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Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO/DIS 8536-4:2018)

Infusionsgeräte zur medizinischen Verwendung - Teil 4: Infusionsgeräte für Schwerkraftinfusionen zur einmaligen Verwendung (ISO/DIS 8536-4:2018)

Matériel de perfusion à usage médical - Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité (ISO/DIS 8536-4:2018)

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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*

ICS: 11.040.20

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This sixth edition cancels and replaces the fifth edition (ISO 8536-4:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the Amendment 1:2013 has been included;
- the Clause 'Designation' refers now to Clause 'Labelling';
- most of the physical and chemical requirements – especially in regard of stand-alone air-inlet devices – have been more clarified;
- the Clause 'Labelling' has been updated;
- in [Annex A](#) the Clause 'Test for leakage' has been updated;
- in [Annex A](#) the Clause 'Determination of flow rate' has been totally reviewed;
- the 'Normative references' and the 'Bibliography' have been updated.

A list of all parts in the ISO 8536- series can be found on the ISO website.

Infusion equipment for medical use —

Part 4:

Infusion sets for single use, gravity feed

1 Scope

This document 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 document 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.

NOTE In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this document.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8536-13, *Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact*

ISO 8536-14, *Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

No terms and definitions are listed in this document.

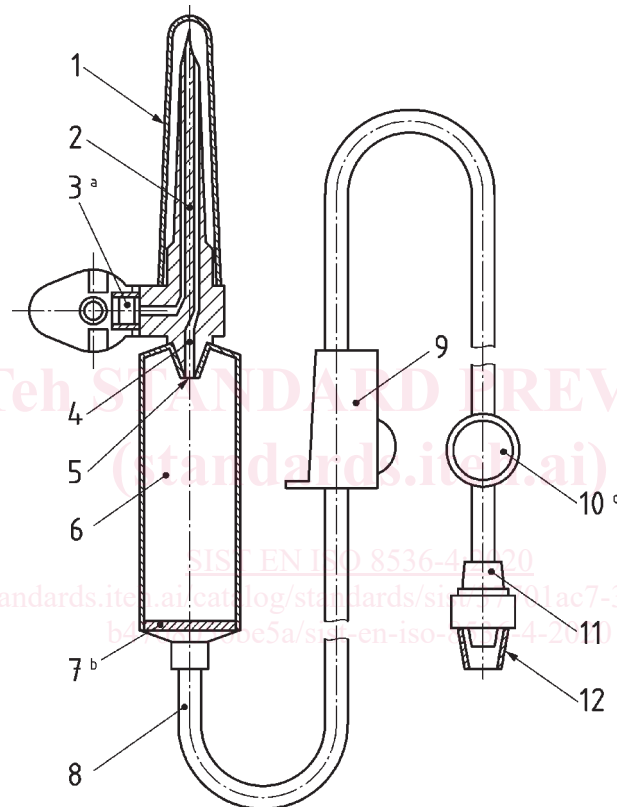
ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 General requirements

4.1 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 plastic 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 3, shall be used for rigid containers.

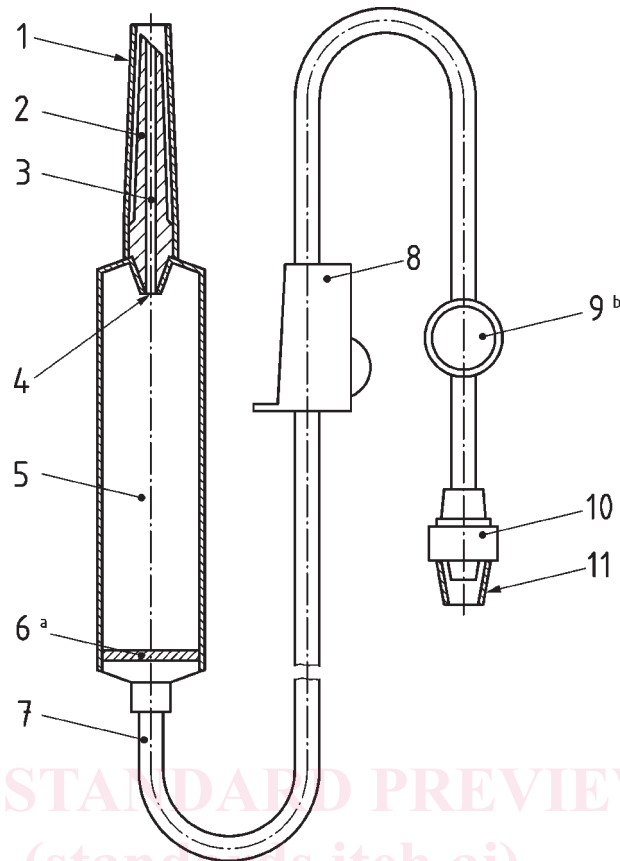
4.2 The infusion set shall be provided with protective caps. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle (see Figure 3).



Key

- | | | | |
|---|--|----|--|
| 1 | protective cap of closure-piercing device | 7 | fluid filter |
| 2 | closure-piercing device | 8 | tubing |
| 3 | integral 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.
- c The injection site is optional.

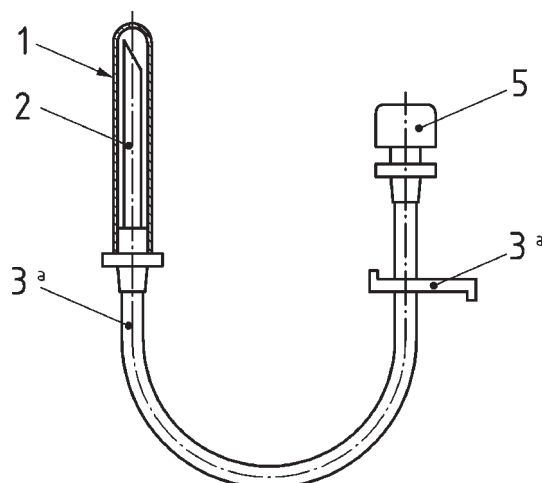
Figure 1 — Example of a vented infusion set



Key

- | | | | |
|---|--|----|--|
| 1 | protective cap of closure-piercing device | 7 | tubing |
| 2 | closure-piercing device | 8 | flow regulator |
| 3 | fluid channel | 9 | injection site |
| 4 | drip tube | 10 | male conical fitting |
| 5 | drip chamber | 11 | protective cap of the male conical fitting |
| 6 | fluid filter | | |
| a | The fluid filter may be positioned at other sites, preferably near the patient access. | | |
| b | The injection site is optional. | | |

Figure 2 — Example of a non-vented infusion set

**Key**

- | | | | |
|---|--|---|---------------------------|
| 1 | protective cap | 4 | clamp |
| 2 | closure-piercing device or needle | 5 | air-inlet with air filter |
| 3 | tubing | | |
| a | Other designs are acceptable if the same safety aspects are ensured. | | |

Figure 3 — Example of a stand-alone air-inlet device

5 Designation

Designation shall follow label requirements according to [Clause 10](#).

6 Materials

The materials from which the infusion set, its components and the stand-alone air-inlet device are manufactured as described in [Clause 4](#) and shall comply with the requirements specified in [Clause 7](#). Where components of the infusion set come into contact with solutions, the materials shall also comply with the requirements specified in [Clauses 8](#) and [9](#).

7 Physical requirements

7.1 Particulate contamination

The infusion set and stand-alone air-inlet device 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.2](#), the number of particles shall not exceed the contamination index limit.

7.2 Leakage

The infusion set, when tested in accordance with [A.3](#), shall show no signs of air leakage.

7.3 Tensile strength

When tested as specified in [A.4](#), the infusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

7.4 Closure-piercing device

The dimensions of the closure-piercing device shall conform to the dimensions shown in Figure 4. The cross-section of the closure-piercing device over the length of 15 mm shall be a circle.

NOTE The dimension of 15 mm in Figure 4 is a reference measurement.

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.

Dimensions in millimetres

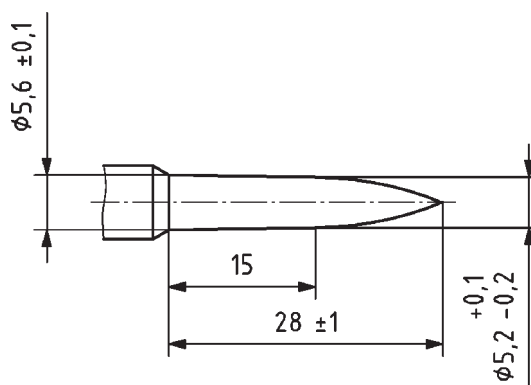


Figure 4 — Dimensions of the closure-piercing device

7.5 Air-inlet device

The air-inlet device can be an integral part of the infusion set (Figure 1) or a stand-alone device (Figure 3).

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.

When the air-inlet device is in use than the air admitted into the container shall not become entrained in the liquid-entry of the closure-piercing device.

The air filter and the design of the air-inlet device shall be such that all air entering the rigid container passes through it, and such 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.5.2](#) and [A.5.3](#)

7.6 Tubing

The tubing, made of flexible material, shall be transparent or sufficiently translucent 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.

7.7 Fluid filter

The infusion set shall be provided with a fluid filter.

When tested in accordance with [A.6](#), the retention of latex particles on the filter shall be not less than 80 %.