

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8536-2:2023 sisaldab Euroopa standardi EN ISO 8536-2:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8536-2:2023 consists of the English text of the European standard EN ISO 8536-2:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.02.2023.	Date of Availability of the European standard is 15.02.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.20

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of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.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

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Shape and dimensions	2
5 Designation	3
6 Material	3
7 Requirements	3
7.1 General	3
7.2 Physical requirements	3
7.2.1 Hardness	3
7.2.2 Fragmentation	3
7.2.3 Spike penetration force	3
7.2.4 Spike retention/sealability	4
7.2.5 Resistance to ageing	4
7.3 Chemical requirements	4
7.4 Biological requirements	4
8 Labelling	4
Annex A (normative) Determination of fragments	5
Annex B (normative) Determination of spike penetration force	7
Annex C (normative) Spike retention/sealability	9
Annex D (normative) Closure piercing device	11
Bibliography	12

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.

Infusion equipment for medical use —

Part 2: Closures for infusion bottles

1 Scope

This document specifies the shape, dimensions, material, performance requirements and labelling of closures for infusion bottles as specified in ISO 8536-1.

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this document are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can strongly be affected by the nature and performance of the primary packaging.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 3302-2, *Rubber — Tolerances for products — Part 2: Geometrical tolerances*

ISO 8536-1, *Infusion equipment for medical use — Part 1: Infusion glass bottles*

ISO 8536-3, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles*

ISO 8536-7, *Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>