ISO 8536-11:2004-10 (E)

Infusion equipment for medical use - Part 11: Infusion filters for use with pressure infusion equipment

Contents

Page

1 Scope 1

2 Normative references 1

3 Designation 1

4 Design 1

5 Materials 1

6 Physical requirements 2
6.1 Transparency 2
6.2 Particulate contamination 2
6.3 Tensile strength 2
6.4 Leakage 2
6.5 Adapters with female and/or male conical fittings 2
6.6 Protective caps 2

7 Chemical requirements 2

8 Biological requirements 2
8.1 Sterility 2
8.2 Pyrogens 2
8.3 Haemolysis 3

9 Packaging 3

10 Labelling 3
10.1 Unit container 3
10.2 Shelf or multi-unit container 3

Annex A (normative) Physical tests 5

Annex B (normative) Chemical tests 6

Annex C (normative) Biological tests 7

Bibliography 8