SLOVENSKI STANDARD
SIST EN ISO 1135-4:2012

01-januar-2012

Nadomešča:
SIST EN ISO 1135-4:2010

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 1135-4:2011**

ICS:

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

SIST EN ISO 1135-4:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 1135-4

October 2011

ICS 11.040.20

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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

Contents

Page

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.

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
ISO 1135-4:2010(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