

MEDITSIINIS KASUTATAVAD INFUSIOONISÜSTEEMID.
OSA 4: ÜHEKORDSEKS KASUTAMISEKS MÕELDUD
RASKUSJÕUL TOIMIVAD INFUSIOONIKOMPLEKTID

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

| | |
|---|--|
| See Eesti standard EVS-EN ISO 8536-4:2020 sisaldab Euroopa standardi EN ISO 8536-4:2020 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 8536-4:2020 consists of the English text of the European standard EN ISO 8536-4:2020. |
| 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. |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.01.2020. | Date of Availability of the European standard is 29.01.2020. |
| Standard on kättesaadav Eesti Standardikeskusest. | The standard is available from the Estonian Centre for Standardisation. |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.20

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD

EN ISO 8536-4

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2020

ICS 11.040.20

Supersedes EN ISO 8536-4:2013

English Version

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)

Matériel de perfusion à usage médical - Partie 4:
Appareils de perfusion non réutilisables, à
alimentation par gravité (ISO 8536-4:2019)

Infusionsgeräte zur medizinischen Verwendung - Teil
4: Infusionsgeräte für Schwerkraftinfusionen zur
einmaligen Verwendung (ISO 8536-4:2019)

This European Standard was approved by CEN on 17 October 2019.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 04 March 2020.

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

CEN members are the national standards bodies of 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, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 8536-4:2020) 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 Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

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 July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

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 8536-4:2013.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 8536-4:2019 has been approved by CEN as EN ISO 8536-4:2020 without any modification.

Contents

| | Page |
|--|-----------|
| Foreword..... | iv |
| 1 Scope..... | 1 |
| 2 Normative references..... | 1 |
| 3 Terms and definitions..... | 1 |
| 4 General requirements..... | 1 |
| 5 Designation..... | 4 |
| 6 Materials..... | 4 |
| 7 Physical requirements..... | 4 |
| 7.1 Particulate contamination..... | 4 |
| 7.2 Leakage..... | 4 |
| 7.3 Tensile strength..... | 4 |
| 7.4 Closure-piercing device..... | 5 |
| 7.5 Air-inlet device..... | 5 |
| 7.6 Tubing..... | 5 |
| 7.7 Fluid filter..... | 5 |
| 7.8 Drip chamber and drip tube..... | 6 |
| 7.9 Flow regulator..... | 6 |
| 7.10 Flow rate of infusion set..... | 6 |
| 7.11 Injection site..... | 6 |
| 7.12 Male conical fitting..... | 6 |
| 7.13 Protective caps..... | 6 |
| 8 Chemical requirements..... | 6 |
| 8.1 Reducing (oxidizable) matter..... | 6 |
| 8.2 Metal ions..... | 6 |
| 8.3 Titration acidity or alkalinity..... | 6 |
| 8.4 Residue on evaporation..... | 7 |
| 8.5 UV absorption of extract solution..... | 7 |
| 9 Biological requirements..... | 7 |
| 9.1 General..... | 7 |
| 9.2 Sterility..... | 7 |
| 9.3 Pyrogenicity..... | 7 |
| 9.4 Haemolysis..... | 7 |
| 9.5 Toxicity..... | 7 |
| 10 Labelling..... | 7 |
| 10.1 General..... | 7 |
| 10.2 Unit container..... | 7 |
| 10.3 Shelf or multi-unit container..... | 8 |
| 11 Packaging..... | 8 |
| 12 Disposal..... | 9 |
| Annex A (normative) Physical tests..... | 10 |
| Annex B (normative) Chemical tests..... | 15 |
| Annex C (normative) Biological tests..... | 17 |
| Bibliography..... | 18 |

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This sixth edition cancels and replaces the fifth edition (ISO 8536-4:2010), which has been technically revised. It also incorporates the Amendment ISO 8536-4:2010/Amd.1:2013.

The main changes compared to the previous edition are as follows:

- [Clause 5](#) 'Designation' now refers to [Clause 10](#) 'Labelling';
- the physical requirements – especially regarding stand-alone air-inlet devices – have been further clarified;
- [Clause 10](#) 'Labelling' has been updated;
- test for leakage in [A.3](#) has been updated;
- determination of flow rate in [A.5](#) has been totally reviewed;
- normative references in [Clause 2](#) and the Bibliography have been updated.

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.

Infusion equipment for medical use —

Part 4:

Infusion sets for single use, gravity feed

1 Scope

This document specifies requirements for single use, gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment.

Secondary aims of this document are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8536-13, *Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact*

ISO 8536-14, *Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

4 General requirements

4.1 The nomenclature to be used for components of infusion sets and of a stand-alone air-inlet device is given in [Figures 1, 2 and 3](#). These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets