SLOVENSKI STANDARD
SIST EN ISO 8536-4:2013/A1:2013

01-junij-2013

Infuzijska oprema za uporabo v medicini - 4. del: Infuzijski seti za enkratno uporabo, delujoči na osnovi gravitacije - Dopolnilo A1 (ISO 8536-4:2010/Amd 1:2013)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2010/Amd 1:2013)

Infusionsgeräte zur medizinischen Verwendung - Teil 4: Infusionsgeräte für Schwerkraftinfusionen zur einmaligen Verwendung (ISO 8536-4:2010/Amd 1:2013)

Matériel de perfusion à usage médical - Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité (ISO 8536-4:2010/Amd 1:2013)

Ta slovenski standard je istoveten z: **EN ISO 8536-4:2013/A1:2013**

ICS:

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

SIST EN ISO 8536-4:2013/A1:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-4:2013/A1

March 2013

ICS 11.040.20

English Version

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2010/Amd 1:2013)

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This amendment A1 modifies the European Standard EN ISO 8536-4:2013; it was approved by CEN on 9 February 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 8536-4:2013/A1:2013) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing 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 September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 8536-4:2010/Amd 1:2013 has been approved by CEN as EN ISO 8536-4:2013/A1:2013 without any modification.

Annex ZA
(informative)

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

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, 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, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.1, 6.7, 8.3, 8.4, 8.5	7.2	
8.1	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 standards
6.2, 6.4, 6.5	7.6	
6.11, 6.13	8	
3.2	8.1	
10	8.3	
8.2	8.4	
6.3, 6.12	9.1	
6.9, 6.10	10	
6.3	12.7.1	
6.6, 6.8, 6.9, 6.10	12.8	
9	13	The part of ER 13.3 a) relating to the authorized representative is not addressed. ERs 13.3 f) and 13.6 h) relating to single-use are not fully addressed. ER 13.6 q) is not addressed.
4	13.3	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 8536-4

Fifth edition
2010-10-01

AMENDMENT 1
2013-03-01

Infusion equipment for medical use —

Part 4: Infusion sets for single use, gravity feed

AMENDMENT 1

Matériel de perfusion à usage médical —
Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité
AMENDEMENT 1

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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.

Amendment 1 to ISO 8536-4:2010was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.