INTERNATIONAL STANDARD

ISO 8536-10

Second edition
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Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 10: Accessoires pour tubulures non réutilisables avec un matériel de perfusion sous pression

Reference number
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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is 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 8536-10:2004), which has been technically revised with the following changes:

— The former Clause 3 on designation has been deleted;

— Clause 8 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725;

— Clause 9 on disposal has been added;

— A.4 'Tests for leakage' has been amended;

— The former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;

— Normative references and the Bibliography have been updated;

— Document has been editorially revised.

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 sets 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*

— *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

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

1 Scope

This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.

This part of ISO 8536 includes the following:

a) two-way stopcocks, three-way stopcocks, four-way stopcocks, and stopcocks manifold;

NOTE Designation of a stopcock depends on the number of connections. The number of possible functional positions can be expressed by addition of a complementary note, using a diagonal stroke and a numeral indicating the number of possible stopcock positions, e.g. 3/4-way stopcock for three-way stopcock with four possible positions.

b) units with injection site or check valve;

c) stoppers or adapters.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

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[1)], *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 — Registered symbols*

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 sets for single use with pressure infusion apparatus*

ISO 8536-12, *Infusion equipment for medical use —Part 12: Check valves*

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*

1) To be replaced by ISO 80369-7.

3 Materials

The materials from which the accessories are manufactured shall comply with the requirements as specified in Clause 4, Clause 5, and Clause 6.

4 Physical requirements

4.1 Avoidance of air bubbles

All components of accessories shall be designed such that no air bubbles are detected in flow channels when tested as specified in A.1.

4.2 Particulate contamination

The accessories 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.

4.3 Tensile strength

When tested as specified in A.3, the accessories and connections between components shall withstand a static tensile force of not less than 15 N for 15 s.

In the case of stopcocks, connections between plug and housing shall withstand this tensile force when in any position.

4.4 Leakage

The accessories shall be impermeable to air, microorganisms, and fluids. There shall be no leakage of air or water. Stopcocks shall be tight in any plug position. When tested as specified in A.4, there shall be no leakage of air or water.

4.5 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.

4.6 Protective caps

ISO 8536-4 applies.

4.7 Manipulation of stopcocks

Stopcocks and stopcock manifolds shall be so designed that when tested as specified in A.5, flow channels can be opened and closed without any adverse effect on the functionality of adjacent components.

4.8 Unit with injection site

Units with injection site shall enable injection. When tested as specified in A.6, no more than 10 drops per batch and no more than 2 drops per unit shall be lost.

4.9 Unit with check valve

When tested as specified in ISO 8536-12, the valve shall close tightly to prevent any leakage of water.

5 Chemical requirements

ISO 8536-4 applies. For test methods, see Annex B.

6 Biological requirements

6.1 Sterility

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

6.2 Pyrogens

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

6.3 Haemolysis

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

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

7 Packaging

ISO 8536-4 applies.

8 Labelling

8.1 General

The labelling shall include the requirements as specified in 8.2 and 8.3. If graphical symbols are used, then refer to ISO 15223-1.

NOTE The presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 by replacing the "XXX" by the abbreviation of the substance. The absence of substances of interest can be indicated by crossing the respective symbol.

8.2 Label on unit container

The unit container shall be labelled at least with the following information:

a) the name and address of the manufacturer;

b) a textual description of the contents, e.g. stopcock manifold for single use;

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

d) indication that the accessory is sterile, using the graphical symbol as given in ISO 15223-1;

e) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223-1;

f) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223-1;

g) indication that the accessory is for single use only, or equivalent wording, or using the graphical symbol according to ISO 15223-1;

h) instructions for use, including warnings, e.g. about detached protective caps;

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

If the available space is too small to give all this information in legible characters and/or symbols, the information can be reduced to e) and f). 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.

8.3 Label on shelf or multi-unit container

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

a) the name and address of the manufacturer;

b) a textual description of the contents, e.g. stopcock manifold for single use;

c) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223-1;

d) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223-1;

e) the wording “Safe for use with pressure infusion equipment”;

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

g) storage note.

9 Disposal

Information for a secure and environmentally sound disposal of single-use infusion sets should be given.

EXAMPLE “Always dispose of blood contaminated products in a manner consistent with established biohazard procedures.”

Annex A
(normative)

Physical tests

A.1 Air bubbles

Fill distilled water into the accessories to be tested as under usual practice conditions. Inspect visually the flow channels of transparent components for the presence of air bubbles.

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 accessory to be tested in longitudinal direction to a static tensile force of 15 N for 15 s. Expose the stopcocks to the same force in the direction of the rotational axis of its plug. 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 the whole system shall be conditioned at the test temperature.

A.4.2 Connect the accessory with its openings closed to a compressed air supply using a male and/or female connector in accordance with ISO 594-2. Apply air with an internal excess pressure of 50 kPa to the accessory 15 s. Inspect the accessory for any leakage of air under water at (40 ± 1) °C.

A.4.3 Fill the accessory with distilled water and apply an internal excess pressure of 200 kPa for 15 min. Inspect for any leakage of water at (40 ± 1) °C.

A.5 Test for manipulation of stopcocks

Move all plugs to all functional positions. Inspect whether adjacent components are adversely affected or wrongly adjusted by plug movement.

A.6 Test of unit with injection site

Perform this test as specified in ISO 8536-4, but apply an internal excess pressure of 200 kPa.

Annex B
(normative)

Chemical tests

B.1 Preparation of test fluids

Take components with an overall surface of 100 cm^2. Disassemble the sterilized, ready-to-use accessories into those pieces which will be in contact with the infusion fluid. Then arrange these pieces according to identical materials.

Reduce the pieces so in size 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 ± 1) °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 ± 1) °C. This is used as control fluid for testing according to ISO 8536-4.

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.