SLOVENSKI STANDARD
oSIST prEN ISO 8536-11:2013

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Infuzijska oprema za uporabo v medicini - 11. del: Infuzijski filtri za enkratno uporabo z infuzijsko opremo, delujočo na osnovi tlaka (ISO/DIS 8536-11:2013)

Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO/DIS 8536-11:2013)

Infusionsgeräte zur medizinischen Verwendung - Teil 11: Infusionsfilter zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO/DIS 8536-11:2013)

Matériel de perfusion à usage médical - Partie 11: Filtres à perfusion non réutilisables avec un matériel de perfusion sous pression (ISO/DIS 8536-11:2013)

Ta slovenski standard je istoveten z: **prEN ISO 8536-11**

ICS:

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

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DRAFT INTERNATIONAL STANDARD

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Infusion equipment for medical use —

Part 11:
Infusion filters for single use with pressure infusion equipment

Matériel de perfusion à usage médical —

Partie 11: Filtres de perfusion non réutilisables avec des appareils de perfusion sous pression

[Revision of first edition (ISO 8536-11:2004)]

ICS: 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
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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, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8536-11:2004), of which A.4 Tests for leakage has been amended and A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted. Clause 10 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725. Finally some minor editorial changes were introduced in the whole document.

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 single use with pressure infusion apparatus*

— *Part 9: Fluid lines for single use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

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

— *Part 12: Check valves*

The following parts are under preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

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

1 Scope

This part of ISO 8536 applies to sterilized infusion filters for single use used up to 200 kPa (2 bar) on fluid lines of pressure infusion equipment and infusion set in 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 8536-4:2010, *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 set for single use with pressure infusion apparatus*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 15223-1*, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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.

6 Physical requirements

6.1 Transparency

The filter housing shall be transparent. When tested as specified in A.1, the air-water interface shall be detectable.

6.2 Particulate contamination

The infusion filters shall be manufactured under conditions that minimize particulate contamination. The inner surfaces shall be smooth and clean. When tested as specified in A.2, the number of particles shall not exceed the contamination index.

6.3 Tensile strength

When tested as specified in A.3, the infusion filters shall withstand a static longitudinal tensile force of not less than 15 N for 15 s.

6.4 Leakage

The filter housing shall be impermeable to micro-organisms and fluids. The filter membrane as well as its connection to the housing shall not burst. When tested as specified in A.4, there shall be no leakage of air or water.

6.5 Adapters with female and/or male conical fittings

Adapters shall be provided with a connector with female conical fitting and/or a connector with male conical fitting according to ISO 594-2.

NOTE ISO 594-2 is expected to be replaced by ISO 80369-7 (under preparation).

6.6 Protective caps

ISO 8536-4 applies.

7 Chemical requirements

ISO 8536-4 applies.

8 Biological requirements

8.1 Sterility

The infusion filters in their unit container shall have been subjected to a validated sterilization process (see Bibliography).

8.2 Pyrogens

The infusion filters shall be assessed for freedom from pyrogens using a suitable test, and the results shall indicate that the infusion filters are free from pyrogens. Guidance on testing for pyrogenicity is given in ISO 8536-4.

8.3 Haemolysis

The infusion filters shall be assessed for freedom from haemolytic constituents and the result shall indicate that the infusion filters are free from haemolytic reactions.