SLOVENSKI STANDARD
SIST EN ISO 8536-9:2015

01-september-2015

Nadomešča:
SIST EN ISO 8536-9:2005

Infuzijska oprema za uporabo v medicini - 9. del: »Fluidne« cevke za enkratno uporabo z infuzijsko opremo, delujočo na osnovi tlaka (ISO 8536-9:2015)

Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 9: Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-9:2015)

Matériel de perfusion à usage médical - Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression (ISO 8536-9:2015)

Ta slovenski standard je istoveten z: **EN ISO 8536-9:2015**

ICS:

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

SIST EN ISO 8536-9:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-9

June 2015

ICS 11.040.20

Supersedes EN ISO 8536-9:2004

English Version

Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015)

Matériel de perfusion à usage médical - Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression (ISO 8536-9:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 9: Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-9:2015)

This European Standard was approved by CEN on 16 April 2015.

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, 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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 8536-9:2015) 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 December 2015, and conflicting national standards shall be withdrawn at the latest by December 2015.

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 8536-9:2004.

In this edition, the following changes have been made:

— the former Clause 3 on designation has been deleted;

— 5.8 has been amended and an appropriate Annex C added;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol “XXX” according ISO 7000, Symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— the former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;

— normative references and the Bibliography have been updated;

— document has been editorially revised..

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, 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 8536-9:2015 has been approved by CEN as EN ISO 8536-9:2015 without any modification.

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 594-2	—	ISO 594-2:1998
ISO 7000	—	ISO 7000:2014
ISO 7864	EN ISO 7864:1995	ISO 7864:1993
ISO 8536-10	EN ISO 8536-10:2015	ISO 8536-10:2015
ISO 8536-11	EN ISO 8536-11:2015	ISO 8536-11:2015
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

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 Communities 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
Clause 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, Clause 6	7.2	The part of ER 7.2 relating to packaging is not addressed. For packaging see Clause 7 of this standard.
4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, Clause 6	7.3	ER covered by biological evaluation.
4.3, 4.4, A.3, A.4	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 ISO 10993-series of standards.
4.2, 4.3	7.6	
4.2, 4.3, 4.4	8.1	The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. Only sterility of product is covered.
	8.3	
6.1	8.4	Only the sterilization method is covered.
4.2	8.5	
8.2, 8.3	8.7	
4.5, 4.8, 8.2 g)	9.1	The second sentence of ER 9.1 is not addressed.

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9	9.2	
4.8	10.1 to 10.3	
4.3, A.3	12.7.1	Only tensile strength is addressed.
8	13.1	
8.2 d), e), f), g), 8.3 c)	13.2	
8.2, 8.3	13.3	The part of 13.3 a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3 a) is only provided if the name and address of the manufacturer are given. 13.3 d) is only covered if the batch number is preceded by the word 'LOT'. 13.3 f) Requirement „indication of single use must be consistent across the Community“ is not addressed in the standard. 13.3 g), h) is not addressed in the standard.
8.2, 8.3	13.4	13.4 is addressed regarding to the label.
8.2, 8.3	13.5	13.5 is not addressed regarding to the detachable components.
8.2, 8.3	13.6	13.6 e), f), h), i), j), l), m), o) are not applicable for devices according to this standard 13.6 q) is not addressed.

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

INTERNATIONAL STANDARD

ISO 8536-9

Second edition
2015-06-15

Infusion equipment for medical use —

Part 9: Fluid lines for single use with pressure infusion equipment

Matériel de perfusion à usage médical —

Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression

Reference number
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