

DIN EN ISO 7396-1:2007-07 (E)

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)

Contents

Page

Foreword.....	4
Introduction	5
1 Scope	6
2 Normative references	7
3 Terms and definitions.....	7
4 General requirements.....	12
4.1 (*) Safety	12
4.2 (*) Alternative construction.....	12
4.3 Materials	13
4.4 System design.....	14
5 Supply systems.....	15
5.1 System components.....	15
5.2 General requirements.....	15
5.3 Supply systems with cylinders or cylinder bundles	17
5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels	18
5.5 Supply systems for air	18
5.6 Supply systems with oxygen concentrator(s)	22
5.7 Supply systems for vacuum	23
5.8 Location of supply systems	23
5.9 Location of cylinder manifolds.....	24
5.10 Location of stationary cryogenic vessels	24
6 Monitoring and alarm systems.....	24
6.1 General.....	24
6.2 Installation requirements	24
6.3 Monitoring and alarm signals.....	25
6.4 Provision of operating alarms	26
6.5 Provision of emergency clinical alarms	27
6.6 (*) Provision of emergency operating alarms	27
7 Pipeline distribution systems.....	27
7.1 Mechanical resistance.....	27
7.2 Distribution pressure.....	27
7.3 Low-pressure hose assemblies and low-pressure flexible connections.....	28
7.4 Double-stage pipeline distribution systems	29
8 Shut-off valves	29
8.1 General.....	29
8.2 Service shut-off valves.....	30
8.3 Area shut-off valves.....	30
9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges	31
10 Marking and colour coding.....	32
10.1 Marking	32
10.2 Colour coding.....	32
11 Pipeline installation	32
11.1 General.....	32
11.2 Pipeline supports	33
11.3 Pipeline joints.....	34

11.4	Extensions and modifications of existing pipeline systems	34
12	Testing, commissioning and certification	34
12.1	General	34
12.2	General requirements for tests	35
12.3	Inspections and checks before concealment	35
12.4	Tests, checks and procedures before use of the system	35
12.5	Requirements for inspections and checks before concealment	36
12.6	Requirements for tests, checks and procedures before use of the system	36
12.7	Certification of the systems	41
13	Information to be supplied by the manufacturer	42
13.1	General	42
13.2	Instructions for use.....	42
13.3	Operational management information	43
13.4	“As-installed” drawings	43
13.5	Electrical diagrams	43
Annex A (informative)	Schematic representations of typical supply systems and area distribution systems	44
Annex B (informative)	Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids.....	67
Annex C (informative)	Example of procedure for testing and commissioning	68
Annex D (informative)	Typical forms for certification of the medical gas pipeline system	80
Annex E (informative)	Temperature and pressure relationships.....	110
Annex F (informative)	Risk management checklist.....	112
Annex G (informative)	Operational management	125
Annex H (informative)	Rationale	143
Bibliography		145
Annex ZA (informative)	Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices	147