SLOVENSKI STANDARD
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SIST EN ISO 1135-4:2005

Transfuzijska oprema za uporabo v medicini - 4. del: Transfuzijske garniture za enkratno uporabo (ISO 1135-4:2010)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2010)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte zur einmaligen Verwendung (ISO 1135-4:2010)

Matériel de transfusion à usage médical - Partie 4: Appareils de transfusion non réutilisables (ISO 1135-4:2010)

Ta slovenski standard je istoveten z: **EN ISO 1135-4:2010**

ICS:

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

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EUROPEAN STANDARD

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English Version

Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2010)

Matériel de transfusion à usage médical - Partie 4: Appareils de transfusion non réutilisables (ISO 1135-4:2010)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte zur einmaligen Verwendung (ISO 1135-4:2010)

This European Standard was approved by CEN on 22 March 2010.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 1135-4:2010) 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 DIN.

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of an identical text or by endorsement, at the latest by October 2010, and conflicting national standards shall be withdrawn at the latest by October 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 1135-4:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 1135-4:2010 has been approved by CEN as a EN ISO 1135-4:2010 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2	7.2, 8.1	
3.3	13.3 b)	
4	1, 2, 3	
5.1	7.2	
5.2	7.6	
5.3	9.1, 12.7.1	
5.4	7.6	
5.5	12.8	
5.6	7.2	
5.7	12.8	
5.8	10, 12.8	
5.9	10, 12.8	
5.10	8	
5.11	9.1	
5.12	8	
6	7	
7.1	7, 7.5	Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards.
7.2	8.4	
7.3	7.1, 7.2	
7.4	7.1, 7.2	
7.5	7.1, 7.2	
8	13	The part of 13.3.a) relating to the authorized representative is not addressed. 13.3.f) and 13.6.h) relating to single use are not fully addressed. 13.6.q) is not addressed.
9	5, 8.3	
10	13.6. n)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 1135-4

Fourth edition
2010-04-15

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

Reference number
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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*, and by Technical Committee CEN/TC 205, *Non-active medical devices* in collaboration.

This fourth edition cancels and replaces the third edition (ISO 1135-4:2004), which has been revised at Clause A.1 (Test for particulate contamination). In addition, all requirements regarding the no-longer-used air inlet device have been deleted. Finally, 5.4 has been revised to improve compatibility between the closure-piercing device and blood bag ports.

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*

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.

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

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 3826-1:2003, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

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

1) To be published. (Revision of ISO 15223-1:2007)