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

Medical gas pipeline systems - Part 1: Pipeline systems for comp ressed 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