

DIN EN ISO 8536-4:2020-05 (E)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)

Contents	Page
European foreword	3
Foreword	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 General requirements	5
5 Designation	8
6 Materials	8
7 Physical requirements	8
7.1 Particulate contamination	8
7.2 Leakage	8
7.3 Tensile strength	8
7.4 Closure-piercing device	9
7.5 Air-inlet device	9
7.6 Tubing	9
7.7 Fluid filter	9
7.8 Drip chamber and drip tube	10
7.9 Flow regulator	10
7.10 Flow rate of infusion set	10
7.11 Injection site	10
7.12 Male conical fitting	10
7.13 Protective caps	10
8 Chemical requirements	10
8.1 Reducing (oxidizable) matter	10
8.2 Metal ions	10
8.3 Titration acidity or alkalinity	10
8.4 Residue on evaporation	11
8.5 UV absorption of extract solution	11
9 Biological requirements	11
9.1 General	11
9.2 Sterility	11
9.3 Pyrogenicity	11
9.4 Haemolysis	11
9.5 Toxicity	11
10 Labelling	11
10.1 General	11
10.2 Unit container	11
10.3 Shelf or multi-unit container	12
11 Packaging	12
12 Disposal	12
Annex A (normative) Physical tests	13
Annex B (normative) Chemical tests	18
Annex C (normative) Biological tests	20
Bibliography	21