

DIN EN ISO 7396-2:2007-07 (E)

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)

| Contents | Page |
|---|-------------|
| Foreword..... | 3 |
| Introduction | 4 |
| 1 Scope | 5 |
| 2 Normative references | 5 |
| 3 Terms and definitions..... | 6 |
| 4 General requirements..... | 10 |
| 4.1 Safety | 10 |
| 4.2 Alternative construction | 10 |
| 4.3 Materials | 10 |
| 4.4 Continuity of operation | 11 |
| 5 Power device | 11 |
| 6 Indicating systems..... | 12 |
| 7 Pipelines, connecting assemblies and disposal hoses..... | 12 |
| 8 Disposal system characteristics and test methods for pressure and flow | 13 |
| 8.1 Requirements | 13 |
| 8.2 Test methods for pressure and flow..... | 14 |
| 8.3 Means to prevent backflow | 16 |
| 9 Terminal units | 16 |
| 10 Marking and colour coding..... | 16 |
| 10.1 Marking | 16 |
| 10.2 Colour coding..... | 17 |
| 10.3 Test for durability..... | 17 |
| 11 Pipeline installation | 17 |
| 12 Testing, commissioning and certification..... | 19 |
| 12.1 General..... | 19 |
| 12.2 General requirements for tests | 19 |
| 12.3 Tests, inspections and checks | 19 |
| 12.4 Requirements for tests, inspections and checks listed in 12.3 | 19 |
| 12.5 Certification of the system..... | 20 |
| 12.6 Extensions or modifications..... | 21 |
| 13 Information to be supplied by the manufacturer..... | 21 |
| 13.1 General..... | 21 |
| 13.2 Instructions for use | 21 |
| 13.3 Operational management information..... | 22 |
| 13.4 "As-installed" drawings | 22 |
| 13.5 Electrical diagrams | 22 |
| Annex A (informative) Guidelines for power devices consisting of fans, blowers or dedicated vacuum pumps..... | 23 |
| Annex B (informative) Example of procedure for testing and commissioning..... | 24 |
| Annex C (informative) Typical forms for certification of AGS disposal systems | 27 |
| Annex D (informative) Risk management checklist..... | 40 |
| Annex E (informative) Rationale | 48 |
| Bibliography | 49 |
| Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices | 50 |