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

Reference number
ISO 8536-11:2004(E)

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Published in Switzerland

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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 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*

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*

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.

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 microorganisms 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. When tested as specified in A.5, no water shall leak from the point of connection.

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.

Guidance on testing for haemolytic constituents is given in ISO 10993-4.

9 Packaging

ISO 8536-4 applies.

10 Labelling

10.1 Unit container

The unit container shall be labelled with the following minimum information:

a) a textual description of the contents, e.g. infusion filter for single use;

b) indication that the infusion filter is sterile, using the graphical symbol as given in ISO 15223;

c) indication that the infusion filter is free from pyrogens, or that the infusion filter is free from bacterial endotoxins;

d) indication that the infusion filter is for single use only, or equivalent wording, or using the graphical symbol according to ISO 15223;

e) instructions for use, including warnings, e.g. about detached protective caps (instructions for use may also take the form of an insert);

f) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223;

g) the wording “Safe for use with pressure infusion equipment” (the name and type of pressure infusion equipment shall be given by the manufacturer);

h) identification block of designation according to Clause 3 (e.g. ISO 8536-11 – IF – P);

i) letter “P” which stands for pressure and the type, the height of which shall stand out clearly from surrounding text;

j) name or logo and address of manufacturer or supplier;

k) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223.

If the available space is too small to give all this information in legible characters and/or symbols, the information may be reduced to f) and k). In this case the information as required in this subclause shall be given on the label of the next bigger shelf or multi-unit container.

10.2 Shelf or multi-unit container

The shelf or multi-unit container shall be labelled with the following minimum information:

a) a textual description of the contents, e.g. infusion filter for single use;

b) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223;

c) the wording “Safe for use with pressure infusion equipment” (the name and type of pressure infusion equipment as indicated by the manufacturer);

d) identification block of designation according to Clause 3 (e.g. ISO 8536-11 – IF – P);

e) letter “P” which stands for pressure and the type, the height of which shall stand out clearly from surrounding text;

f) name or logo and address of manufacturer or supplier;

g) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223;

h) storage note.

Annex A
(normative)

Physical tests

A.1 Test for transparency

Fill the infusion filter with distilled water as under usual practice conditions. Inspect visually whether the air-water interface is detectable.

A.2 Test for particulate contamination

The volume of rinse fluid shall be at least 50 times the inner volume of a test specimen. Perform the test as specified in ISO 8536-4.

A.3 Test for tensile strength

Expose the infusion filter to be tested to a static longitudinal tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.4 Test for leakage

A.4.1 In the beginning of the test, condition the whole system at the test temperature.

A.4.2 Connect the infusion filter with its openings closed to a compressed air supply. Apply air with an internal excess pressure of 20 kPa at (23 ± 1) °C and (40 ± 1) °C to the infusion filter for 15 min. Inspect the infusion filter for any leakage of air.

A.4.3 Fill the infusion set with degassed, distilled water, connect it with its openings sealed to a vacuum device and subject it to an internal excess pressure of −20 kPa at (23 ± 1) °C and (40 ± 1) °C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, according to ISO 31-3, can assume positive or negative values. Inspect whether air enters the infusion set.

A.4.4 Fill the infusion filter with distilled water and apply an internal excess pressure of 200 kPa at (23 ± 1) °C and (40 ± 1) °C for 15 min. Inspect the infusion filter for any leakage of water.

A.5 Test for leakage of adapters with female and/or male conical fittings

A.5.1 In the beginning of the test, condition the whole system at the test temperature.

A.5.2 Test the female and/or male conical fitting of the adapter with the reference connector in accordance with ISO 594-2. Test the conical connection for 15 min, using distilled water under internal excess pressure of 200 kPa at (23 ± 1) °C and (40 ± 1) °C. Inspect it for any leakage of water.