

DIN EN 14180:2014-09 (E)

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

| Contents | | Page |
|---------------------|---|-------------|
| Foreword | | 3 |
| Introduction | | 4 |
| 1 | Scope | 5 |
| 2 | Normative references | 5 |
| 3 | Terms and definitions | 6 |
| 4 | Technical requirements | 11 |
| 4.1 | Sterilizer chamber | 11 |
| 4.2 | Design and construction | 14 |
| 4.3 | Indicating, measuring, operating and recording devices | 16 |
| 5 | Process control | 22 |
| 5.1 | General | 22 |
| 5.2 | Software verification and validation | 22 |
| 5.3 | Operating cycle and automatic control | 23 |
| 5.4 | Override of automatic control | 24 |
| 5.5 | Fault | 24 |
| 6 | Performance requirements | 25 |
| 6.1 | Sterilizing performance | 25 |
| 6.2 | Desorption efficacy | 27 |
| 6.3 | Drying | 27 |
| 7 | Sound power and vibration | 27 |
| 8 | Packaging, marking and labelling | 28 |
| 9 | Information to be supplied by the manufacturer | 29 |
| 10 | Service and local environment | 31 |
| 10.1 | General | 31 |
| 10.2 | Electricity | 31 |
| 10.3 | Sterilant | 31 |
| 10.4 | Steam | 32 |
| 10.5 | Water | 32 |
| 10.6 | Compressed air | 32 |
| 10.7 | Drainage and discharges | 32 |
| 10.8 | Ventilation and environment | 33 |
| 10.9 | Lighting | 33 |
| Annex A (normative) | Test methods | 34 |
| Annex B (normative) | Sterilizer classification and testing | 40 |
| Annex C (normative) | Test equipment | 43 |
| Annex D (normative) | Determination of formaldehyde residuals in a filter indicator | 46 |

| | |
|---|-----------|
| Annex E (informative) Formaldehyde residues on medical devices | 49 |
| Annex F (informative) Environmental aspects | 51 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices | 54 |
| Bibliography | 60 |