

ISO 1135-5:2025-05 (E)

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus

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