ISO 8536-9:2004-10 (E)

Infusion equipment for medical use - Part 9: Fluid lines for use with pressure infusion equipment

Contents

Page

1 Scope 1

2 Normative references 1

3 Designation 2

4 Materials 2

5 Physical requirements 2
5.1 Transparency 2
5.2 Particulate contamination 2
5.3 Tensile strength 2
5.4 Leakage 2
5.5 Adapters with female and/or male conical fittings 2
5.6 Accessories 2
5.7 Filters 3
5.8 Storage volume 3
5.9 Injection needles 3
5.10 Protective caps 3

6 Chemical requirements 3

7 Biological requirements 3
7.1 Sterility 3
7.2 Pyrogens 3
7.3 Haemolysis 3

8 Packaging 3

9 Labelling 4
9.1 Unit container 4
9.2 Shelf or multi-unit container 4

Annex A (normative) Physical tests 5

Annex B (normative) Chemical tests 6

Annex C (normative) Biological tests 7

Bibliography 8