SLOVENSKI STANDARD
SIST EN ISO 8536-4:2010

01-december-2010

Nadomešča:

SIST EN ISO 8536-4:2007

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

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 8536-4:2010**

ICS:

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

SIST EN ISO 8536-4:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-4

October 2010

ICS 11.040.20

Supersedes EN ISO 8536-4:2007

English Version

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

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This European Standard was approved by CEN on 14 September 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.

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

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Foreword

The text of ISO 8536-4:2010 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8536-4:2010 by 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 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

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 8536-4:2007.

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 8536-4:2010 has been approved by CEN as a EN ISO 8536-4:2010 without any modification.

Annex ZA
(informative)

Relationship between this International 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, 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 International Standard and Directive 93/42/EEC, Medical devices

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2	8.1	
4	13.3	
5	1, 2, 3	
6.1	7.2	
6.2	7.6	
6.3	9.1, 12.7.1	
6.4	7.6	
6.5	7.6	
6.6	12.8	
6.7	7.2	
6.8	12.8	
6.9	10, 12.8	
6.10	10, 12.8	
6.11	8	
6.12	9.1	
6.13	8	
7	7	

8.1	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 ISO 10993 series of standards.
8.2	8.4	
8.3	7.1, 7.2	
8.4	7.1, 7.2	
8.5	7.1, 7.2	
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.
10	5, 8.3	

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

INTERNATIONAL STANDARD

ISO 8536-4

Fifth edition
2010-10-01

Infusion equipment for medical use —

Part 4: Infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —

Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité

Reference number
ISO 8536-4:2010(E)

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Published in Switzerland

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