MEDITSIINILISED INFUSIOONISEADMED. OSA 13: MÕÕTESKAALAGA ÜHEKORDSE KASUTUSEGA VEDELIK-KOKKUPUUTEGA VOOLUREGULAATORID

Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8536-13:2016 sisaldab Euroopa standardi EN ISO 8536-13:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8536-13:2016 consists of the English text of the European standard EN ISO 8536-13:2016.
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 19.10.2016.	Date of Availability of the European standard is 19.10.2016.
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 8536-13

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English Version

Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2016)

Matériel de perfusion à usage médical - Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide (ISO 8536-13:2016)

Infusionsgeräte zur medizinischen Verwendung - Teil 13: Graduierte Durchflussregler zur einmaligen Verwendung mit Flüssigkeitskontakt (ISO 8536-13:2016)

This European Standard was approved by CEN on 17 September 2016.

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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 8536-13:2016 E

European foreword

This document (EN ISO 8536-13:2016) 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 April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

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 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.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated ISO or IEC standard, as listed in Table 1.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 8536-4	EN ISO 8536-4:2013 + A1:2013	ISO 8536-4:2010 + Amd.1:2013
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 80000-4	EN ISO 80000-4:2013	ISO 80000-4:2006

Endorsement notice

The text of ISO 8536-13:2016 has been approved by CEN as EN ISO 8536-13:2016 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/295 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/notes
7.2	5, 6, 7, 8	Clause 7 and Clause 8 refer to ISO 8536-4. The part of ER 7.2 relating to packaging is not addressed.
7.3	5, 6, 7, 8	Sections 7 and 8 refer to ISO 8536-4. ER covered by biological evaluation.

7.5	6.3, 6.4, A.2, A.3	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 standards.
7.6	6.2, 6.3, 6.4, A.1, A.2, A.3	
8.1	6.2, 6.3, 6.4, 7, 8, A.1, A.2, A.3	Sections 7 and 8 refer to ISO 8536-4. The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. The reduction of the risk of infection is not fully covered.
8.5	6.2, A.1	ER 8.5 is covered by 6.2 only for particulate contamination.
9.1	4	The second sentence of ER 9.1 is not addressed.
12.7	6.3, A.2	Only 12.7.1 is addressed. Only tensile strength is addressed.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Contents

Page