



SLOVENSKI STANDARD SIST EN ISO 1135-5:2016

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Nadomešča:

SIST EN ISO 1135-4:2012

Transfuzijska oprema za uporabo v medicini - 5. del: Transfuzijske garniture za enkratno uporabo s tlačno črpalko (ISO 1135-5:2015)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 1135-5:2015

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
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 1135-5

December 2015

ICS 11.040.20

Supersedes EN ISO 1135-4:2012

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.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

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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.

EN ISO 1135-5:2015 (E)

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 |

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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 | |

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| 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.

INTERNATIONAL
STANDARD

ISO
1135-5

First edition
2015-12-01

**Transfusion equipment for medical
use —**

**Part 5:
Transfusion sets for single use with
pressure infusion apparatus**

iTeh STANDARD PREVIEW —
Matériel de transfusion à usage médical —

(standards.iteh.ai)
*Partie 5: Appareils de transfusion non réutilisables avec les appareils
de perfusion sous pression*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](http://www.iso.org/standards/foreword-supplementary-information)

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This first edition of ISO 1135-5, together with ISO 1135-4, cancels and replaces ISO 1135-4:2012, which has been technically revised with the following changes:

- the scope of ISO 1135-4 has been restricted to gravity feed applications, whereby, ISO 1135-5 is focused on pressure infusion applications;
- a new Annex D on 'Storage volume' has been added.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

- *Part 3: Blood-taking sets for single use*
- *Part 4: Transfusion sets for single use, gravity feed*
- *Part 5: Transfusion sets for single use with pressure infusion apparatus*