



SLOVENSKI STANDARD SIST EN ISO 1135-4:2005

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Transfuzijska oprema za uporabo v medicini – 4. del: Transfuzijske garniture za enkratno uporabo (ISO 1135-4:2004)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2004)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte zur einmaligen Verwendung (ISO 1135-4:2004)

Matériel de transfusion a usage médical - Partie 4: Appareils de transfusion non réutilisables (ISO 1135-4:2004)

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ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 1135-4

July 2004

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English version

Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2004)

Matériel de transfusion à usage médical - Partie 4:
Appareils de transfusion non réutilisables (ISO 1135-
4:2004)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4:
Transfusionsgeräte zur einmaligen Verwendung (ISO 1135-
4:2004)

This European Standard was approved by CEN on 22 June 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 1135-4:2004 (E)**Foreword**

This document (EN ISO 1135-4:2004) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2005, and conflicting national standards shall be withdrawn at the latest by January 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 1135-4:2004 has been approved by CEN as EN ISO 1135-4:2004 without any modifications.

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ISO
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Third edition
2004-07-15

**Transfusion equipment for medical use —
Part 4:
Transfusion sets for single use**

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables

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Contents

	Page
1 Scope	1
2 Normative references	1
3 General requirements	1
3.1 Nomenclature for components of the transfusion set	1
3.2 Maintenance of sterility	3
3.3 Designation	3
4 Materials	4
5 Physical requirements	4
5.1 Particulate contamination	4
5.2 Leakage	4
5.3 Tensile strength	4
5.4 Closure-piercing device	4
5.5 Air-inlet device	5
5.6 Tubing	5
5.7 Filter for blood and blood components	5
5.8 Drip chamber and drip tube	5
5.9 Flow regulator	5
5.10 Flow rate of blood and blood components	5
5.11 Injection site	6
5.12 Male conical fitting	6
5.13 Protective caps	6
6 Chemical requirements	6
6.1 Reducing (oxidizable) matter	6
6.2 Metal ions	6
6.3 Titration acidity or alkalinity	6
6.4 Residue on evaporation	6
6.5 UV absorption of extract solution	6
7 Biological requirements	7
7.1 General	7
7.2 Sterility	7
7.3 Pyrogenicity	7
7.4 Haemolysis	7
7.5 Toxicity	7
8 Labelling	7
8.1 Unit container	7
8.2 Shelf or multi-unit container	8
9 Packaging	8
Annex A (normative) Physical tests	9
Annex B (normative) Chemical tests	13

ISO 1135-4:2004(E)

Annex C (normative) Biological tests	15
Bibliography	16

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[SIST EN ISO 1135-4:2005](#)

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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 1135-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 1135-4:1998), which has been technically revised.

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

- *Part 3: Blood-taking set* [SIST EN ISO 1135-4:2005](https://standards.iteh.ai/catalog/standards/sist/420c9969-5201-45d8-1135-775d1682b5b/sist-en-iso-1135-4-2005)
- *Part 4: Transfusion sets for single use* [SIST EN ISO 1135-4:2005](https://standards.iteh.ai/catalog/standards/sist/420c9969-5201-45d8-1135-775d1682b5b/sist-en-iso-1135-4-2005)

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Transfusion equipment for medical use —

Part 4: Transfusion sets for single use

1 Scope

This part of ISO 1135 specifies requirements for single-use transfusion sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

This part of ISO 1135 also specifies requirements for air-inlet devices for use with rigid containers for blood and blood components.

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 and to present designations for transfusion set components.

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

SIST EN ISO 1135-4:2005

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*

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

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

ISO 7864:1993, *Sterile hypodermic needles for single use*

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

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 General requirements

3.1 Nomenclature for components of the transfusion set

The nomenclature for components of transfusion sets is given in Figure 1. An air-inlet device as shown in Figure 2 is required for use with rigid containers for blood and blood components.