



SLOVENSKI STANDARD
SIST EN ISO 8536-11:2005
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Infusion equipment for medical use - Part 11: Infusion filters for use with pressure infusion equipment (ISO 8536-11:2004)

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

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

Ta slovenski standard je istoveten z: EN ISO 8536-11:2004

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ICS:

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

EN ISO 8536-11

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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)

This European Standard was approved by CEN on 30 September 2004.

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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 Central Secretariat has the same status as the official versions.

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

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

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

EN ISO 8536-11:2004 (E)**Foreword**

This document (EN ISO 8536-11:2004) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection 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 BSI.

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 June 2005, and conflicting national standards shall be withdrawn at the latest by June 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8536-11:2004 has been approved by CEN as EN ISO 8536-11:2004 without any modifications.

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INTERNATIONAL
STANDARD

ISO
8536-11

First edition
2004-10-01

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

Matériel de perfusion à usage médical —

*Partie 11: Filtres de perfusion pour utilisation avec des appareils de
perfusion sous pression*

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ISO 8536-11:2004(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8536-11 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- Part 1: *Infusion glass bottles*
- Part 2: *Closures for infusion bottles*
- Part 3: *Aluminium caps for infusion bottles*
- Part 4: *Infusion sets for single use, gravity feed*
- Part 5: *Burette infusion sets for single use, gravity feed*
- Part 6: *Freeze drying closures for infusion bottles*
- Part 7: *Caps made of aluminium-plastics combinations for infusion bottles*
- Part 8: *Infusion equipment for use with pressure infusion apparatus*
- Part 9: *Fluid lines for use with pressure infusion equipment*
- Part 10: *Accessories for fluid lines for use with pressure infusion equipment*
- Part 11: *Infusion filters for use with pressure infusion equipment*

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Infusion equipment for medical use —

Part 11:

Infusion filters for use with pressure infusion equipment

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*

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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.