DIN EN ISO 8536-8:2015-11 (E)

Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8:20 15)

Contents

Page

European foreword ... **3**

1 Scope ... **5**

2 Normative references ... **5**

3 Terms and definitions ... **5**

4 General requirements ... **6**

5 Materials ... **9**

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

7 Chemical requirements ... **10**

8 Biological requirements ... **10**

9 Packaging ... **11**

10 Labelling ... **11**
10.1 General ... 11
10.2 Label on unit container ... 11
10.3 Label on shelf or multi-unit container ... 11

11 Disposal ... **12**

Annex A (normative) **Physical tests** ... **13**

Annex B (normative) **Storage volume** ... **14**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices** ... **17**

Bibliography ... **19**