

# DIN EN ISO 7396-1:2019-06 (E)

## Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2017) (includes Amendment A1:2019)

---

<b>Contents</b>		<b>Page</b>
European foreword .....		5
European foreword to Amendment A1 .....		6
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices .....		7
Foreword .....		9
Foreword to Amendment 1 .....		10
Introduction .....		11
1	(*) Scope .....	13
2	Normative references .....	14
3	Terms and definitions .....	15
4	General requirements .....	21
4.1	(*) Safety .....	21
4.2	(*) Alternative construction .....	22
4.3	Materials .....	22
4.4	System design .....	24
4.4.1	General .....	24
4.4.2	Extensions and modifications of existing pipeline systems .....	24
5	Supply systems .....	25
5.1	System components .....	25
5.2	General requirements .....	25
5.2.1	Capacity and storage .....	25
5.2.2	Continuity of supply .....	25
5.2.3	Primary source of supply .....	26
5.2.4	Secondary source of supply .....	26
5.2.5	Reserve source(s) of supply .....	26
5.2.6	Means of pressure relief .....	27
5.2.7	Maintenance supply assembly .....	27
5.2.8	Pressure regulators .....	27
5.2.9	(*)Ozone Sterilizers .....	28
5.3	Supply systems with cylinders, cylinder bundles or high-pressure reservoir(s) .....	28
5.4	Supply systems with cryogenic or non-cryogenic vessels .....	29
5.5	Supply systems for air .....	29
5.5.1	General requirements .....	29
5.5.2	Supply systems with air compressor(s) .....	30
5.5.3	Supply systems with proportioning unit(s) .....	33
5.6	Supply systems with oxygen concentrator(s) .....	35
5.6.1	General requirements .....	35
5.6.2	Primary source of supply .....	35
5.6.3	Secondary source of supply .....	35
5.6.4	Reserve source of supply .....	36
5.6.5	Specifications for oxygen 93 .....	36

5.6.6	Oxygen concentrator unit .....	37
5.6.7	Oxygen 93 reservoirs .....	37
5.6.8	Oxygen analysers .....	37
5.6.9	Local filling of permanently attached high-pressure reservoir(s), acting as reserve source of supply .....	38
5.7	Supply systems for vacuum .....	39
5.8	Location of supply systems .....	40
5.9	Location of cylinder manifolds .....	41
5.10	Location of stationary cryogenic vessels .....	41
6	Monitoring and alarm systems .....	41
6.1	General .....	41
6.2	Installation requirements .....	41
6.3	Monitoring and alarm signals .....	42
6.3.1	General .....	42
6.3.2	Auditory signals .....	42
6.3.3	Visual signals .....	43
6.3.4	Emergency and operating alarm characteristics .....	43
6.3.5	Information signals .....	44
6.3.6	Remote alarm extensions .....	44
6.4	Provision of operating alarms .....	44
6.5	Provision of emergency clinical alarms .....	45
6.6	(*) Provision of emergency operating alarms .....	45
7	Pipeline distribution systems .....	46
7.1	Mechanical resistance .....	46
7.2	Distribution pressure .....	46
7.3	Low-pressure hose assemblies and low-pressure flexible connections .....	47
7.4	Double-stage pipeline distribution systems .....	48
8	Shut-off valves .....	48
8.1	General .....	48
8.2	Service shut-off valves .....	49
8.3	Area shut-off valves .....	49
9	Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges .....	51
10	Marking and colour coding .....	51
10.1	Marking .....	51
10.2	Colour coding .....	51
11	Pipeline installation .....	52
11.1	General .....	52
11.2	Pipeline supports .....	53
11.3	Pipeline joints .....	53
11.4	Extensions and modifications of existing pipeline systems .....	54
12	Testing and commissioning .....	54
12.1	General .....	54
12.2	General requirements for tests .....	55
12.3	Inspections and checks before concealment .....	55
12.4	Tests, checks and procedures before use of the system .....	55
12.5	Requirements for inspections and checks before concealment .....	56
12.5.1	Inspection of marking and pipeline supports .....	56
12.5.2	Check for compliance with design specifications .....	56
12.6	Requirements for tests, checks and procedures before use of the system .....	56
12.6.1	General .....	56
12.6.2	(*) Tests of area shut-off valves for leakage and closure and checks for correct zoning and correct identification .....	58
12.6.3	Test for cross-connection .....	58
12.6.4	Test for obstruction and flow .....	59

12.6.5	Checks of terminal units and NIST, DISS or SIS connectors for mechanical function, gas specificity and identification .....	60
12.6.6	Tests or checks of system performance .....	60
12.6.7	(*) Tests of pressure-relief valves .....	60
12.6.8	Tests of all sources of supply .....	61
12.6.9	Tests of monitoring and alarm systems .....	61
12.6.10	Test for particulate contamination of pipeline distribution systems .....	61
12.6.11	Tests of the quality of medical air produced by supply systems with air compressor(s) ...	62
12.6.12	Tests of the quality of air for driving surgical tools produced by supply systems with air compressor(s) .....	62
12.6.13	Tests of the quality of medical air produced by supply systems with proportioning unit(s) .....	62
12.6.14	Tests of the quality of oxygen 93 produced by supply systems with oxygen concentrator(s) .....	62
12.6.15	Filling with specific gas .....	62
12.6.16	Tests of gas identity .....	62
12.6.17	Verification of restart after power supply failure .....	63
12.7	Statement of compliance to this part of ISO 7396 .....	63
13	Information to be supplied by the manufacturer .....	63
13.1	General .....	63
13.2	Instructions for installation .....	63
13.3	Instructions for use .....	63
13.4	Operational management information .....	64
13.5	"As-installed" drawings .....	65
13.6	Electrical diagrams .....	65
Annex A	(informative) Schematic representations of typical supply systems and area distribution systems .....	66
Annex B	(informative) Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids .....	96
Annex C	(informative) Example of procedure for testing and commissioning .....	97
Annex D	(informative) Typical forms for documenting compliance of the pipeline systems for compressed medical gas and vacuum .....	110
Annex E	(informative) Temperature and pressure relationships .....	140
Annex F	(informative) Risk management checklist .....	142
Annex G	(informative) Operational management .....	159
Annex H	(informative) Rationale .....	179
Annex I	(informative) Rationale for compressor hazards .....	182
Annex J	(informative) Considerations for implementation and use of oxygen 93 .....	183
Annex K	(informative) Manufacture of medical gases on site, Responsibility for medical gas quality .....	185
Bibliography	.....	188