

DIN EN ISO 8536-4:2007-06 (Englisc h)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2007)

Contents		Page
Foreword		3
1	Scope	4
2	Normative references	4
3	General requirements	4
4	Designation	7
4.1	Infusion set	7
4.2	Air-inlet device	7
5	Materials	7
6	Physical requirements	8
6.1	Particulate contamination	8
6.2	Leakage	8
6.3	Tensile strength	8
6.4	Closure-piercing device	8
6.5	Air-inlet device	8
6.6	Tubing	9
6.7	Fluid filter	9
6.8	Drip chamber and drip tube	9
6.9	Flow regulator	9
6.10	Flow rate of infusion fluid	9
6.11	Injection site	9
6.12	Male conical fitting	9
6.13	Protective caps	9
7	Chemical requirements	10
7.1	Reducing (oxidizable) matter	10
7.2	Metal ions	10
7.3	Titration acidity or alkalinity	10
7.4	Residue on evaporation	10
7.5	UV absorption of extract solution	10
8	Biological requirements	10
8.1	General	10
8.2	Sterility	10
8.3	Pyrogenicity	10
8.4	Haemolysis	10
8.5	Toxicity	11
9	Labelling	11
9.1	Unit container	11
9.2	Shelf or multi-unit container	11
10	Packaging	12
Annex A (normative) Physical tests		13

Annex B (normative) Chemical tests	17
Annex C (normative) Biological tests	19
Bibliography	20
Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices	21