Infusionsutrustning för medicinskt bruk –
Del 4: Infusionsaggregat för infusion utan övertryck för engångsbruk (ISO 8536-4:2004)

Infusion equipment for medical use –

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

Matériel de perfusion à usage médical - Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité (ISO 8536-4:2004)


This European Standard was approved by CEN on 29 July 2004.

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Foreword

This document (EN ISO 8536-4:2004) has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8536-4:2004 has been approved by CEN as EN ISO 8536-4:2004 without any modifications.
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 7 fluid filter
2 closure-piercing device 8 tubing
3 air inlet with air filter and closure 9 flow regulator
4 fluid channel 10 injection site
5 drip tube 11 male conical fitting
6 drip chamber 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
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:

\[ \text{Infusion set ISO 8536-4 — IS — G} \]

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:

\[ \text{Air-inlet device ISO 8536-4 — IS — AD} \]

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.
6 Physical requirements

6.1 Particulate contamination

The infusion sets shall be manufactured under conditions that minimize particulate contamination. All parts shall be smooth and clean at the fluid pathway surfaces. When tested as specified in A.1, the number of particles shall not exceed the contamination index.

6.2 Leakage

The infusion set, when tested in accordance with A.2, shall show no signs of air leakage.

6.3 Tensile strength

When tested as specified in A.3, the infusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

6.4 Closure-piercing device

The dimensions of the closure-piercing device shall conform with the dimensions shown in Figure 4.

NOTE The dimension of 15 mm in Figure 4 is a reference measurement. The cross section of the piercing device at this site is a circle.

The closure-piercing device shall be capable of piercing and penetrating the closure of a fluid container without pre-piercing. No coring should occur during this procedure.

6.5 Air-inlet device

The air-inlet device shall conform with 3.2 and 8.2.

The air-inlet device shall be provided with an air filter to prevent the ingress of microorganisms into the container into which the device is to be inserted.

The air-inlet device shall be separate from, or integral with, the closure-piercing device.

When the air-inlet device is inserted into a rigid infusion container, the air admitted into the container shall not become entrained in the liquid outflow.

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**Figure 4 — Dimensions of the closure-piercing device**
The air filter shall be fitted so that all air entering the rigid container passes through it and that the flow of fluid is not reduced by more than 20 % of that from a freely ventilated container when tested in accordance with A.4.

6.6 Tubing

The tubing, made of flexible material, shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.

The tubing from the distal end to the drip chamber shall be not less than 1 500 mm in length, including the injection site, when provided, and the male conical fitting.

6.7 Fluid filter

The infusion set shall be provided with a fluid filter.

When tested in accordance with A.5, the retention of latex particles on the filter shall be not less than 80 %.

6.8 Drip chamber and drip tube

The drip chamber shall permit continuous observation of the fall of drops. The liquid shall enter the drip chamber through a tube which projects into the chamber. There shall be a distance of not less than 40 mm between the end of the drip tube and the outlet of the chamber, or a distance of not less than 20 mm between the drip tube and the fluid filter. The wall of the drip chamber shall not be closer than 5 mm to the end of the drip tube. The drip tube shall be such that 20 drops of distilled water or 60 drops of distilled water at (23 ± 2) °C at a flow rate of (50 ± 10) drops/min deliver a volume of (1 ± 0,1) ml or a mass of (1 ± 0,1) g. The drip chamber should permit and facilitate the priming procedure.

6.9 Flow regulator

The flow regulator shall adjust the flow of the infusion solution between zero and the maximum. For gravity systems, the colour orange for the flow regulator cannot be used. The flow regulator should be capable of continuous use throughout an infusion without the tubing being damaged. There should be no deleterious reaction between the flow regulator and the tubing when stored in such a manner that there is contact.

6.10 Flow rate of infusion fluid

The infusion set shall deliver not less than 1 000 ml of a sodium chloride solution [mass concentration \( \rho(\text{NaCl}) = 9 \text{ g/l} \)] in 10 min under a static head of 1 m.

6.11 Injection site

When provided, the self-sealing injection site shall reseal when tested in accordance with A.6, and there shall be no leakage of more than one falling drop of water. The injection site should be located near the male conical fitting.

6.12 Male conical fitting

The distal end of the tubing shall terminate in a male conical fitting in accordance with ISO 594-1 or ISO 594-2. Luer lock fittings according to ISO 594-2 should preferably be used.

6.13 Protective caps

The protective caps at the end of the infusion set shall maintain the sterility of the closure-piercing device, the male conical fitting and the interior of the infusion set. Protective caps should be secure but easily removable.