

DIN EN 1422:2014-08 (E)

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

| Contents | | Page |
|--------------------|--|-------------|
| Foreword | | 4 |
| Introduction | | 5 |
| 1 | Scope | 6 |
| 2 | Normative references | 6 |
| 3 | Terms and definitions | 7 |
| 4 | Technical requirements | 12 |
| 4.1 | General | 12 |
| 4.1.1 | Risk control and usability | 12 |
| 4.1.2 | Materials | 13 |
| 4.2 | Sterilizer chamber | 13 |
| 4.2.1 | Chamber size | 13 |
| 4.2.2 | Doors, closures and interlocks of the sterilizer chamber | 13 |
| 4.2.3 | Test connections | 14 |
| 4.3 | Design and construction | 15 |
| 4.3.1 | General | 15 |
| 4.3.2 | EO vaporizers | 15 |
| 4.3.3 | Pipework and fittings | 15 |
| 4.3.4 | Evacuation system | 15 |
| 4.3.5 | Control valves | 16 |
| 4.3.6 | Thermal insulation | 16 |
| 4.3.7 | Electrical and mechanical safety | 16 |
| 4.3.8 | Air or inert gas filter | 16 |
| 4.3.9 | Emission control | 16 |
| 4.3.10 | Framework and panelling | 17 |
| 4.3.11 | Loading equipment | 17 |
| 4.3.12 | Transport | 17 |
| 4.4 | Indicating, measuring, and recording instruments | 17 |
| 4.4.1 | General | 17 |
| 4.4.2 | Temperature sensor | 18 |
| 4.4.3 | Temperature indicating instruments | 18 |
| 4.4.4 | Pressure sensors | 19 |
| 4.4.5 | Timers and time indicating instruments | 19 |
| 4.4.6 | Sterilizing cycle counter | 19 |
| 4.4.7 | Relative humidity (RH) sensors | 19 |
| 4.4.8 | Ethylene Oxide (EO) concentration-measurement | 19 |
| 4.4.9 | Recording instruments | 20 |
| 4.4.10 | Indicating instruments | 21 |
| 5 | Process control | 22 |
| 5.1 | General | 22 |
| 5.2 | Software verification and validation | 23 |
| 5.3 | Sterilization cycle and automatic control | 23 |
| 5.3.1 | Automatic control | 23 |
| 5.3.2 | Sterilization cycle | 24 |
| 5.4 | Override of automatic control | 27 |
| 5.5 | Fault | 27 |

| | | |
|---|--|-----------|
| 6 | Performance requirements | 28 |
| 6.1 | Sterilizing performance | 28 |
| 6.1.1 | Loading configuration | 28 |
| 6.1.2 | Physical parameters | 28 |
| 6.1.3 | Microbiological efficacy | 28 |
| 6.2 | EO removal (flushing) | 29 |
| 6.3 | Aeration | 29 |
| 7 | Sound power | 29 |
| 8 | Packaging, marking and labelling | 29 |
| 9 | Information to be supplied by the manufacturer | 30 |
| 10 | Service and local environment | 32 |
| 10.1 | General | 32 |
| 10.2 | Electricity | 33 |
| 10.3 | Sterilant | 33 |
| 10.4 | Circulation systems | 33 |
| 10.5 | Steam | 33 |
| 10.6 | Water | 34 |
| 10.7 | Air and inert gasses | 34 |
| 10.8 | Drainage and discharges | 34 |
| 10.9 | Ventilation and environment | 34 |
| 10.10 | Lighting | 34 |
| Annex A (normative) Test instrumentation | | 35 |
| Annex B (normative) Leak test cycle | | 36 |
| Annex C (normative) Sterilizer chamber profile testing | | 37 |
| C.1 | Sterilizer chamber internal surfaces | 37 |
| C.2 | Empty sterilizer chamber | 37 |
| Annex D (normative) Microbiological test for EO sterilizers | | 38 |
| D.1 | General | 38 |
| D.2 | Test equipment | 38 |
| D.3 | Procedure | 39 |
| D.4 | Interpretation of results | 40 |
| Annex E (informative) Environmental aspects | | 41 |
| E.1 | Environmental aspects regarding the life cycle of EO sterilizers | 41 |
| E.2 | EO (brief description) | 41 |
| E.3 | Environmental impact | 41 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices | | 44 |
| Bibliography | | 48 |