# DIN EN ISO 8536-10:2015-11 (E)

## Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with p ressure infusion equipment (ISO 8536-10:2015)

## Contents

Page


European foreword ..... 3

1 Scope ..... 5

2 Normative references ..... 5

3 Materials ..... 6

4 Physical requirements ..... 6
4.1 Avoidance of air bubbles ..... 6
4.2 Particulate contamination ..... 6
4.3 Tensile strength ..... 6
4.4 Leakage ..... 6
4.5 Adapters with female and/or male conical fittings ..... 6
4.6 Protective caps ..... 6
4.7 Manipulation of stopcocks ..... 6
4.8 Unit with injection site ..... 6
4.9 Unit with check valve ..... 6

5 Chemical requirements ..... 7

6 Biological requirements ..... 7
6.1 Sterility ..... 7
6.2 Pyrogens ..... 7
6.3 Haemolysis ..... 7

7 Packaging ..... 7

8 Labelling ..... 7
8.1 General ..... 7
8.2 Label on unit container ..... 7
8.3 Label on shelf or multi-unit container ..... 8

9 Disposal ..... 8

Annex A (normative) Physical tests ..... 9

Annex B (normative) Chemical tests ..... 10

Annex C (normative) Biological tests ..... 11

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices ..... 12

Bibliography ..... 14