
**Transfusion equipment for medical
use —**

**Part 3:
Blood-taking sets for single use**

Matériel de transfusion à usage médical —

Partie 3: Appareils non réutilisables pour prélèvement sanguin
**iTeh STANDARD PREVIEW
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ISO 1135-3:2016

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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 1135-3:1986), which has been technically revised with the following changes:

- part title has been amended by “for single use” in alignment with the other parts of ISO 1135;
- figures have been updated;
- subclause 3.6, “Designation examples” has been deleted;
- physical, chemical and biological requirements have been aligned with ISO 1135-4;
- [Clause 10](#), “Disposal” has been added;
- [Annexes A, B and C](#) have been aligned with ISO 1135-4;
- all references have been updated.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

- *Part 3: Blood-taking sets for single use*
- *Part 4: Transfusion sets for single use, gravity feed*
- *Part 5: Transfusion sets for single use with pressure infusion apparatus*

Transfusion equipment for medical use —

Part 3: Blood-taking sets for single use

1 Scope

This part of ISO 1135 specifies requirements for types of blood-taking sets for medical use in order to ensure functional interchangeability of transfusion equipment. It is applicable to sterilized blood-taking sets intended for single use only.

This part of ISO 1135 also aims to provide

- a) specifications relating to the quality and performance of materials used in transfusion equipment, and
- b) a unified presentation of terms for such equipment.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 1135.

2 Normative references (standards.iteh.ai)

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

ISO 7864, *Sterile hypodermic needles for single use*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

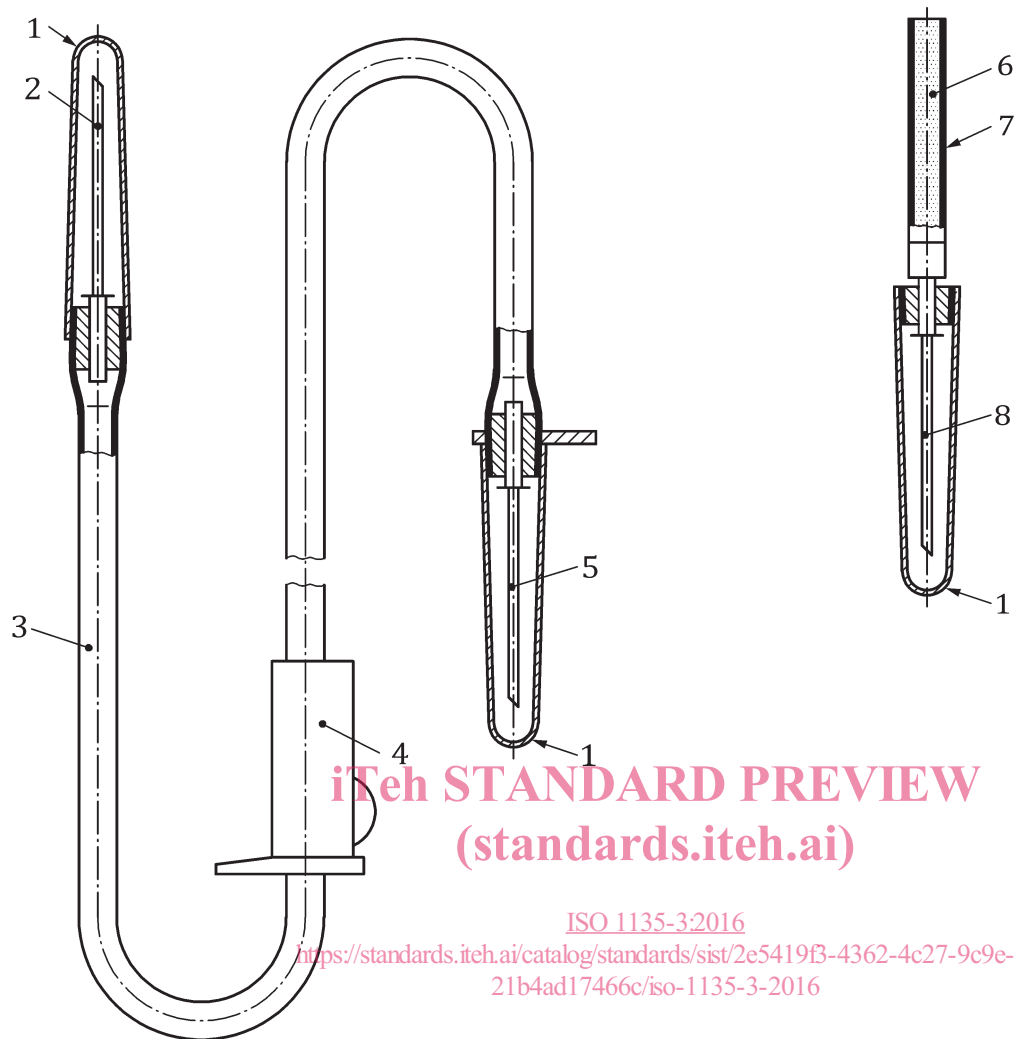
ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 General requirements

3.1 Types of sets

The blood-taking set shall consist of the blood-taking assembly and the air-outlet assembly, which may be separate or combined.

A diagram of a typical blood-taking set is illustrated in [Figure 1](#).



a) Blood-taking assembly

b) Air outlet assembly

Key

- | | | | |
|---|---------------------------|---|---------------------|
| 1 | protective cap | 5 | blood-taking needle |
| 2 | bottle needle | 6 | air filter |
| 3 | tubing | 7 | air filter housing |
| 4 | flow regulator (optional) | 8 | air-outlet needle |

Figure 1 — Examples of typical blood-taking sets

3.2 Blood taking assembly

The blood-taking assembly shall consist of a blood-taking needle for vein puncture and of a bottle needle to be inserted through one of the specified areas provided on the bottle closure. Each needle is connected to one end of a length of tubing.

3.3 Air-outlet assembly

The air-outlet assembly shall consist of an air filter housing with air filter combined with an air-outlet needle for piercing the specified area provided on the bottle closure.

The filter shall be capable of preventing microbial ingress.

3.4 Sterilization

The blood-taking set shall be sterile in its unit container. Evidence of the effectiveness of the sterilization process used shall be provided.

3.5 Maintenance of sterility

The blood-taking set shall be provided with protective caps designed to maintain sterility of the internal surface of the set and the internal and external surfaces of the needles until the set is used.

4 Materials

The materials from which the blood-taking set is made shall not have undesirable effects on the blood passing through the set under ordinary conditions of use, or on the fluids used in connection with the blood. They shall not produce any general toxic effects or any local reaction on the recipient of the blood.

Appropriate type tests for assessing biological compatibility are given in [Annex C](#).

5 Physical requirements

5.1 Particulate contamination

The blood-taking 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 detected shall not exceed the contamination index limit.

5.2 Leakage

The blood-taking set, when tested in accordance with [A.2](#), shall show no signs of air leakage.

5.3 Tensile strength

Any connections between the components of the blood-taking set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

5.4 Bottle needle

5.4.1 The bottle needle shall not be less than 35 mm in length. The external diameter shall not be less than 1,8 mm and the internal diameter shall not be less than 70 % of the external diameter.

5.4.2 The internal and external surfaces of the needle tube shall be clean and smooth.

5.4.3 The bottle needle shall be designed in accordance with ISO 7864 in order to minimize the number of rubber particles when the closure is pierced.

5.5 Air-outlet needle

The air-outlet needle shall have an internal diameter not less than 0,7 mm, an external diameter not greater than 1,9 mm and a needle not exceeding 25 mm in length.

5.6 Blood-taking needle

5.6.1 The blood taking needle shall not be less than 35 mm in length. The external diameter shall not be greater than 2 mm and the internal diameter shall not be less than 70 % of the external diameter.

5.6.2 The internal and external surface of the needle tube shall be clean and smooth. The bevel of the needle shall be sharp and free from ridges, burrs and barbs.

5.6.3 For further requirements on needles, see ISO 9626, DIN 13097-4 and DIN 13097-5.

5.7 Tubing

The tubing shall have an internal diameter of not less than 2,7 mm. It shall not be less than 600 mm in length. The tubing shall be flexible and shall not have any kinks.

5.8 Flow regulator

5.8.1 The flow regulator shall be capable of adjusting the flow of the blood between zero and the maximum.

5.8.2 The flow regulator shall be capable of continuous use throughout a donation without damaging the tubing. There shall be no deleterious reaction between the flow regulator and the tubing when stored in contact.

5.8.3 For further requirements on the flow regulator, see ISO 8536-14.

5.9 Protective caps

The protective caps at the end of the blood-taking set shall maintain the sterility or prevent contamination of the blood-taking needle, the bottle needle and the interior of the blood-taking set.

Protective caps should be secure but easily removable.

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6 Chemical requirements

6.1 Reducing (oxidizable) matter

When tested in accordance with [B.2](#), the difference of volume of $\text{Na}_2\text{S}_2\text{O}_3$ solution [$c(\text{Na}_2\text{S}_2\text{O}_3) = 0,005 \text{ mol/l}$] for the extract solution, S_1 , and of volume of $\text{Na}_2\text{S}_2\text{O}_3$ solution for blank solution, S_0 , shall not exceed 2,0 ml.

6.2 Metal ions

The extract shall not contain in total more than 1 $\mu\text{g/ml}$ of barium, chromium, copper, lead and tin, and not more than 0,1 $\mu\text{g/ml}$ of cadmium, when determined by atomic absorption spectroscopy (AAS) or an equivalent method.

When tested in accordance with [B.3](#), the intensity of the colour produced in the test solution shall not exceed that of the standard matching solution containing $(\text{Pb}^{2+}) = 1 \mu\text{g/ml}$.

6.3 Titration acidity or alkalinity

When tested in accordance with [B.4](#), not more than 1 ml of either standard volumetric solution shall be required for the indicator to change to the colour grey.

6.4 Residue on evaporation

When tested in accordance with [B.5](#), the total amount of dry residue shall not exceed 5 mg.

6.5 UV absorption of extract solution

When tested in accordance with [B.6](#), the extract solution S₁ shall not show absorbance greater than 0,1 (optical density).

7 Biological requirements

7.1 General

The blood-taking set shall not release any substances which may adversely affect the therapeutic effectiveness of the blood (see [C.2](#)).

7.2 Sterility

The blood-taking set in its unit container shall have been subjected to a validated sterilization process (see Bibliography).

7.3 Pyrogenicity

The blood-taking set shall be assessed for freedom from pyrogens using a suitable test and the results shall indicate that the blood-taking set is free from pyrogenicity. Testing for pyrogenicity shall be carried out in accordance with [Annex C](#).

7.4 Haemolysis

The blood-taking set shall be assessed for freedom from haemolytic constituents and the result shall indicate that the blood-taking set is free from haemolytic reactions. Guidance on testing for haemolytic constituents is given in ISO 10993-4. [ISO 1135-3:2016](#)

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7.5 Toxicity

Materials shall be assessed for toxicity by carrying out suitable tests and the results of the tests shall indicate freedom from toxicity. Guidance on testing for toxicity is given in ISO 10993-1.

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 3826-2 and 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 Unit container

The unit container shall be labelled at least with the following information using the graphical symbols in accordance with ISO 15223-1, where appropriate:

- a) the name and address of the manufacturer;
- b) description of the contents;
- c) indication that the blood-taking set is sterile;
- d) the lot (batch) designation;