



**ISO 1135-5**

**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*

**Second edition  
2025-05**



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This second edition 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 Normative references have been updated.

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