Meditsiinilised infusiooniseadmed. Osa 5: Ühekordse kasutusega isevooluga bürett-infusioonikomplekt (ISO 8536-5:2004)

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8536-5:2013 sisaldab Euroopa standardi EN ISO 8536-5:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8536-5:2013 consists of the English text of the European standard EN ISO 8536-5:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.02.2013.	Date of Availability of the European standard is 06.02.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-5

February 2013

ICS 11.040.20

Supersedes EN ISO 8536-5:2011

English Version

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

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

This European Standard was approved by CEN on 8 January 2013.

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

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Ref. No. EN ISO 8536-5:2013: E

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 EN ISO 8536-5:2013 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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 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 supersedes EN ISO 8536-5:2011.

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 8536-5:2004 has been approved by CEN as EN ISO 8536-5:2013 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU 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)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2, 8	7.2	
8	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 of standards. However, the part of ER 7.5 relating to phthalates is not specifically addressed in the EN ISO 10993 series.
3.3, 6.2.2, 6.2.3	7.6	
3.2	8.1	
10	8.3	
8	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 EN 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.
6.1	9.1	
6.3, 6.4	10	
6.1	12.7.1	
6.2.1	12.8	

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
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 product(s) falling within the scope of this standard.

Infusion equipment for medical use —

Part 5:
Burette infusion sets for single use, gravity feed

1 Scope

This part of ISO 8536 specifies requirements for types of single-use, gravity feed burette infusion sets of 50 ml, 100 ml and 150 ml nominal capacity for medical use in order to ensure compatibility of use with containers for infusion solutions and intravenous equipment.

This part of ISO 8536 also provides guidance on specifications relating to the quality and performance of materials used in infusion sets.

NOTE In some countries, national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

3 General requirements

3.1 The nomenclature to be used for components of burette infusion sets is given in Figure 1.

Figure 1 illustrate examples of the configuration of burette infusion sets; other configurations may be used provided they lead to the same results.

3.2 The burette infusion set shall be provided with protective caps to maintain sterility of the internal parts of the set until the set is used.

3.3 If a separate air-inlet device is used, it shall comply with ISO 8536-4.