	пп	
		4
_		

Infúzne prístroje na zdravotnícke použitie Časť 16: Infúzne súpravy na jednorazové použitie s regulátormi objemu infúzie (ISO 8536-16: 2025)

STN EN ISO 8536-16

70 3350

Infusion equipment for medical use - Part 16: Infusion sets for single use with volumetric infusion controllers (ISO 8536-16:2025)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

Obsahuje: EN ISO 8536-16:2025, ISO 8536-16:2025

141318

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 8536-16

August 2025

ICS 11.040.20

English Version

Infusion equipment for medical use - Part 16: Infusion sets for single use with volumetric infusion controllers (ISO 8536-16:2025)

Matériel de perfusion à usage médical - Partie 16: Appareils de perfusion à usage unique avec régulateurs de perfusion volumétriques (ISO 8536-16:2025) Infusionsgeräte zur medizinischen Verwendung - Teil 16: Infusionsgeräte mit volumetrischen Infusionsreglern zur einmaligen Verwendung (ISO 8536-16:2025)

This European Standard was approved by CEN on 12 August 2025.

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, Türkiye 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

EN ISO 8536-16:2025 (E)

Contents	Page
European foreword	3

European foreword

This document (EN ISO 8536-16:2025) 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 February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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.

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 8536-16:2025 has been approved by CEN as EN ISO 8536-16:2025 without any modification.



International Standard

ISO 8536-16

Infusion equipment for medical use —

Part 16:

Infusion sets for single use with volumetric infusion controllers

Matériel de perfusion à usage médical —

Partie 16: Appareils de perfusion à usage unique avec régulateurs de perfusion volumétriques

First edition 2025-08



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Website: <u>www.iso.or</u>
Published in Switzerland

Foreword iv 1 Scope 1 2 Normative references 1 3 Terms and definitions 1 4 General requirements 2 5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.12 Injection site 7 6.13 Male conical fitting 7 7<	Contents		Page	
2 Normative references 1 3 Terms and definitions 1 4 General requirements 2 5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9.1 General 7 9.2 Unit container 7 9.3 <th>Fore</th> <th>eword</th> <th></th> <th>iv</th>	Fore	eword		iv
3 Terms and definitions 1 4 General requirements 2 5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 <td< th=""><th>1</th><th>Scop</th><th>e</th><th>1</th></td<>	1	Scop	e	1
3 Terms and definitions 1 4 General requirements 2 5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 <td< th=""><th>2</th><th>Norn</th><th>native references</th><th>1</th></td<>	2	Norn	native references	1
4 General requirements 2 5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11				
5 Materials 6 6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative				
6 Physical requirements 6 6.1 General 6 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11			•	
6.1 General 66 6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9				
6.2 Particulate contamination 6 6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9			-	
6.3 Leakage 6 6.4 Tensile resistance 6 6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9				
6.4 Tensile resistance 66 6.5 Flow rate of infusion set 66 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		_		
6.5 Flow rate of infusion set 6 6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9			e e e e e e e e e e e e e e e e e e e	
6.6 Flow regulator 6 6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		_		
6.7 Closure-piercing device 6 6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9				
6.8 Air-inlet device 7 6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9				
6.9 Tubing 7 6.10 Fluid filter 7 6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9			1 0	
6.11 Drip chamber and drip tube 7 6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.9		
6.12 Injection site 7 6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.10	Fluid filter	7
6.13 Male conical fitting 7 6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.11	Drip chamber and drip tube	7
6.14 Protective caps 7 7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.12		
7 Chemical requirements 7 8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.13	Male conical fitting	7
8 Biological requirements 7 9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		6.14	Protective caps	7
9 Labelling 7 9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9	7	Chen	nical requirements	7
9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9	8	Biolo	ogical requirements	7
9.1 General 7 9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9	9	Labe	lling	7
9.2 Unit container 7 9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9			0	
9.3 Shelf or multi-unit container 8 10 Packaging 8 11 Disposal 8 Annex A (normative) Physical tests 9		9.2		
11 Disposal 8 Annex A (normative) Physical tests 9		9.3		
Annex A (normative) Physical tests 9	10	Pack	aging	8
	11	Disposal		8
Bibliography12	Ann	ex A (no	ormative) Physical tests	9
	Bibl	iograph	iy	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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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 16:

Infusion sets for single use with volumetric infusion controllers

1 Scope

This document specifies the requirements for sterilized, single-use, gravity feed infusion sets, used together with the volumetric infusion controllers of IEC 60601-2-24. [1]

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 7000, Graphical symbols for use on equipment — Registered symbols

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

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 information to be supplied by the manufacturer — Part 1: General requirements

koniec náhľadu – text ďalej pokračuje v platenej verzii STN