ICS 11.040.20 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2026

STN	**Transfúzne prístroje používané v zdravotníctve Časť 5: Transfúzne súpravy na jednorazové použitie s tlakovými infúznymi prístrojmi (ISO 1135-5: 2025)**	**STN EN ISO 1135-5** 85 6209

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/26

Obsahuje: EN ISO 1135-5:2025, ISO 1135-5:2025

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 1135-5

December 2025

ICS 11.040.20

Supersedes EN ISO 1135-5:2015

English Version

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2025)

Matériel de transfusion à usage médical - Partie 5: Transfuseurs non réutilisables avec des appareils de perfusion sous pression (ISO 1135-5:2025)

Transfusionsgeräte zur medizinischen Verwendung - Teil 5: Transfusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 1135-5:2025)

This European Standard was approved by CEN on 18 May 2025.

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Ref. No. EN ISO 1135-5:2025 E

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European foreword

This document (EN ISO 1135-5:2025) 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of an identical text or by endorsement, at the latest by June 2026, and conflicting national standards shall be withdrawn at the latest by June 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 1135-5:2015.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 1135-5:2025 has been approved by CEN as EN ISO 1135-5:2025 without any modification.

Annex ZA
(informative)

Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in the Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
01	4, 5, 6, 7, 8	Requirement is partially covered by giving the state of the art of safe and effective performance and design. Normal conditions of use are determined by providing pressure and tensile strength requirements that reflect the related physical impact to the devices and by description of the interfaces to products to be used with or common performance parameters like the flow rate, drip formation and flow regulation. Safety requirements are covered with respect to biological and chemical safety as well as for particulate contamination. These requirements also address the manufacturing of those devices. Full assessment of risks associated with particulate contamination is not covered by the standard.
04(a)	4, 5, 6, 7, 8	Requirement is partially covered by giving the state of the art of safe design as elaborated for GSPR 01. Designs or features that go beyond the generic design described in clause 4 might require additional control measures. The same applies to the used manufacturing methods.

04(b)	4.2, 6.13	Requirement is partially covered for generic designs in relation to risks that cannot be eliminated by the provision of protective caps to prevent contamination from surrounding environment, to avoid stick injuries and packaging damages (sub-clauses 4.2 and 6.13) as well as by addressing a test method for the determination of the level of particulate contamination. Full assessment of risks associated with particulate contamination is not covered by the standard.
04(c)	9.2 g), 9.3 e)	Requirement of providing, where appropriate, training to users is not covered.
05(a)	6.5, 6.7, 6.12, 6.13	Requirement is partially covered by defining parameters that users rely on when using the devices, such as filter performance, connector compatibility and prevention of misconnection and protection from contamination by requiring protective caps. Additional specific design and/or ergonomic features might have to be validated by the manufacturer with appropriate measures that are not addressed by the standard.
06	5, 6.2, 6.3, 6.4, 6.5.2, 6.5.3, 6.5.4, 6.6, 6.7, 6.8, 6.9, 6.10, 6.11, 6.12, 6.13, 6.14, 7, 8	Requirement is partially covered by providing the related performance criteria for the devices and addressing the disposal of the device. However, the standard does not directly require or address methods of verifying the entire product lifetime (eg. Shelf Life Studies).
10.1(b)	5, 7, 8	Requirement is fully covered by providing biocompatibility and chemical requirements.

10.1(d)	5, 6.2, 7, 8, 10.2	Requirement is partially covered by performing biological and chemical testing on finished medical devices that cover the influence of manufacturing processes. Further the influence of packaging processes is addressed by 10.2. The formation of particles during the manufacturing processes is addressed by clause 6.2. Full assessment of risks associated with particulate contamination is not covered by the standard.
10.1(f)	6.3, 6.4, 6.5.2, 6.5.3, 6.5.4, 6.6.3, 6.9, 6.11, 6.12, 6.13	Requirement is fully covered by testing for tensile strength and resistance against leakage, properties of closure piercing devices, interactions between tubing material and flow regulators, resealing of injection sites and material properties specified for conical fittings.
10.1(h)	5, 6, 7	Requirement is fully covered by providing requirements on used materials in clause 5, physical requirements in clause 6 and chemical requirements in clause 7.
10.2	4.2, 6.2, 6.3, 6.4, 6.5.4, 6.7, 6.11, 6.12, 6.13, 7, 8, 11	Requirement is partially covered with respect to chemical and biological requirements, and testing for leakage, properties of closure-piercing devices, filter and residues in form of particulate contamination. Full assessment of risks associated with particulate contamination is not covered by the standard. Requirements related to minimising the risk to persons involved in transport of the devices are not covered. The document does not specify a specific assessment method for bacterial endotoxins and their related pyrogenicity.

10.5	4.2, 6.3, 6.5.2, 6.5.4, 6.12, 6.13	Requirement is partially covered with respect to the contamination prevention by requiring caps on the closure piercing device and resealing properties of injection sites.
10.6	4.2, 6.2, 6.5.2, 6.7, 6.13	Requirement related to special attention regarding nanomaterials is not covered. Requirement is partially covered by addressing a test method for the determination of the level of particulate contamination. Full assessment of risks associated with particulate contamination is not covered by the standard.
11.1(a)	6.13	Requirement is covered as applicable for a generic design by requiring protective caps according to clause 6.13.
11.1 (c)	6.3, 6.5.4, 6.11	Requirement is covered with respect to leakage requirements, physical integrity and (re-) sealing to prevent exposure of blood and the included microbes by leaking from the device.
11.1 (d)	4.2, 6.2, 6.3, 6.5.4, 6.11, 6.13, 10.1	Requirement is covered with respect to contamination prevention by the presence of protective caps, resealing of injections sites and sterile packaging requirements.
14.1	6.5, 6.11, 6.12	Requirements for the following device combinations are covered: — closure-piercing device and closure of a container for blood and blood components (sub-clause 6.5) — self-sealing injection site and hypodermic needle / needle-free injection ports or Luer-activated devices and male Luer cone (sub-clause 6.11) — male and female conical fitting (sub-clause 6.12)
14.2 (a)	4.2, 6.5.2, 6.6.3, 6.13	Requirement partially covered by requiring needle stick prevention with protective caps.

14.2 (e)	4.2, 6.3, 6.4, 6.5.3, 6.5.4, 6.11, 6.12, 6.13	Requirement related to reduce the risks of accidental ingress of substances into the devices is covered by: — protective caps (sub-clauses 4.2, 6.13) — prevention of leakage (sub-clauses 6.3, 6.5.4, 6.11) — tensile strength of connections (sub-clauses 6.4, 6.5.3) — standardized connection of male conical fitting (sub-clause 6.12)
14.5	6.5.3, 6.5.4, 6.11, 6.12	Requirement related to interoperability and compatibility with other devices or products are covered as follows: — compatibility of closure-piercing device and blood bag port (sub-clauses 6.5.3, 6.5.4) — compatibility of self-sealing injection site and hypodermic needle as well as needle-free injection ports or Luer-activated devices and male Luer cone (sub-clause 6.11) — compatibility of male and female conical fittings (sub-clause 6.12)
23.1 (b)	9	Requirement is fully covered by specifying labelling requirements for packaging, as labelling on the device itself does not seem reasonable for these devices.
23.2 (b)	9.2 b), c), f), g), h), j), k), l), 9.3 b), e), f)	Requirement covered by specifying the determining design parameters of the devices, such as the sterility, non-pyrogenicity, number of drops per 1 ml and the indication of the gravity application.

Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 1135-4	ISO 1135-4:2025	Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed	EN ISO 1135-4:2025
ISO 3696	ISO 3696:1987	Water for analytical laboratory use — Specification and test methods	EN ISO 3696:1995
ISO 3826-1:2019	ISO 3826-1:2019 ISO 3826-1:2019/Amd 1:2023	Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers	EN ISO 3826-1:2019 EN ISO 3826-1:2019/A1:2023
ISO 10993-1	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 10993-4:2017	ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
ISO 10993-12	ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
ISO 11607-1	ISO 11607-1:2019 ISO 11607-12019/Amd 1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020 EN ISO 11607-1:2020/A11:2022 EN ISO 11607-1:2020/A1:2023
ISO 14644-1	ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
ISO 15223-1	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1:	EN ISO 15223-1:2021

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
		General requirements	
ISO 80369-7	ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	EN ISO 80369-7:2021
ISO 80369-20	ISO 80369-20:2024	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	EN ISO 80369-20:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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.

International Standard

ISO 1135-5

Second edition
2025-05

Transfusion equipment for medical use —

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

Matériel de transfusion à usage médical —

Partie 5: Transfuseurs non réutilisables avec des appareils de perfusion sous pression

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second cancels and replaces the first edition (ISO 1135-5:2015), which has been technically revised.

The main changes are as follows:

— the definitions of the different ‘volume’ terms have been amended;

— 6.11 “Injection site” has been amended regarding the use of needle-free injection ports and Luer-activated devices;

— 6.13 “Protective caps” has been amended to clarify how to prevent contamination;

— 6.14 has been completely revised and renamed to clarify the described volume;

— Clause 8 has been revised to meet state-of-the-art methodology:

  — biological risk assessment shall follow ISO 10993-1;

  — sterility subclause remains;

  — subclause on hemocompatibility assessment has been revised;

— Clause 9 “Labelling” has been updated especially regarding the referenced ISO 15223-1;

— Clause 10 “Packaging” has been amended by adding a reference to ISO 11607-1;

— Annex A “Physical test” has been amended by a general introduction on the pre-conditioning. In addition, the description of the test for leakage has been extended;

— Annex C “Biological tests” has been deleted;

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— the former Annex D (now Annex C) has been revised; it has been renamed from "Storage volume" to "Determination of tube volumes", and the subclause D.3 "Labelling" has been deleted;

— the Normative references have been updated.

A list of all parts in the ISO 1135 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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International Standard **ISO 1135-5:2025(en)**

Transfusion equipment for medical use —

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

1 Scope

This document specifies requirements for single use transfusion sets for use with pressure infusion equipment capable of generating pressures. It ensures compatibility with containers for blood and blood components as well as intravenous equipment.

This document also provides guidance on specifications relating to the quality and performance of materials used in transfusion sets, to present designations for transfusion set components, and to ensure the compatibility of sets with red cell and plasma blood components.

NOTE In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1:2019[1)], *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4:2017, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

1) As impacted by ISO 3826-1:2019/Amd 1:2023

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ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN