SLOVENSKI STANDARD
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Transfuzijska oprema za uporabo v medicini - 4. del: Transfuzijske garniture za enkratno uporabo, delujoče na osnovi gravitacije (ISO/DIS 1135-4:2023)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO/DIS 1135-4:2023)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte für Schwerkrafttransfusionen zur einmaligen Verwendung (ISO/DIS 1135-4:2023)

Matériel de transfusion à usage médical - Partie 4: Transfuseurs non réutilisables, à alimentation par gravité (ISO/DIS 1135-4:2023)

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Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use, gravity feed

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables à alimentation par gravité

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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 of 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 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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This seventh edition of ISO 1135-4 cancels and replaces the sixth edition (ISO 1135-4:2015), which has been technically revised with the following changes:

- 6.10 “Injection site” has been amended in regard of the use of needle-free injection ports and Luer-activated devices;
- 6.12 “Protective caps” has been more clarified how to prevent contamination;
- Clause 9 “Labelling” has been updated especially in regard of the referenced ISO 15223-1;
- Clause 10 “Packaging” has been amended by a reference to ISO 11607-1;
- Annex A “Physical test” has been amended by a general introduction on the pre-conditioning. In addition the description of the test for leakage has been extended;
- the Normative references have been updated;
- some minor editorial changes were introduced in the whole document.

A list of all parts in the ISO 1135 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use, gravity feed

1 Scope

This document specifies requirements for single use transfusion gravity sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

Secondary aims of this document 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 a range of cellular and plasma blood 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1:2019, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

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

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — 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*

ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

3 Terms and definitions

No terms and definitions are listed in this document.

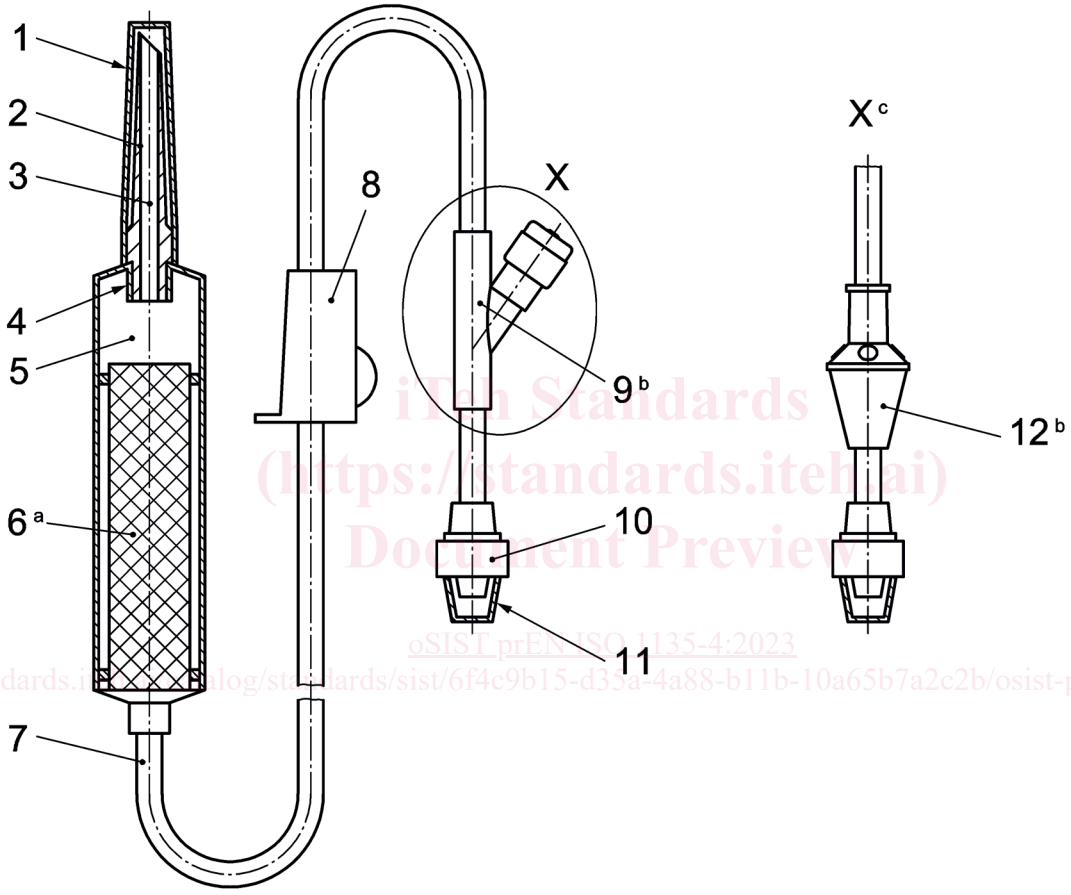
ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 General requirements

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



Key

1	protective cap of the closure-piercing device	9	injection site
2	closure-piercing device	10	male conical fitting
3	fluid channel	11	protective cap of the male conical fitting
4	drip tube	12	elastomeric buffer
5	drip chamber	a	Indicates alternative locations of the filter for blood and blood components. Other designs are acceptable, if the same safety aspects are ensured.
6	filter for blood and blood components	b	Injection site and elastomeric buffer are optional.
7	tubing	c	Optional design.
8	flow regulator		

Figure 1 — Example of a transfusion set

4.2 The transfusion set shall be provided with protective caps.

5 Materials

The materials from which the transfusion sets given in Clause 4 are manufactured shall comply with the requirements specified in Clause 6. If components of the transfusion set come into contact with blood and blood components, they shall additionally comply with the requirements specified in Clauses 7 and 8.

6 Physical requirements

6.1 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.2, the number of particles detected shall not exceed the contamination index limit.

6.2 Leakage

The transfusion set, when tested in accordance with A.3, shall show no signs of air leakage.

6.3 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.

6.4 Closure-piercing device

6.4.1 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

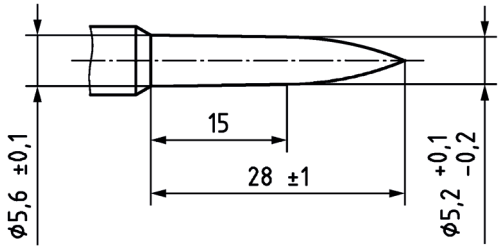


Figure 2 — Dimensions of the closure-piercing device

6.4.2 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 can 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 [9] and [10].

NOTE 2 A central closure-piercing device tip is preferred to an asymmetric design in order to aid its insertion.

6.4.3 When inserted into a blood bag port conforming to ISO 3826-1:2019, the closure-piercing device shall resist a pull force of 15 N for 15 s.

6.4.4 When tested in accordance with ISO 3826-1:2019, 5.3, the connection between the closure-piercing device and the blood bag port shall show no evidence of leakage.

6.5 Tubing

6.5.1 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-to-normal vision.

6.5.2 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.

6.6 Filter for blood and blood components

The transfusion set shall be provided with a filter for blood and blood components. The filter shall have uniform pores and shall cover a total area of not less than 10 cm^2. When tested in accordance with A.4[1)], the mass of solid material retained on the filter shall be not less than 80 % (mass fraction) of that retained on the reference filter.

If the filter has a confirmed thread diameter of (100 ± 10) µm and a pore size of (200 ± 20) µm, with a single warp and a single weft, a filtration performance test can be exempted.

Pore size measurement can be performed by microscopic inspection.

6.7 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 filter for blood and blood components. 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 at (23 ± 2) °C and at a flow rate of (50 ± 10) drops/min deliver (1 ± 0,1) ml [(1 ± 0,1) g].

The drip chamber should permit and facilitate the procedure of priming.

6.8 Flow regulator

The flow regulator shall adjust the flow of the blood and blood components between zero and maximum.

The flow regulator should be capable of continuous use throughout a transfusion 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.

6.9 Flow rate of blood and blood components

The transfusion set shall deliver not less than 1 000 ml of blood at (23 ± 2) °C in 30 min with a pressure difference of 10 kPa[2)]. The transfusion set shall also deliver not less than 500 ml of blood in 2 min under a gauge pressure of 30 kPa above atmospheric pressure.

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1) In countries where human blood is not available for testing, equivalent test methods may be established.