SLOVENSKI STANDARD
oSIST prEN ISO 1135-5:2013

01-december-2013

Transfuzijska oprema za uporabo v medicini - 5. del: Transfuzijske garniture za enkratno uporabo s tlačno črpalko (ISO/DIS 1135-5:2013)

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO/DIS 1135-5:2013)

Transfusionsgeräte zur medizinischen Verwendung - Teil 5: Transfusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO/DIS 1135-5:2013)

Matériel de transfusion à usage médical - Partie 5: Appareils de transfusion non réutilisables avec des appareils de perfusion sous pression (ISO/DIS 1135-5:2013)

Ta slovenski standard je istoveten z: prEN ISO 1135-5

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

oSIST prEN ISO 1135-5:2013 en

DRAFT INTERNATIONAL STANDARD

ISO/DIS 1135-5

ISO/TC **76**

Secretariat: **DIN**

Voting begins on:
2013-10-03

Voting terminates on:
2014-03-03

Transfusion equipment for medical use —

Part 5:
Transfusion sets for single use with pressure infusion apparatus

Matériel de transfusion à usage médical —

Partie 5: Appareils de transfusion non réutilisables avec des appareils de perfusion sous pression

[Revision of first edition (ISO 1135:1997) and of five edition ISO 1135-4:2012]

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 1135-5:2013(E)

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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 1135-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This first edition of ISO 1135-5 together with ISO 1135-4, sixth edition, cancels and replaces the fifth edition (ISO 1135-4:2012), of which the scope has been restricted to gravity feed and the whole document aligned accordingly.

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

— *Part 3: Blood-taking set*

— *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 5: Transfusion sets for single use with pressure infusion apparatus

1 Scope

This part of ISO 1135 specifies requirements for single use transfusion sets for use with pressure infusion equipment capable of generating pressures up to 200 kPa (2 bar). The standard ensures compatibility with containers for blood and blood components as well as intravenous equipment.

Secondary aims of this part of ISO 1135 are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets, to present designations for transfusion set components and to ensure the compatibility of sets with red cell and plasma blood components.

Platelet components should not be transfused under pressure using these sets.

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 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*[1)]

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

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

ISO 3826-1:2013, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7864, *Sterile hypodermic needles for single use*

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

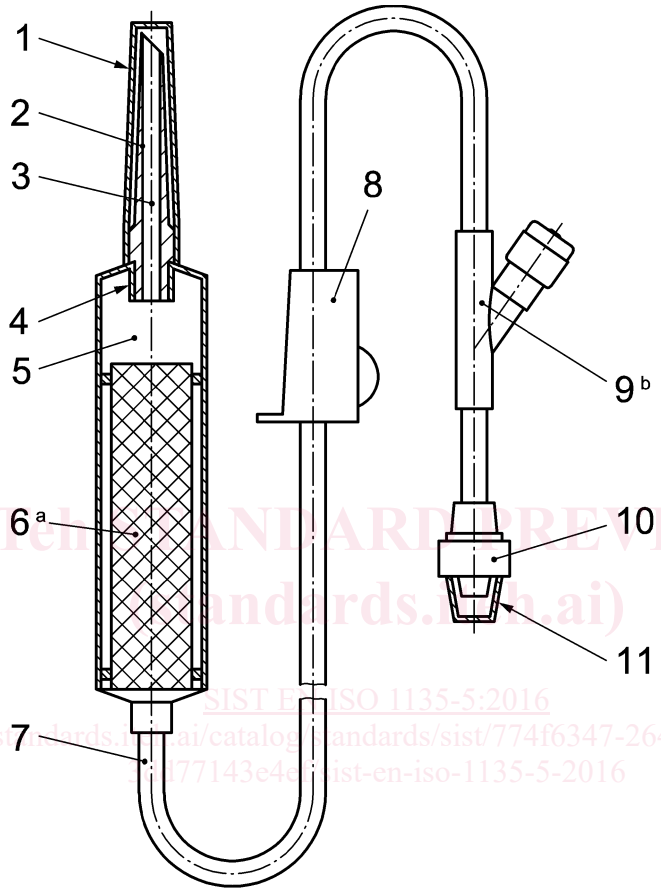
ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

1) Will be replaced by ISO 80369-7.

3 General requirements

3.1 Nomenclature for components of the transfusion set

The nomenclature for components of transfusion sets is given in Figure 1.



Key

1	protective cap of the 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	filter for blood and blood components		

[a] Indicates alternative locations of the filter for blood and blood components. Other designs are acceptable if the same safety aspects are ensured.

[b] Injection site is optional.

Figure 1 — Example of a transfusion set

3.2 Maintenance of sterility

The transfusion set shall be provided with protective caps to maintain sterility of the internal parts of the set until the set is used.

3.3 Designation

A transfusion set complying with the requirements of this part of ISO 1135 is designated as follows:

Transfusion set ISO 1135-5

4 Materials

The materials from which the transfusion sets given in Clause 3 are manufactured shall comply with the requirements specified in Clause 5. If components of the transfusion set come into contact with blood and blood components, they shall additionally comply with the requirements specified in Clauses 6 and 7.

5 Physical requirements

5.1 Particulate contamination

The transfusion 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 transfusion 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 transfusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

5.4 Closure-piercing device

5.4.1 The dimensions of the closure-piercing device shall conform to the dimensions shown in Figure 2.

NOTE The dimension of 15 mm in Figure 2 is a reference measurement. The cross-section of the piercing device at this site is a circle.

Dimensions in millimetres

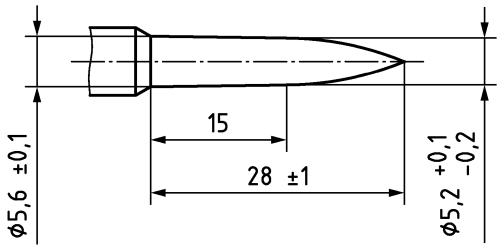


Figure 2 — Dimensions of the closure-piercing device

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

NOTE 1 A carefully controlled surface treatment of the closure-piercing device (e.g. siliconization) is recommended to facilitate its insertion into the blood bag port. The same effect may be achieved by a careful selection of material for the closure-piercing device. Typical results including test equipment for penetration forces between spikes and blood bag ports have been published. See References [11] and [12].