



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
2025-05**



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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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