

DIN EN ISO 1135-4:2026-06 (E)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO 1135-4:2025)

Contents		Page
Foreword.....		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements	2
5	Materials	3
6	Physical requirements	3
6.1	General.....	3
6.2	Particulate contamination.....	3
6.3	Leakage.....	3
6.4	Tensile strength.....	3
6.5	Closure-piercing device.....	3
6.6	Tubing.....	4
6.7	Filter for blood and blood components.....	4
6.8	Drip chamber and drip tube.....	4
6.9	Flow regulator.....	4
6.10	Flow rate of blood and blood components.....	4
6.11	Injection site.....	5
6.12	Male conical fitting.....	5
6.13	Protective caps.....	5
7	Chemical requirements	5
7.1	Reducing (oxidizable) matter.....	5
7.2	Metal ions.....	5
7.3	Titration acidity or alkalinity.....	5
7.4	Residue on evaporation.....	5
7.5	UV absorption of extract solution.....	6
8	Biological requirements	6
8.1	General.....	6
8.2	Sterility.....	6
8.3	Additional device specific requirements.....	6
9	Labelling	6
9.1	General.....	6
9.2	Unit container.....	7
9.3	Shelf or multi-unit container.....	7
10	Packaging	8
11	Disposal	8
Annex A (normative) Physical tests		9
Annex B (normative) Chemical tests		13
Bibliography		15