Meditsiiniliseks kasutamiseks ettenähtud transfusiooniseadmed. Osa 4: Ühekordsed transfusioonikomplektid (ISO 1135-4:2010)

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 1135-4:2011 sisaldab Euroopa standardi EN ISO 1135-4:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 1135-4:2011 consists of the English text of the European standard EN ISO 1135-4:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.10.2011.	Date of Availability of the European standard text 19.10.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EN ISO 1135-4

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Supersedes EN ISO 1135-4:2010

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 20 September 2011.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 1135-4:2011: E

Foreword

This document (EN ISO 1135-4:2011) 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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 1135-4:2010.

This new edition contains a revised Annex ZA.

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 EN ISO 1135-4:2011 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 European 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 on medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6, 7.1, 7.3, 7.4, 7.5	7.1	Only chemical toxicity is addressed (in Clause 6). 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 standards (in Clause 7.1) Prevention of pyrogenicity covered (in Clause 7.3) Prevention of haemolysis covered (in Clause 7.4) Prevention of toxicity covered (in Clause 7.5)
3.2, 5.1, 5.6, 6, 7.1, 7.3, 7.4, 7.5	7.2	The part of ER 7.2 relating to packaging is not addressed (→ for packaging see Clause 9 of this standard). 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 standards (in Clause 7.1) Prevention of pyrogenicity covered (in Clause 7.3) Prevention of haemolysis covered (in Clause 7.4) Prevention of toxicity covered (in

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		Clause 7.5)
6, 7.1	7.3	Only the first half sentence of ER 7.3 is addressed. 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 standards (in Clause 7.1)
6, 7.1	7.5	Only the first sentence is covered. 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 standards (in Clause 7.1).
3.2, 5.2, 5.4	7.6	
3.2, 5.10, 5.12	8.1	The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. The reduction of the risk of infection is not fully covered.
9	8.3	Only packaging related protection of sterility is covered.
7.2	8.4	Only the sterilisation method is covered.
5.3, 5.11	9.1	The second sentence of ER 9.1 is not addressed.
5.7, 5.8, 5.9	10.1	Information relating to the limits of accuracy is not addressed.
5.3	12.7.1	Only tensile strength is addressed.
5.5, 5.7, 5.8, 5.9	12.8.1	
5.5, 5.7, 5.8, 5.9	12.8.2	Only the first paragraph is addressed.
8	13.1	
8	13.2	

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.3, 8	13.3	The part of 13.3a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3a) is only provided if the name and address of the manufacturer are given. 13.3b) is addressed in Clause 3.3. 13.3d) is only covered if the batch number is preceded by the word 'LOT'. 13.3f) relating to single use is not addressed.
8	13.4	Only addressed regarding the label.

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

Contents

Page

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)