

# DIN EN ISO 7396-1:2010-08 (E)

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007 + Amd 1:2010 + Amd 2:2010) (includes Amendment A1:2010 + Amendment A2:2010)

---

## Contents

Page

|                                                                                                                |    |
|----------------------------------------------------------------------------------------------------------------|----|
| Introduction .....                                                                                             | 6  |
| 1 Scope .....                                                                                                  | 7  |
| 2 Normative references .....                                                                                   | 8  |
| 3 Terms and definitions .....                                                                                  | 8  |
| 4 General requirements .....                                                                                   | 13 |
| 4.1 (*) Safety .....                                                                                           | 13 |
| 4.2 (*) Alternative construction .....                                                                         | 13 |
| 4.3 Materials .....                                                                                            | 14 |
| 4.4 System design .....                                                                                        | 15 |
| 5 Supply systems .....                                                                                         | 16 |
| 5.1 System components .....                                                                                    | 16 |
| 5.2 General requirements .....                                                                                 | 16 |
| 5.3 Supply systems with cylinders or cylinder bundles .....                                                    | 18 |
| 5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels .....                          | 19 |
| 5.5 Supply systems for air .....                                                                               | 19 |
| 5.6 Supply systems with oxygen concentrator(s) .....                                                           | 23 |
| 5.7 Supply systems for vacuum .....                                                                            | 24 |
| 5.8 Location of supply systems .....                                                                           | 24 |
| 5.9 Location of cylinder manifolds .....                                                                       | 25 |
| 5.10 Location of stationary cryogenic vessels .....                                                            | 25 |
| 6 Monitoring and alarm systems .....                                                                           | 25 |
| 6.1 General .....                                                                                              | 25 |
| 6.2 Installation requirements .....                                                                            | 25 |
| 6.3 Monitoring and alarm signals .....                                                                         | 26 |
| 6.4 Provision of operating alarms .....                                                                        | 27 |
| 6.5 Provision of emergency clinical alarms .....                                                               | 28 |
| 6.6 (*) Provision of emergency operating alarms .....                                                          | 28 |
| 7 Pipeline distribution systems .....                                                                          | 28 |
| 7.1 Mechanical resistance .....                                                                                | 28 |
| 7.2 Distribution pressure .....                                                                                | 28 |
| 7.3 Low-pressure hose assemblies and low-pressure flexible connections .....                                   | 29 |
| 7.4 Double-stage pipeline distribution systems .....                                                           | 30 |
| 8 Shut-off valves .....                                                                                        | 30 |
| 8.1 General .....                                                                                              | 30 |
| 8.2 Service shut-off valves .....                                                                              | 31 |
| 8.3 Area shut-off valves .....                                                                                 | 31 |
| 9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges ..... | 32 |
| 10 Marking and colour coding .....                                                                             | 33 |

|                        |                                                                                                                                           |     |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 10.1                   | Marking .....                                                                                                                             | 33  |
| 10.2                   | Colour coding .....                                                                                                                       | 33  |
| 11                     | Pipeline installation .....                                                                                                               | 33  |
| 11.1                   | General .....                                                                                                                             | 33  |
| 11.2                   | Pipeline supports .....                                                                                                                   | 34  |
| 11.3                   | Pipeline joints .....                                                                                                                     | 35  |
| 11.4                   | Extensions and modifications of existing pipeline systems .....                                                                           | 35  |
| 12                     | Testing, commissioning and certification .....                                                                                            | 35  |
| 12.1                   | General .....                                                                                                                             | 35  |
| 12.2                   | General requirements for tests .....                                                                                                      | 36  |
| 12.3                   | Inspections and checks before concealment .....                                                                                           | 36  |
| 12.4                   | Tests, checks and procedures before use of the system .....                                                                               | 36  |
| 12.5                   | Requirements for inspections and checks before concealment .....                                                                          | 37  |
| 12.6                   | Requirements for tests, checks and procedures before use of the system .....                                                              | 37  |
| 12.7                   | Certification of the systems .....                                                                                                        | 42  |
| 13                     | Information to be supplied by the manufacturer .....                                                                                      | 43  |
| 13.1                   | General .....                                                                                                                             | 43  |
| 13.2                   | Instructions for use .....                                                                                                                | 43  |
| 13.3                   | Operational management information .....                                                                                                  | 44  |
| 13.4                   | "As-installed" drawings .....                                                                                                             | 44  |
| 13.5                   | Electrical diagrams .....                                                                                                                 | 44  |
| Annex A (informative)  | Schematic representations of typical supply systems and area distribution systems .....                                                   | 45  |
| Annex B (informative)  | Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids ..... | 68  |
| Annex C (informative)  | Example of procedure for testing and commissioning .....                                                                                  | 69  |
| Annex D (informative)  | Typical forms for certification of the medical gas pipeline system .....                                                                  | 81  |
| Annex E (informative)  | Temperature and pressure relationships .....                                                                                              | 111 |
| Annex F (informative)  | Risk management checklist .....                                                                                                           | 113 |
| Annex G (informative)  | Operational management .....                                                                                                              | 126 |
| Annex H (informative)  | Rationale .....                                                                                                                           | 144 |
| Bibliography           | .....                                                                                                                                     | 146 |
| Annex ZA (informative) | Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices .....        | 148 |