



SLOVENSKI STANDARD SIST EN ISO 1135-3:2017

01-maj-2017

Transfuzijska oprema za uporabo v medicini - 3. del: Seti za odvzem krvi za enkratno uporabo (ISO 1135-3:2016)

Transfusion equipment for medical use - Part 3: Blood-taking sets for single use (ISO 1135-3:2016)

Transfusionsgeräte zur medizinischen Verwendung - Teil 3: Blutentnahmegерäte zur einmaligen Verwendung (ISO 1135-3:2016)

Matériel de transfusion à usage médical - Partie 3: Appareils non réutilisables pour prélèvement de sang (ISO 1135-3:2016)

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Ta slovenski standard je istoveten z: EN ISO 1135-3:2017

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 1135-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2017

ICS 11.040.20

English Version

Transfusion equipment for medical use - Part 3: Blood-taking sets for single use (ISO 1135-3:2016)

Matériel de transfusion à usage médical - Partie 3:
Appareils non réutilisables pour prélèvement sanguin
(ISO 1135-3:2016)

Transfusionsgeräte zur medizinischen Verwendung -
Teil 3: Blutentnahmegерäte zur einmaligen
Verwendung (ISO 1135-3:2016)

This European Standard was approved by CEN on 24 August 2016.

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, Serbia, 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 1135-3:2017) 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 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, Serbia, 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 version of the ISO or IEC standard, as listed below.

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 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 7864	EN ISO 7864:2016	ISO 7864:2016

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ISO 11607-1	EN ISO 11607-1:2009 + A1:2014	ISO 11607-1:2006 plus ISO 11607-1 Amd 1:2014
ISO 14644-1:2015	EN ISO 14644-1:2015	ISO 14644-1:2015
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

Endorsement notice

The text of ISO 1135-3:2016 has been approved by CEN as EN ISO 1135-3:2017 without any modification.

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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 a 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 Table 1 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	3.3, 5.1, 5.2, 5.3, Clause 6, Clause 7, A.1, A.2	The part of ER 7.2 relating to packaging is not addressed (for packaging see Clause 9 of this standard).
7.3 (first part only)	Clause 4, 5.1, 5.2, 5.3, Clause 6, Clause 7, A.1, A.2	
7.5	5.2, 5.3, Clause 7, A.2	Only the first paragraph 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.

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7.6	5.1, 5.2, 5.3, A.1, A.2	
8.1	3.4, 3.5, Clause 5	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.
8.3	3.3, 3.4, 5.9, Clause 9	
8.4	7.2	Only the sterilization method is covered.
8.5	5.1, A.1	
8.7	8.2, 8.3	
9.1	5.4, 5.5	The second sentence of ER 9.1 is not addressed. Coverage of this ER is partly provided by normative reference to EN ISO 7864.
9.2 (first indent)	Clause 5, 7.1 https://standards.iteh.ai/catalog/standards/sist/ccfeb925-4d11-4885-b360-1c1fc61b07b2/sist-en-iso-1135-3-2017	Covered in respect of the following: - Particulate contamination; - Leakage; - Tensile strength; - Dimensions; - Physical characteristics of tube and needle.
9.2 (second indent)	5.2	Covered in respect of the following: - Variations in pressure.
9.2 (fourth indent)	Clause 4	Covered in respect of the following: - Undesirable effects on blood or fluid used.
12.7.1	5.3	Only tensile strength is addressed.
13.1	Clause 8	Only requirements for labelling are covered.
13.2	8.1, 8.2, 8.3	The final sentence is not addressed.
13.3 b)	8.2 b), 8.3 b)	
13.3 c)	8.2 c), 8.3 c)	

13.3 d)	8.2 d), 8.3 d)	Only covered if the batch number is preceded by the word "LOT".
13.3 e)	8.2 e), 8.3 e)	
13.3 f)	8.2, 8.3	Requirement "indication of single use must be consistent across the Community" is not addressed in the standard.
13.4	8.2, 8.3	13.4 is addressed regarding to the label.

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 product(s) falling within the scope of this standard.

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INTERNATIONAL
STANDARD

ISO
1135-3

Second edition
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**Transfusion equipment for medical
use —**

**Part 3:
Blood-taking sets for single use**

Matériel de transfusion à usage médical —

Partie 3: Appareils non réutilisables pour prélèvement sanguin
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