

DIN EN ISO 1135-5:2016-06 (E)

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (I SO 1135-5:2015)

Contents	Page
European foreword	4
Foreword	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 General requirements	8
4.1 Nomenclature for components of the transfusion set	8
4.2 Maintenance of sterility	9
5 Materials	9
6 Physical requirements	10
6.1 Particulate contamination	10
6.2 Leakage	10
6.3 Tensile strength	10
6.4 Closure-piercing device	10
6.5 Tubing	11
6.6 Filter for blood and blood components	11
6.7 Drip chamber and drip tube	11
6.8 Flow regulator	11
6.9 Flow rate of blood and blood components	11
6.10 Injection site	12
6.11 Male conical fitting	12
6.12 Protective caps	12
6.13 Storage volume	12
7 Chemical requirements	12
7.1 Reducing (oxidizable) matter	12
7.2 Metal ions	12
7.3 Titration acidity or alkalinity	12
7.4 Residue on evaporation	12
7.5 UV absorption of extract solution	13
8 Biological requirements	13
8.1 General	13
8.2 Sterility	13
8.3 Pyrogenicity	13
8.4 Haemolysis	13
8.5 Toxicity	13
8.6 Assessment of blood component depletion	13
8.7 Assessment of damage to blood components	13
9 Labelling	14
9.1 General	14
9.2 Unit container	14
9.3 Shelf or multi-unit container	15

10	Packaging	15
11	Disposal	15
	Annex A (normative) Physical tests	16
	Annex B (normative) Chemical tests	20
	Annex C (normative) Biological tests	22
	Annex D (normative) Storage volume	23
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices	26
	Bibliography	28