

DIN EN ISO 1135-4:2010-09 (E)

Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2010)

Contents		Page
Foreword		3
1	Scope	4
2	Normative references	4
3	General requirements	5
3.1	Nomenclature for components of the transfusion set	5
3.2	Maintenance of sterility	6
3.3	Designation	6
4	Materials	6
5	Physical requirements	6
5.1	Particulate contamination	6
5.2	Leakage	6
5.3	Tensile strength	6
5.4	Closure-piercing device	6
5.5	Tubing	7
5.6	Filter for blood and blood components	7
5.7	Drip chamber and drip tube	7
5.8	Flow regulator	7
5.9	Flow rate of blood and blood components	7
5.10	Injection site	8
5.11	Male conical fitting	8
5.12	Protective caps	8
6	Chemical requirements	8
6.1	Reducing (oxidizable) matter	8
6.2	Metal ions	8
6.3	Titration acidity or alkalinity	8
6.4	Residue on evaporation	8
6.5	UV absorption of extract solution	8
7	Biological requirements	9
7.1	General	9
7.2	Sterility	9
7.3	Pyrogenicity	9
7.4	Haemolysis	9
7.5	Toxicity	9
8	Labelling	9
8.1	Unit container	9
8.2	Shelf or multi-unit container	10
9	Packaging	10
10	Disposal	10
Annex A (normative)	Physical tests	11

Annex B (normative) Chemical tests	15
Annex C (normative) Biological tests	17
Bibliography	18
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	19