

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

Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 85 36-11:2015)

| Contents | | Page |
|---|---|-------------|
| European foreword | | 3 |
| 1 | Scope | 5 |
| 2 | Normative references | 5 |
| 3 | Design | 5 |
| 4 | Materials | 5 |
| 5 | Physical requirements | 5 |
| 5.1 | Transparency | 5 |
| 5.2 | Particulate contamination | 6 |
| 5.3 | Tensile strength | 6 |
| 5.4 | Leakage | 6 |
| 5.5 | Adapters with female and/or male conical fittings | 6 |
| 5.6 | Protective caps | 6 |
| 6 | Chemical requirements | 6 |
| 7 | Biological requirements | 6 |
| 7.1 | Sterility | 6 |
| 7.2 | Pyrogens | 6 |
| 7.3 | Haemolysis | 6 |
| 8 | Packaging | 6 |
| 9 | Labelling | 7 |
| 9.1 | General | 7 |
| 9.2 | Label on unit container | 7 |
| 9.3 | Label on shelf or multi-unit container | 7 |
| 10 | 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 |