INTERNATIONAL STANDARD

ISO 8536-9

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Infusion equipment for medical use —

Part 9: Fluid lines for use with pressure infusion equipment

Matériel de perfusion à usage médical —

Partie 9: Tubulures pour utilisation avec des appareils de perfusion sous pression

Reference number
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Contents

Page

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 8536-9 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 9:
Fluid lines for use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized fluid lines for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

The following items are covered by this part of ISO 8536:

a) syringe pump lines (SPL);

b) connecting lines (CL);

c) lines with integrated injection cannula (LIC).

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 7864, *Sterile hypodermic needles for single use*

ISO 8536-4:2004, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

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

ISO 8536-11, *Infusion equipment for medical use — Part 11: Infusion filters for use with pressure infusion equipment*

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

IEC 60601-2-24, *Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers*

3 Designation

The designation of a syringe pump line (SPL) for infusions under pressure (P) is as follows:

Pump line ISO 8536-9 –SPL – P

The designation of a connecting line (CL) for infusions under pressure (P) is as follows:

Connecting line ISO 8536-9 –CL – P

The designation of a line with injection cannula (LIC) for infusions under pressure (P) is as follows:

Cannular line ISO 8536-9 –LIC – P

4 Materials

The materials from which the fluid lines as given in Clause 3 are manufactured shall comply with the requirements as specified in Clauses 5, 6 and 7.

5 Physical requirements

5.1 Transparency

Tubing of fluid lines shall be transparent. When tested as specified in A.1, the air-water interface shall be detectable.

5.2 Particulate contamination

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

5.3 Tensile strength

When tested as specified in A.3 all parts of a fluid line shall withstand a static tensile force of at least 15 N for 15 s.

5.4 Leakage

In the beginning of the test the whole system shall be conditioned at the test temperature.

The fluid lines shall be impermeable to air, microorganisms, and fluids. When tested as specified in A.4, there shall be no leakage of air or water.

5.5 Adapters with female and/or male conical fittings

In the beginning of the test the whole system shall be conditioned at the test temperature.

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.

5.6 Accessories

Accessories of fluid lines, other than infusion filters, shall comply with the requirements as specified in ISO 8536-10.

5.7 Filters

Infusion filters shall comply with the requirements as specified in ISO 8536-11.

5.8 Storage volume

The storage volume shall be determined in accordance with IEC 60601-2-24 and shall be stated according to 9.1 g).

5.9 Injection needles

Injection needles shall comply with ISO 7864 when tested as specified in A.6.

5.10 Protective caps

ISO 8536-4 applies.

6 Chemical requirements

ISO 8536-4 applies.

7 Biological requirements

7.1 Sterility

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

7.2 Pyrogens

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

7.3 Haemolysis

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

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

8 Packaging

ISO 8536-4 applies.

9 Labelling

9.1 Unit container

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

a) a textual description of the contents, e.g. cannular line for single use;

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

c) indication that the fluid line is free from pyrogens, or that the fluid line is free from bacterial endotoxins;

d) indication that the fluid line 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. Storage volume at 40 °C ... ml.” (the name and type of pressure infusion equipment, as well as the storage volume, shall be given by the manufacturer);

h) identification block of designation according to Clause 3 (e.g. ISO 8536-9 – CL – P);

i) letter “P” which stands for pressure and the type 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.

9.2 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. cannular line for single use;

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

c) identification block of designation according to Clause 3 (e.g. ISO 8536-9 – CL – P);

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

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

f) storage note.

Annex A
(normative)

Physical tests

A.1 Test for transparency

Fill the fluid line with distilled water. 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. The test shall be performed as specified in ISO 8536-4.

A.3 Test for tensile strength

Expose the fluid lines in longitudinal direction to a static tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.4 Tests for leakage

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

A.4.2 Connect the fluid lines with the air supply and close all other openings. Apply air with an internal excess pressure of 50 kPa at (23 ± 1) °C and (40 ± 1) °C to the fluid lines for 15 s. Inspect the fluid lines for any leakage of air under water.

A.4.3 Fill the fluid lines 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 fluid lines for any leakage of water.

A.4.4 Fill the fluid lines 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 fluid lines.

A.5 Testing 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 according to 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.

A.6 Injection needle test

The test shall be done in accordance with ISO 7864.

Annex B
(normative)

Chemical tests

B.1 Preparation of test fluids

Take 450 cm of tubing and the equivalent of 100 cm^2 of surface of all the other components, e.g. connecting pieces. Disassemble the sterilized, ready-to-use fluid line into those pieces which will be in contact with the infusion fluid. Then arrange these pieces according to identical materials.

Reduce the pieces in size so that all inner and outer surfaces can be wetted. Then fill them into a 250 ml wide-neck Erlenmeyer flask, add 200 ml of distilled water as specified in the current edition of the pharmacopoeia, cover the flask and keep for 24 h at $(37 \pm 1)\,^{\circ}C$.

Fill another Erlenmeyer flask with 200 ml of distilled water as specified in the current edition of the pharmacopoeia, cover the flask and keep for 24 h at $(37 \pm 1)\,^{\circ}C$. This is used as control fluid for testing according to B.2 of ISO 8536-4:2004.

B.2 Test procedures

The tests shall be performed as specified in ISO 8536-4, but using the test fluids as specified in B.1 of this part of ISO 8536.

Annex C
(normative)

Biological tests

ISO 8536-4 applies.