SLOVENSKI STANDARD
oSIST prEN ISO 8536-2:2009

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Infuzijska oprema za uporabo v medicini - 2. del: Zapirala za infuzijske steklenice (ISO/DIS 8536-2:2008)

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO/DIS 8536-2:2008)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen (ISO/DIS 8536-2:2008)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO/DIS 8536-2:2008)

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

ICS:

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

oSIST prEN ISO 8536-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 8536-2

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Will supersede EN ISO 8536-2:2002

English Version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO/DIS 8536-2:2008)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion (ISO/DIS 8536-2:2008)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/SS S02.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. prEN ISO 8536-2:2008: E

Contents

Page

Foreword

This document (prEN ISO 8536-2:2008) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with Technical CommitteeCEN/SS S02 “Transfusion equipment” the secretariat of which is held by CMC.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 8536-2:2002.

Endorsement notice

The text of ISO/DIS 8536-2:2008 has been approved by CEN as a prEN ISO 8536-2:2008 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 8536-2

ISO/TC **76** Secretariat: **DIN**

Voting begins on: **2008-12-11** Voting terminates on: **2009-05-11**

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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

[Revision of second edition (ISO 8536-2:2001)]

ICS 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

Page

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), which has been technically revised in order to align this Standard 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*

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 Practices (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.