Infusion equipment for medical use —
Part 4:
Infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —
Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité
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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 8536-4 was prepared by Technical Committee ISO/TC 76, Transfusion, infusion and injection equipment for medical and pharmaceutical use.

This third edition cancels and replaces the second edition (ISO 8536-4:1998) which has been technically 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 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 4:
Infusion sets for single use, gravity feed

1 Scope

This part of ISO 8536 specifies requirements for single-use, gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment.

Secondary aims of this part of ISO 8536 are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

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 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 594-1:1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements

ISO 594-2:1998, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings

ISO 3696:1987, Water for analytical laboratory use — Specification and test methods

ISO 7864:1993, Sterile hypodermic needles for single use

ISO 14644-1:1999, Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness

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

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1, shall be used for rigid containers.
Key

1 protective cap of closure-piercing device
2 closure-piercing device
3 air inlet with air filter and closure
4 fluid channel
5 drip tube
6 drip chamber
7 fluid filter
8 tubing
9 flow regulator
10 injection site
11 male conical fitting
12 protective cap of male conical fitting

a Closure of the air inlet is optional.
b The fluid filter may be positioned at other sites, preferably near the patient access. Generally, the fluid filter used has a nominal pore size of 15 µm.
c The injection site is optional.

Figure 1 — Example of a vented infusion set
Key
1 protective cap of the closure-piercing device
2 closure-piercing device
3 fluid channel
4 drip tube
5 drip chamber
6 fluid filter
7 tubing
8 flow regulator
9 injection site
10 male conical fitting
11 protective cap of the male conical fitting

a The fluid filter may be positioned at other sites, preferably near the patient access. Generally, the fluid filter used has a nominal pore size of 15 µm.
b The injection site is optional.

Figure 2 — Example of a non-vented infusion set
3.2 The infusion set shall be provided with protective caps to maintain sterility of the internal parts of the set until the set is used. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle.

4 Designation

4.1 Infusion set

Infusion sets complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters IS, followed by the letter G:

Infusion set ISO 8536-4 — IS — G

4.2 Air-inlet device

Air-inlet devices complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters AD:

Air-inlet device ISO 8536-4 — IS — AD

5 Materials

The materials from which the infusion set and its components as given in Clause 3 are manufactured shall comply with the requirements as specified in Clause 6. Where components of the infusion set come into contact with solutions, the materials additionally shall comply with the requirements as specified in Clauses 7 and 8.