



**International  
Standard**

**ISO 1135-4**

**Transfusion equipment for  
medical use —**

**Part 4:  
Transfusion sets for single use,  
gravity feed**

*Matériel de transfusion à usage médical —*

*Partie 4: Transfuseurs non réutilisables, à alimentation par gravité*

**Seventh edition  
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# Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 General requirements</b> .....	<b>2</b>
<b>5 Materials</b> .....	<b>3</b>
<b>6 Physical requirements</b> .....	<b>3</b>
6.1 General.....	3
6.2 Particulate contamination.....	3
6.3 Leakage.....	3
6.4 Tensile strength.....	3
6.5 Closure-piercing device.....	3
6.6 Tubing.....	4
6.7 Filter for blood and blood components.....	4
6.8 Drip chamber and drip tube.....	4
6.9 Flow regulator.....	4
6.10 Flow rate of blood and blood components.....	4
6.11 Injection site.....	5
6.12 Male conical fitting.....	5
6.13 Protective caps.....	5
<b>7 Chemical requirements</b> .....	<b>5</b>
7.1 Reducing (oxidizable) matter.....	5
7.2 Metal ions.....	5
7.3 Titration acidity or alkalinity.....	5
7.4 Residue on evaporation.....	5
7.5 UV absorption of extract solution.....	6
<b>8 Biological requirements</b> .....	<b>6</b>
8.1 General.....	6
8.2 Sterility.....	6
8.3 Additional device specific requirements.....	6
<b>9 Labelling</b> .....	<b>6</b>
9.1 General.....	6
9.2 Unit container.....	7
9.3 Shelf or multi-unit container.....	7
<b>10 Packaging</b> .....	<b>8</b>
<b>11 Disposal</b> .....	<b>8</b>
<b>Annex A (normative) Physical tests</b> .....	<b>9</b>
<b>Annex B (normative) Chemical tests</b> .....	<b>13</b>
<b>Bibliography</b> .....	<b>15</b>

## 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](http://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](http://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](http://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 seventh edition cancels and replaces the sixth edition (ISO 1135-4:2015), which has been technically revised.

The main changes are as follows:

- [6.11](#) “Injection site” has been amended regarding to the use of needle-free injection ports and Luer-activated devices;
- [6.13](#) “Protective caps” has been amended to clarify how to prevent contamination;
- [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 to 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;
- the Normative references have been updated.

## ISO 1135-4:2025(en)

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](http://www.iso.org/members.html).

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# Transfusion equipment for medical use —

## Part 4: Transfusion sets for single use, gravity feed

### 1 Scope

This document specifies requirements for single use transfusion gravity sets for medical use to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

It also provides guidance on specifications relating to the quality and performance of materials used in transfusion sets, presents designations for transfusion set components, and ensures the compatibility of sets with a range of cellular 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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1:2019<sup>1)</sup>, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

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*

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

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