DRAFT INTERNATIONAL STANDARD

ISO/DIS 1135-3

ISO/TC **76**

Secretariat: **DIN**

Voting begins on:
2014-09-25

Voting terminates on:
2015-02-25

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 de sang

ICS: 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 1135-3:2014(E)

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 General requirements 1
3.1 Types of sets 1
3.2 Blood taking assembly 2
3.3 Air-outlet assembly 3
3.4 Sterilization 3
3.5 Maintenance of sterility 3

4 Materials 3

5 Physical requirements 3
5.1 Particulate contamination 3
5.2 Leakage 3
5.3 Tensile strength 3
5.4 Bottle needle 3
5.5 Air-outlet needle 3
5.6 Blood-taking needle 4
5.7 Tubing 4
5.8 Flow regulator 4

6 Chemical requirements 4
6.1 Reducing (oxidizable) matter 4
6.2 Metal ions 4
6.3 Titration acidity or alkalinity 4
6.4 Residue on evaporation 4
6.5 UV absorption of extract solution 4

7 Biological requirements 5
7.1 General 5
7.2 Sterility 5
7.3 Pyrogenicity 5
7.4 Haemolysis 5
7.5 Toxicity 5

8 Labelling 5
8.1 General 5
8.2 Unit container 5
8.3 Shelf or multi-unit container 6

9 Packaging 6

10 Disposal 6

Annex A (normative) Physical tests 7

Annex B (normative) Chemical tests 9

Annex C (normative) Biological tests 11

Bibliography 12

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices 13

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 1135-3 was prepared by Technical Committee 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), of which the following revisions have been introduced:

- The part title has been amended by "for single use" in alignment with the other parts of ISO 1135;
- The Figures have been updated;
- Clause 3.6 "Designation examples" has been deleted;
- The 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.

The materials and the components of the sets are validated by various test methods.

The manufacturer shall select appropriate test methods to comply with the requirements laid down in this part of ISO 1135.

Secondary aims of this part of ISO 1135 are to provide

a) specifications relating to the quality and performance of materials used in transfusion equipment;

b) a unified presentation of terms and designations 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

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 laboratory use — Specifications and test methods*

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

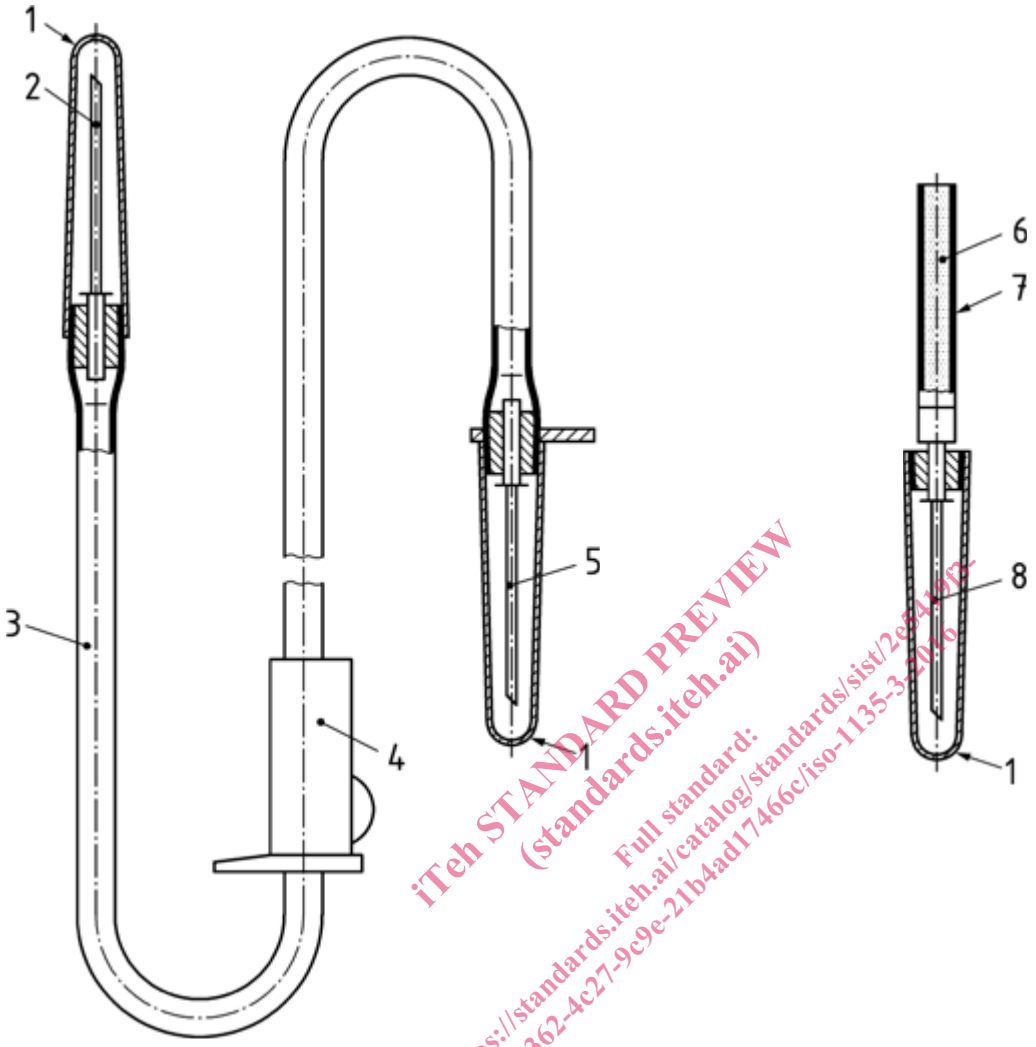
ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 Figures 1 and 2.



Key for Figures 1 and 2

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 — Example of a blood-taking assembly

Figure 2 — Example of an air-outlet assembly

3.2 Blood taking assembly

The blood-taking assembly shall consist of a needle for vein puncture (the blood-taking needle) and of a needle (the 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 a needle (the 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 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 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.

5.7 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.

6 Chemical requirements

6.1 Reducing (oxidizable) matter

When tested in accordance with B.2, the difference of volume of $Na_2S_2O_3$ solution [$c(Na_2S_2O_3)$ = 0,005 mol/l] for the extract solution, S_1, and of volume of $Na_2S_2O_3$ 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 µg/ml of barium, chromium, copper, lead and tin, and not more than 0,1 µg/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 $\beta(Pb^{2+})$ = 1 µg/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 S_1 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.

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.

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 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;

e) year and month of expiry;

f) indication that the blood-taking set is for single use only, or equivalent wording;