

**Infusion equipment for medical use -  
Part 10: Accessories for fluid lines for  
use with pressure infusion equipment**

Infusion equipment for medical use - Part 10:  
Accessories for fluid lines for use with pressure  
infusion equipment

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 8536-10:2005 sisaldab Euroopa standardi EN ISO 8536-10:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 25.01.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 8536-10:2005 consists of the English text of the European standard EN ISO 8536-10:2004.</p> <p>This document is endorsed on 25.01.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p><b>Käsitlusala:</b> This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.</p>	<p><b>Scope:</b> This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.</p>
--	--

**ICS** 11.040.20

**Võtmesõnad:**

**English version**

**Infusion equipment for medical use**

**Part 10: Accessories for fluid lines for use with pressure infusion equipment  
(ISO 8536-10:2004)**

Matériel de perfusion à usage médical – Partie 10: Accessoires de tubulures pour utilisation avec des appareils de perfusion sous pression (ISO 8536-10:2004)

Infusionsgeräte zur medizinischen Verwendung – Teil 10: Zubehörteile für Übertragungsleitungen zur Verwendung mit Druckinfusionsapparaten (ISO 8536-10:2004)

This European Standard was approved by CEN on 2004-09-30.

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 Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

**CEN**

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

**Management Centre: 36, rue de Stassart, B-1050 Brussels**

## Foreword

International Standard

ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment,

which was prepared by ISO/TC 76 'Transfusion, infusion and injection equipment for medical and pharmaceutical use' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 2005 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

## Endorsement notice

The text of the International Standard ISO 8536-10:2004 was approved by CEN as a European Standard without any modification.

## Contents

	Page
<b>1 Scope</b> .....	<b>3</b>
<b>2 Normative references</b> .....	<b>3</b>
<b>3 Designation</b> .....	<b>4</b>
<b>4 Materials</b> .....	<b>4</b>
<b>5 Physical requirements</b> .....	<b>4</b>
5.1 Avoidance of air bubbles .....	4
5.2 Particulate contamination .....	5
5.3 Tensile strength .....	5
5.4 Leakage .....	5
5.5 Adapters with female and/or male conical fittings .....	5
5.6 Protective caps .....	5
5.7 Manipulation of stopcocks .....	5
5.8 Unit with injection site .....	5
5.9 Unit with check valve .....	5
<b>6 Chemical requirements</b> .....	<b>5</b>
<b>7 Biological requirements</b> .....	<b>6</b>
7.1 Sterility .....	6
7.2 Pyrogens .....	6
7.3 Haemolysis .....	6
<b>8 Packaging</b> .....	<b>6</b>
<b>9 Labelling</b> .....	<b>6</b>
9.1 Unit container .....	6
9.2 Shelf or multi-unit container .....	7
<b>Annex A (normative) Physical tests</b> .....	<b>8</b>
<b>Annex B (normative) Chemical tests</b> .....	<b>9</b>
<b>Annex C (normative) Biological tests</b> .....	<b>9</b>
<b>Bibliography</b> .....	<b>10</b>

## 1 Scope

This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.

This part of ISO 8536 includes:

- a) Two-way stopcocks (2SC), three-way stopcocks (3SC), four-way stopcocks (4SC) and stopcocks manifold (SM);

NOTE Designation of a stopcock depends on the number of connections. The number of possible functional positions can be expressed by addition of a complementary note, using a diagonal stroke and a numeral indicating the number of possible stopcock positions, e.g. 3/4-way stopcock for three-way stopcock with four possible positions.

- b) units with injection site (UIS) or check valve (UCV);
- c) stoppers (S) or adapters (A).

## 2 Normative references

The following referenced documents are indispensable for the application 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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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 8536-8, *Infusion equipment for medical use — Part 8: Infusion equipment for use with pressure infusion apparatus*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*