ISO 8536-10:2015-06 (E)

Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 Materials 2

4 Physical requirements 2
4.1 Avoidance of air bubbles 2
4.2 Particulate contamination 2
4.3 Tensile strength 2
4.4 Leakage 2
4.5 Adapters with female and/or male conical fittings 2
4.6 Protective caps 2
4.7 Manipulation of stopcocks 2
4.8 Unit with injection site 2
4.9 Unit with check valve 2

5 Chemical requirements 3

6 Biological requirements 3
6.1 Sterility 3
6.2 Pyrogens 3
6.3 Haemolysis 3

7 Packaging 3

8 Labelling 3
8.1 General 3
8.2 Label on unit container 3
8.3 Label on shelf or multi-unit container 4

9 Disposal 4

Annex A (normative) Physical tests 5

Annex B (normative) Chemical tests 6

Annex C (normative) Biological tests 7

Bibliography 8