DIN EN ISO 1135-3:2017-05 (E)

Transfusion equipment for medical use - Part 3: Blood-taking sets for single use (ISO 1135-3:2016)

Contents

Page

European foreword ... **3**

Foreword ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 General requirements ... **6**
3.1 Types of sets ... 6
3.2 Blood taking assembly ... 7
3.3 Air-outlet assembly ... 7
3.4 Sterilization ... 8
3.5 Maintenance of sterility ... 8

4 Materials ... **8**

5 Physical requirements ... **8**
5.1 Particulate contamination ... 8
5.2 Leakage ... 8
5.3 Tensile strength ... 8
5.4 Bottle needle ... 8
5.5 Air-outlet needle ... 8
5.6 Blood-taking needle ... 8
5.7 Tubing ... 9
5.8 Flow regulator ... 9
5.9 Protective caps ... 9

6 Chemical requirements ... **9**
6.1 Reducing (oxidizable) matter ... 9
6.2 Metal ions ... 9
6.3 Titration acidity or alkalinity ... 9
6.4 Residue on evaporation ... 9
6.5 UV absorption of extract solution ... 10

7 Biological requirements ... **10**
7.1 General ... 10
7.2 Sterility ... 10
7.3 Pyrogenicity ... 10
7.4 Haemolysis ... 10
7.5 Toxicity ... 10

8 Labelling ... **10**
8.1 General ... 10
8.2 Unit container ... 10
8.3 Shelf or multi-unit container ... 11

9 Packaging ... **11**

10 Disposal ... **11**

Annex A (normative) **Physical tests** ... **12**

Annex B (normative) **Chemical tests** ... **14**

Annex C (normative) **Biological tests** ... **16**

Annex ZA (informative) **Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered** ... **17**

Bibliography ... **20**