MEDITSIINILISED TRANSFUSIOONISEADMED. OSA 5: RÕHKINFUSIOONISEADME ÜHEKORDSE KASUTUSEGA TRANSFUSIOONIKOMPLEKTID

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 1135-5:2015 sisaldab Euroopa standardi EN ISO 1135-5:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 1135-5:2015 consists of the English text of the European standard EN ISO 1135-5:2015.
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 23.12.2015.	Date of Availability of the European standard is 23.12.2015.
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

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EN ISO 1135-5

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English Version

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2015)

Matériel de transfusion à usage médical - Partie 5: Appareils de transfusion non réutilisables avec les appareils de perfusion sous pression (ISO 1135-5:2015)

Transfusionsgeräte zur medizinischen Verwendung - Teil 5: Transfusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 1135-5:2015)

This European Standard was approved by CEN on 24 July 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

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Ref. No. EN ISO 1135-5:2015 E

European foreword

This document (EN ISO 1135-5:2015) 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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.

Together with EN ISO 1135-4:2015 this document supersedes EN ISO 1135-4:2012.

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.

Endorsement notice

The text of ISO 1135-5:2015 has been approved by CEN as EN ISO 1135-5:2015 without any modification.

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 references 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 594-1	---	ISO 594-1:1986
ISO 594-2	---	ISO 594-2:1998
ISO 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 3826-1:2013	EN ISO 3826-1:2013	ISO 3826-1:2013
ISO 3826-2	EN ISO 3826-2:2008	ISO 3826-2:2008
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus ISO 10993-4 AMD 1:2006
ISO 14644-1	EN ISO 14644-1:1999	ISO 14644-1:1999
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 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, 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.

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 / Directive 90/385/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 Table of References, 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 Directive 93/42/EEC, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2, 6.1, 6.2, 6.3, Clause 7, Clause 8	7.2	The part of ER 7.2 relating to packaging is not addressed (→ for packaging see Clause 10 of this standard).
Clause 5, 6.1, 6.2, 6.3, Clause 7, Clause 8	7.3	ER covered by biological evaluation
6.2, 6.3, 6.10, 9.2, 9.3, A.2, A.4	7.5	Only the first paragraph is covered.
6.1, 6.3	7.6	
4.2, Clause 6	8.1	
6.12, Clause 9, Clause 10	8.3	Maintenance of sterility in storage is covered.
8.2	8.4	Sterilization process is covered.
6.1, A.1	8.5	
9.2, 9.3	8.7	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.4	9.1	The second sentence of ER 9.1 is not addressed. 6.4 refers to ISO 3826-1.
Clauses 4, 5, 6, 7, 8	9.2	
6.2, 6.3, A.2	12.7	Only 12.7.1 is addressed. Only tensile strength is addressed.
Clause 9	13.1	
9.2, 9.3	13.2	ISO 15223-1 and ISO 3826-2 are addressed when using symbols.
9.2 a), b), c), d), e), f), g), i), j), k), 9.3 a), b), c), d), e), f), g)	13.3	The part of 13.3a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3a) is only provided if the name and address of the manufacturer are given. 13.3b) is addressed in Clause 3.1 and 4.3. 13.3d) is only covered if the batch number is preceded by the word 'LOT'. 13.3f) Requirement „indication of single use must be consistent across the Community“ is not addressed in the standard. 13.3g) and h) are not addressed in the standard.
9.2, 9.3	13.4	13.4 is addressed regarding to the label.

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

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