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**