



SLOVENSKI STANDARD SIST EN ISO 8536-2:2023

01-maj-2023

Nadomešča:

SIST EN ISO 8536-2:2010

**Infuzijska oprema za uporabo v medicini - 2. del: Zapirala za infuzijske steklenice
(ISO 8536-2:2023)**

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2023)

Infusionsgeräte zur medizinischen Verwendung - Teil 2: Stopfen für Infusionsflaschen
(ISO 8536-2:2023)

Matériel de perfusion à usage médical - Partie 2: Bouchons pour flacons de perfusion
(ISO 8536-2:2023)

Ta slovenski standard je istoveten z: EN ISO 8536-2:2023

ICS:

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

EN ISO 8536-2

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February 2023

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Supersedes EN ISO 8536-2:2010

English Version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2023)

Matériel de perfusion à usage médical - Partie 2:
Bouchons pour flacons de perfusion (ISO 8536-2:2023)

Infusionsgeräte zur medizinischen Verwendung - Teil
2: Stopfen für Infusionsflaschen (ISO 8536-2:2023)

This European Standard was approved by CEN on 17 June 2022.

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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-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 8536-2:2023) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with CCMC.

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of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.

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

This document supersedes EN ISO 8536-2:2010.

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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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 8536-2:2023 has been approved by CEN as EN ISO 8536-2:2023 without any modification.

INTERNATIONAL
STANDARD

ISO
8536-2

Fourth edition
2023-01

**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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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS S02, *Transfusion equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 8536-2:2010), which has been technically revised.

The main changes are as follows:

- removal of reference to ISO 7619-1,
- addition of 29 mm size closures to align with ISO 8536-1.

A list of all parts in the ISO 8536 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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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