DIN EN ISO 7396-2:2007-07 (E)

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)

Contents

Page

Foreword ... 3

Introduction ... 4

1 **Scope** ... 5

2 **Normative references** ... 5

3 **Terms and definitions** ... 6

4 **General requirements** ... 10
4.1 **Safety** ... 10
4.2 **Alternative construction** ... 10
4.3 **Materials** ... 10
4.4 **Continuity of operation** ... 11

5 **Power device** ... 11

6 **Indicating systems** ... 12

7 **Pipelines, connecting assemblies and disposal hoses** ... 12

8 **Disposal system characteristics and test methods for pressure and flow** ... 13
8.1 **Requirements** ... 13
8.2 **Test methods for pressure and flow** ... 14
8.3 **Means to prevent backflow** ... 16

9 **Terminal units** ... 16

10 **Marking and colour coding** ... 16
10.1 **Marking** ... 16
10.2 **Colour coding** ... 17
10.3 **Test for durability** ... 17

11 **Pipeline installation** ... 17

12 **Testing, commissioning and certification** ... 19
12.1 **General** ... 19
12.2 **General requirements for tests** ... 19
12.3 **Tests, inspections and checks** ... 19
12.4 **Requirements for tests, inspections and checks listed in 12.3** ... 19
12.5 **Certification of the system** ... 20
12.6 **Extensions or modifications** ... 21

13 **Information to be supplied by the manufacturer** ... 21
13.1 **General** ... 21
13.2 **Instructions for use** ... 21
13.3 **Operational management information** ... 22
13.4 **"As-installed" drawings** ... 22
13.5 **Electrical diagrams** ... 22

Annex A (informative) **Guidelines for power devices consisting of fans, blowers or dedicated vacuum pumps** ... 23

Annex B (informative) **Example of procedure for testing and commissioning** ... 24

Annex C (informative) **Typical forms for certification of AGS disposal systems** ... 27

Annex D (informative) **Risk management checklist** ... 40

Annex E (informative) **Rationale** ... 48

Bibliography ... 49

Annex ZA (informative) **Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices** ... 50