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**Infusion equipment for medical use -  
Part 11: Infusion filters for use with  
pressure infusion equipment**

Infusion equipment for medical use - Part 11:  
Infusion filters for use with pressure infusion  
equipment

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 8536-11:2005 sisaldab Euroopa standardi EN ISO 8536-11:2004 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 8536-11:2005 consists of the English text of the European standard EN ISO 8536-11:2004.</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>
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<p><b>Käsitlusala:</b> This part of ISO 8536 applies to sterilized infusion filters for single use up to 200 kPa (2 bar ) on fluid lines of pressure infusion equipment and infusion set as specified in ISO 8536-8. It does not include the effectiveness of filters for separation of particles or germs.</p>	<p><b>Scope:</b> This part of ISO 8536 applies to sterilized infusion filters for single use up to 200 kPa (2 bar ) on fluid lines of pressure infusion equipment and infusion set as specified in ISO 8536-8. It does not include the effectiveness of filters for separation of particles or germs.</p>
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ICS 11.040.20

Võtmesõnad:

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English version

Infusion equipment for medical use

Part 11: Infusion filters for use with pressure infusion equipment  
(ISO 8536-11:2004)

Matériel de perfusion à usage médical – Partie 11: Filtres de perfusion pour utilisation avec des appareils de perfusion sous pression (ISO 8536-11:2004)

Infusionsgeräte zur medizinischen Verwendung – Teil 11: Infusionsfilter zur Verwendung mit Druckinfusionsapparaten (ISO 8536-11:2004)

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 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters 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 8536-11:2004 was approved by CEN as a European Standard without any modification.

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## 1 Scope

This part of ISO 8536 applies to sterilized infusion filters for single use up to 200 kPa (2 bar) on fluid lines of pressure infusion equipment and infusion set as specified in ISO 8536-8. It does not include the effectiveness of filters for separation of particles or germs.

## 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 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*

## 3 Designation

Designation of an infusion filter (IF) for infusions under pressure (P):

**Infusion filter ISO 8536-11 – IF – P**

## 4 Design

The infusion filter housing shall be provided with a venting system to anticipate the blocking of the filter by the accumulation of air bubbles.

## 5 Materials

The materials from which the infusion filters as given in Clause 3 are manufactured shall comply with the requirements as specified in Clauses 6, 7 and 8.