DIN EN ISO 8536-4:2013-07 (E)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2010 + Amd 1:2013) (includes Amendment A1:2013)

Contents

Page

Foreword to ISO 8536-4:2010 3

1 Scope 5

2 Normative references 5

3 General requirements 5

4 Designation 8
4.1 Infusion set 8
4.2 Air-inlet device 8

5 Materials 8

6 Physical requirements 9
6.1 Particulate contamination 9
6.2 Leakage 9
6.3 Tensile strength 9
6.4 Closure-piercing device 9
6.5 Air-inlet device 9
6.6 Tubing 10
6.7 Fluid filter 10
6.8 Drip chamber and drip tube 10
6.9 Flow regulator 10
6.10 Flow rate of infusion fluid 10
6.11 Injection site 10
6.12 Male conical fitting 10
6.13 Protective caps 10

7 Chemical requirements 11
7.1 Reducing (oxidizable) matter 11
7.2 Metal ions 11
7.3 Titration acidity or alkalinity 11
7.4 Residue on evaporation 11
7.5 UV absorption of extract solution 11

8 Biological requirements 11
8.1 General 11
8.2 Sterility 11
8.3 Pyrogenicity 11
8.4 Haemolysis 11
8.5 Toxicity 12

9 Labelling 12
9.1 Unit container 12
9.2 Shelf or multi-unit container 12

10 Packaging 13

11 !Disposal" 13

Annex A (normative) Physical tests **14**

Annex B (normative) Chemical tests **18**

Annex C (normative) Biological tests **20**

Bibliography **21**

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC **22**