SLOVENSKI STANDARD
kSIST FprEN ISO 8536-5:2011

01-julij-2011

Infuzijska oprema za uporabo v medicini - 5. del: Infuzijski seti z dozirnikom za primere težje infuzije za enkratno uporabo, delujoči na osnovi gravitacije (ISO 8536 -5:2004)

Infusion equipment for medical use - Part 5: Burette infusion sets for single use, gravity feed (ISO 8536-5:2004)

Infusionsgeräte zur medizinischen Verwendung - Teil 5: Infusionsgeräte mit Dosierbehälter für Schwerkraftinfusionen zur einmaligen Verwendung (ISO 8536-5:2004)

Matériel de perfusion à usage médical - Partie 5: Appareils non réutilisables de perfusion à burette, à alimentation par gravité (ISO 8536-5:2004)

Ta slovenski standard je istoveten z: **FprEN ISO 8536-5**

ICS:

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
FprEN ISO 8536-5

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ICS 11.040.20

English Version

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This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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 8536-5:2004 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as FprEN ISO 8536-5:2011 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

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(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 8536-5:2004 has been approved by CEN as a FprEN ISO 8536-5:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC 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)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2	7.2, 8.1	
3.3	7.6	
4	13.3	
5	1, 2, 3	
6.1	9.1, 12.7.1	
6.2.1	12.8	
6.2.2	7.6	
6.2.3	7.6	
6.3	10	
6.4	10	
7	7	
8	7.1, 7.2, 7.5, 8.4	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. However, the part of ER 7.5 relating to phthalates is not specifically addressed in the EN ISO 10993 series.
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 EC Directives may be applicable to the product(s) falling within the scope of this standard.