SLOVENSKI STANDARD
SIST EN ISO 1135-4:2005

01-januar-2005

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)

Ta slovenski standard je istoveten z: **EN ISO 1135-4:2004**

ICS:

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

SIST EN ISO 1135-4:2005 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 1135-4

July 2004

ICS 11.040.20

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.

CEN members are the national standards bodies of 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. 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.

INTERNATIONAL STANDARD

ISO 1135-4

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

Reference number
ISO 1135-4:2004(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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*

— *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.

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

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.