



# SLOVENSKI STANDARD SIST EN ISO 8536-12:2021

01-maj-2021

---

## Infuzijska oprema za uporabo v medicini - 12. del: Kontrolni ventili za enkratno uporabo (ISO 8536-12:2021)

Infusion equipment for medical use - Part 12: Check valves for single use (ISO 8536-12:2021)

Infusionsgeräte zur medizinischen Verwendung - Teil 12: Rückschlagventile zur einmaligen Verwendung (ISO 8536-12:2021)

Matériel de perfusion à usage médical - Partie 12: Clapet antiretour non réutilisables (ISO 8536-12:2021)

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a105ed2516/sist-en-iso-8536-12-2021)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a105ed2516/sist-en-iso-8536-12-2021>

Ta slovenski standard je istoveten z: **EN ISO 8536-12:2021**

---

### **ICS:**

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

**SIST EN ISO 8536-12:2021**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>

EUROPEAN STANDARD

EN ISO 8536-12

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2021

ICS 11.040.20

English Version

## Infusion equipment for medical use - Part 12: Check valves for single use (ISO 8536-12:2021)

Matériel de perfusion à usage médical - Partie 12:  
Clapet antiretour à usage unique (ISO 8536-12:2021)

Infusionsgeräte zur medizinischen Verwendung - Teil  
12: Rückschlagventile zur einmaligen Verwendung  
(ISO 8536-12:2021)

This European Standard was approved by CEN on 25 January 2021.

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

Contents	Page
European foreword.....	3

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021)  
<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>

## European foreword

This document (EN ISO 8536-12:2021) 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 August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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.

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.

## iTeh STANDARD PREVIEW Endorsement notice (standards.iteh.ai)

The text of ISO 8536-12:2021 has been approved by CEN as EN ISO 8536-12:2021 without any modification.

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 8536-12:2021](#)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>

INTERNATIONAL  
STANDARD

ISO  
8536-12

Second edition  
2021-02

---

---

**Infusion equipment for medical use —  
Part 12:  
Check valves for single use**

*Matériel de perfusion à usage médical —  
Partie 12: Clapets antiretour à usage unique*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>



Reference number  
ISO 8536-12:2021(E)

© ISO 2021

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 8536-12:2021](https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021)

<https://standards.iteh.ai/catalog/standards/sist/643f8b5b-fb25-4be9-af15-1a1f95ad2516/sist-en-iso-8536-12-2021>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland



# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Designation</b> .....	<b>2</b>
<b>5 Materials</b> .....	<b>2</b>
<b>6 Physical requirements</b> .....	<b>2</b>
6.1 Particulate contamination.....	2
6.2 Leakage.....	2
6.3 ISO 80369 (all parts) compatibility.....	2
6.4 Counterflow pressure resistance.....	2
6.5 Flow rate.....	3
6.6 Blocking performance.....	3
6.7 Opening pressure.....	3
6.8 Protective caps.....	3
<b>7 Chemical requirements</b> .....	<b>3</b>
<b>8 Biological requirements</b> .....	<b>3</b>
8.1 General.....	3
8.2 Sterility.....	3
8.3 Pyrogenicity.....	3
<b>9 Labelling</b> .....	<b>3</b>
9.1 General.....	3
9.2 Label on unit container.....	4
9.3 Label on shelf or multi-unit container.....	4
<b>10 Packaging</b> .....	<b>4</b>
<b>11 Disposal</b> .....	<b>4</b>
<b>Annex A (normative) Physical tests</b> .....	<b>5</b>
<b>Bibliography</b> .....	<b>11</b>

## ISO 8536-12:2021(E)

### 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](http://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](http://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](http://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).

This second edition cancels and replaces the first edition (ISO 8536-12:2007), which has been technically revised. It also incorporates the Amendment ISO 8536-12:2007/Amd.1:2012.

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

- the title of this document has been amended by "for single use";
- [Clause 3](#) has been completely reviewed;
- [Clause 4](#), 'Designation' refers now to 'Labelling';
- the requirement on tensile strength has been deleted;
- the connecting requirements have been aligned to the ISO 80369 series;
- [Clause 11](#) has been added;
- [Annex A](#) has been completely updated and aligned with the physical requirements given in [Clause 6](#);
- the normative references have been updated;
- a bibliography has been added;
- complete editorial review.

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](http://www.iso.org/members.html).

# Infusion equipment for medical use —

## Part 12: Check valves for single use

### 1 Scope

This document specifies requirements for check valves intended for single use and used with infusion equipment both with gravity-feed infusion and with pressure infusion apparatus.

The functional requirements in this document also apply to inline check valves.

### 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 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

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

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

ISO 8871-2, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/>

#### 3.1

##### **blocking**

prevention of counterflow through the *check valve* (3.2)

#### 3.2

##### **check valve**

valve that allows flow only in one direction

Note 1 to entry: A check valve is normally in the closed position.