

ISO 8637:2004-10 (E)

Cardiovascular implants and artificial organs - Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

| Contents | | Page |
|-----------------|--|-------------|
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 2 |
| 4 | Requirements | 3 |
| 4.1 | Biological safety | 3 |
| 4.2 | Sterility | 4 |
| 4.3 | Nonpyrogenicity | 4 |
| 4.4 | Mechanical characteristics | 4 |
| 4.5 | Performance characteristics | 5 |
| 4.6 | Expiration date | 6 |
| 5 | Test methods | 7 |
| 5.1 | General | 7 |
| 5.2 | Biological safety | 7 |
| 5.3 | Sterility | 7 |
| 5.4 | Nonpyrogenicity | 7 |
| 5.5 | Mechanical characteristics | 8 |
| 5.6 | Performance characteristics | 8 |
| 5.7 | Expiration date | 14 |
| 6 | Labelling | 14 |
| 6.1 | Labelling on the device | 14 |
| 6.2 | Labelling on the unit containers | 14 |
| 6.3 | Labelling on the outer containers | 15 |
| 6.4 | Accompanying documentation | 15 |
| | Bibliography | 17 |