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

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)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (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**

ICS:

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

SIST EN ISO 8536-2:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-2

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)

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

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

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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of an identical text or by endorsement, at the latest by September 2010, and conflicting national standards shall be withdrawn at the latest by September 2010.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.

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Endorsement notice

The text of ISO 8536-2:2010 has been approved by CEN as a EN ISO 8536-2:2010 without any modification.

INTERNATIONAL STANDARD

ISO 8536-2

Third edition
2010-03-15

Corrected version
2010-05-15

Infusion equipment for medical use —

Part 2: Closures for infusion bottles

Matériel de perfusion à usage médical —

Partie 2: Bouchons pour flacons de perfusion

Reference number
ISO 8536-2:2010(E)

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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 8536-2 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.