INTERNATIONAL STANDARD

**ISO 8536-10**

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# Infusion equipment for medical use —

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

*Matériel de perfusion à usage médical —*

*Partie 10: Accessoires de tubulures pour utilisation avec des appareils de perfusion sous pression*

Reference number
ISO 8536-10:2004(E)

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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 8536-10 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 10: Accessories for fluid lines for 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:

a) Two-way stopcocks (2SC), three-way stopcocks (3SC), four-way stopcocks (4SC) and stopcocks manifold (SM);

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 (UIS) or check valve (UCV);

c) stoppers (S) or adapters (A).

## 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 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

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 two-way stopcock (2SC) for infusions under pressure (P):

**Two-way stopcock ISO 8536-10 – 2SC –P**

Designation of three-way stopcock (3SC) for infusions under pressure (P):

**Three-way stopcock ISO 8536-10 – 3SC –P**

Designation of four-way stopcock (4SC) for infusions under pressure (P):

**Four-way stopcock ISO 8536-10 – 4SC –P**

Designation of stopcock manifold (SM) for infusions under pressure (P):

**Stopcock manifold ISO 8536-10 – SM –P**

Designation of two-stopcock manifold (2SM) for infusions under pressure (P):

**Stopcock manifold ISO 8536-10 – 2SM –P**

Designation of three-stopcock manifold (3SM) for infusions under pressure (P):

**Stopcock manifold ISO 8536-10 – 3SM –P**

Designation of four-stopcock manifold (4SM) for infusions under pressure (P):

**Stopcock manifold ISO 8536-10 – 4SM –P**

Designation of unit with injection site (UIS) for infusions under pressure (P):

**Injection unit ISO 8536-10 – UIS –P**

Designation of unit with check valve (UCV) for infusions under pressure (P):

**Injection unit ISO 8536-10 – UCV –P**

Designation of stopper (S) for infusions under pressure (P):

**Stopper ISO 8536-10 – S –P**

Designation of adapter (A) for infusions under pressure (P):

**Adapter ISO 8536-10 – A –P**

## 4 Materials

The materials from which the accessories 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 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.

### 5.2 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.

### 5.3 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.

### 5.4 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.

### 5.5 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.

### 5.6 Protective caps

ISO 8536-4 applies.

### 5.7 Manipulation of stopcocks

Stopcocks and stopcock manifolds shall be so designed that when tested as specified in A.6, flow channels can be opened and closed without any adverse effect on the functionality of adjacent components.

### 5.8 Unit with injection site

Units with injection site shall enable injection. When tested as specified in A.7, no more than 10 drops per batch and no more than 2 drops per unit shall be lost.

### 5.9 Unit with check valve

When tested as specified in A.8, the valve shall close tightly to prevent any leakage of water.

## 6 Chemical requirements

ISO 8536-4 applies.

# 7 Biological requirements

## 7.1 Sterility

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

## 7.2 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.

## 7.3 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.

# 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. stopcock manifold for single use;

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

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

d) indication that the accessory is for single use only, or equivalent wording, or 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 8536-10 – SM – 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.

## 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. stopcock manifold 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 shall be given by the manufacturer);

d) identification block of designation according to Clause 3 (e.g. ISO 8536-10 – SM – 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 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 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 accessory with its openings closed to a compressed air supply. Apply air with an internal excess pressure of 20 kPa at $(23 \pm 1)$ °C and $(40 \pm 1)$ °C to the accessory for 15 min. Inspect the accessory 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 $(23 \pm 1)$ °C and $(40 \pm 1)$ °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 accessory with distilled water and apply an internal excess pressure of 200 kPa at $(23 \pm 1)$ °C and $(40 \pm 1)$ °C for 15 min. Inspect the accessory 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 according to ISO 594-2. Test the conical connection for 15 min, using distilled water under internal excess pressure of 200 kPa at $(23 \pm 1)$ °C and $(40 \pm 1)$ °C. Inspect it for any leakage of water.

## A.6 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.7 Test of unit with injection site

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

## A.8 Test of unit with check valve

Fill the unit with distilled water. Empty the unit through the check valve by an amount of distilled water which is equivalent to the nominal volume of 5 ml of a hypodermic syringe for single use as specified in ISO 7886-1 under an internal excess pressure of 200 kPa and without excess pressure. Perform this test 10 times each. Inspect whether there is any leakage of water.

# 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 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 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.

# Annex C
(normative)

# Biological tests

ISO 8536-4 applies.

# Bibliography

[1] ISO 31-3, *Quantities and units — Part 3: Mechanics*

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

[3] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

[4] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

[5] ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

[6] European Pharmacopoeia

[7] United States Pharmacopeia

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