



International Standard

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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Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	3
5 Materials	4
6 Physical requirements	4
6.1 General	4
6.2 Particulate contamination	5
6.3 Leakage	5
6.4 Tensile strength	5
6.5 Closure-piercing device	5
6.6 Tubing	5
6.7 Filter for blood and blood components	6
6.8 Drip chamber and drip tube	6
6.9 Flow regulator	6
6.10 Flow rate of blood and blood components	6
6.11 Injection site	6
6.12 Male conical fitting	7
6.13 Protective caps	7
6.14 Post-occlusion bolus volume	7
7 Chemical requirements	7
7.1 General	7
7.2 Reducing (oxidizable) matter	7
7.3 Metal ions	7
7.4 Titration acidity or alkalinity	7
7.5 Residue on evaporation	7
7.6 UV absorption of extract solution	7
8 Biological requirements	8
8.1 General	8
8.2 Sterility	8
8.3 Additional device specific requirements	8
9 Labelling	8
9.1 General	8
9.2 Unit container	8
9.3 Shelf or multi-unit container	9
10 Packaging	9
11 Disposal	10
Annex A (normative) Physical tests	11
Annex B (normative) Chemical tests	15
Annex C (normative) Determination of tube volumes	17
Bibliography	20

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 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;