
**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*

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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.

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*

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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 594-2¹⁾, *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.

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7 Packaging

ISO 8536-4 applies.

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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;