number  
ISO 8536-2:2010(E)

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Fax + 41 22 749 09 47  
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## ISO 8536-2:2010(E)

## 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 8536-2 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 8536-2:2001) and ISO 8536:2001/Cor.1:2003 which have been technically revised in order to align this part of ISO 8536 with ISO 8871-1, ISO 8871-4 and ISO 8871-5.

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*

This corrected version of ISO 8536-2:2010 incorporates the following correction:

- Page 6, Note in A.3.7: “50 mm” has been replaced by “50 µm”.

## Introduction

The purpose of this part of ISO 8536 is to specify the shape and dimensions of and the requirements for elastomeric closures intended for infusion bottles. In order to provide seal integrity of the container closure systems the dimensions of the elastomeric closures have to be compatible with the dimensions of the infusion bottles and the caps as specified in corresponding parts of ISO 8536.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practice (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, e.g. ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.

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