

ISO 1135-4:2015-12 (E)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	General requirements	2
3.1	Nomenclature for components of the transfusion set	2
3.2	Maintenance of sterility	2
4	Materials	3
5	Physical requirements	3
5.1	Particulate contamination	3
5.2	Leakage	3
5.3	Tensile strength	3
5.4	Closure-piercing device	3
5.5	Tubing	4
5.6	Filter for blood and blood components	4
5.7	Drip chamber and drip tube	4
5.8	Flow regulator	4
5.9	Flow rate of blood and blood components	4
5.10	Injection site	5
5.11	Male conical fitting	5
5.12	Protective caps	5
6	Chemical requirements	5
6.1	Reducing (oxidizable) matter	5
6.2	Metal ions	5
6.3	Titration acidity or alkalinity	5
6.4	Residue on evaporation	5
6.5	UV absorption of extract solution	5
7	Biological requirements	6
7.1	General	6
7.2	Sterility	6
7.3	Pyrogenicity	6
7.4	Haemolysis	6
7.5	Toxicity	6
7.6	Assessment of blood component depletion	6
7.7	Assessment of damage to blood components	6
8	Labelling	7
8.1	General	7
8.2	Unit container	7
8.3	Shelf or multi-unit container	7
9	Packaging	8
10	Disposal	8

Annex A (normative) Physical tests	9
Annex B (normative) Chemical tests	13
Annex C (normative) Biological tests	15
Bibliography	16