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2025-05

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

Reference number
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Foreword

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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.

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

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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[1)], *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

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