



SLOVENSKI STANDARD SIST EN ISO 8536-8:2015

01-september-2015

Nadomešča:
SIST EN ISO 8536-8:2005

Infuzijska oprema za uporabo v medicini - 8. del: Infuzijski seti za enkratno uporabo s tlačno črpalko (ISO 8536-8:2015)

Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 8: Infusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-8:2015)

Matériel de perfusion à usage médical - Partie 8: Appareils de perfusion non réutilisables avec des appareils de perfusion sous pression (ISO 8536-8:2015)

Ta slovenski standard je istoveten z: EN ISO 8536-8:2015

ICS:

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

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EUROPEAN STANDARD

EN ISO 8536-8

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2015

ICS 11.040.20

Supersedes EN ISO 8536-8:2004

English Version

Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8:2015)

Matériel de perfusion à usage médical - Partie 8: Appareils de perfusion non réutilisables avec des appareils de perfusion sous pression (ISO 8536-8:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 8: Infusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-8:2015)

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.

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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 8536-8:2015) 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 8536-8:2004.

In this edition the following changes have been made:

- the part title has been changed from 'Infusion equipment ...' to 'Infusion sets ...';
- the former Clause 4 on designation has been deleted;
- 6.14 has been amended and an appropriate Annex B 'Storage volume' added;
- Clause 10 on labelling was amended by a note regarding the usage of the symbol “XXX” according ISO 7000-2725;
- Clause 11 on disposal has been added;
- A.3 'Tests for leakage' has been amended;
- the former A.4 specifying a test of male conical fitting for leakage 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.

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.

EN ISO 8536-8:2015 (E)

Endorsement notice

The text of ISO 8536-8:2015 has been approved by CEN as EN ISO 8536-8:2015 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 8536-4	EN ISO 8536-4:2013 and EN ISO 8536-4:2013/A1:2013	ISO 8536-4:2010 and Amd.1:2013
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

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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
3.2, Clause 4	7.2	The part of ER 7.2 relating to packaging is not addressed. For packaging see Clause 8 of this standard
Clause 4	7.3	ER covered by biological evaluation
5.3, 5.5, A.3	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
5.2	7.6	Section 5.1 of this EN refers to ISO 8536-4, sections 6.1
3.2, Clause 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	
	8.4	
	8.5	
9.2, 9.3	8.7	
Clause 4, 9.2 i)	9.1	The second sentence of ER 9.1 is not addressed
3.2	9.2	

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Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.2, A.2	12.7.1	Only tensile strength is addressed
Clause 9	13.1	
9.2 d), e), f), g), 9.3 c) and d)	13.2	
9.2, 9.3	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
9.2, 9.3	13.4	13.4 is addressed regarding to the label
9.2, 9.3	13.5	13.5 is not addressed regarding to the detachable components
9.2, 9.3	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
8536-8

Second edition
2015-06-15

**Infusion equipment for medical use —
Part 8:
Infusion sets for single use with
pressure infusion apparatus**

Matériel de perfusion à usage médical —

*Partie 8: Appareils de perfusion non réutilisables avec des appareils
de perfusion sous pression*
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