DIN ISO 8536-12:2010-07 (E)

Infusion equipment for medical use - Part 12: Check valves (ISO 8536-12:2007)

Contents

Page

National foreword 3

National Annex NA (informative) Bibliography 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 Designation 6

5 Materials 6

6 Physical requirements 6
6.1 Particulate contamination 6
6.2 Tensile strength 6
6.3 Leakage 6
6.4 Connecting pieces having internal and/or external connector 6
6.5 Counterflow pressure resistance 6
6.6 Volumetric flow rate 7
6.7 Blocking performance 7
6.8 Opening pressure 7
6.9 Protective caps 7

7 Chemical requirements 7

8 Biological requirements 7
8.1 Sterility 7
8.2 Pyrogenicity 7
8.3 Biocompatibility 7

9 Packaging 7

10 Labelling 7
10.1 Unit container 7
10.2 Shelf or multi-unit container 8

Annex A (normative) Physical tests 9