DIN EN ISO 5359:2018-05 (E)

Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 53 59:2014 + Amd 1:2017) (includes Amendment :2017)

Contents

Page

European foreword to EN ISO 5359:2014 ... 3

[A1] European foreword to Amendment A1 [A1] ... 4

Annex ZA (informative) [A1] Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered [A1] ... 6

[A1] Foreword to Amendment 1 [A1] ... 8

Introduction ... 9

[A1] Introduction to Amendment 1 [A1] ... 10

1 Scope ... 11

2 Normative references ... 12

3 Terms and definitions ... 12

4 General requirements ... 16
4.1 Risk management ... 16
4.2 Usability ... 16
4.3 Clinical investigation ... 16
4.4 Safety ... 16
4.5 Materials ... 17
4.6 Design requirements ... 17
4.7 Constructional requirements ... 20

5 Test methods ... 21
5.1 General ... 21
5.2 Test method for pressure drop ... 21
5.3 Test method for leakage ... 21
5.4 Test method for gas specificity ... 21
5.5 Test method for mechanical strength ... 21
5.6 Test method for deformation under pressure ... 22
5.7 Test method for resistance to occlusion ... 22
5.8 Test method for durability of markings and colour coding ... 23

6 Marking, colour coding and packaging ... 23
6.1 Marking ... 23
6.2 Colour coding ... 24
6.3 Packaging ... 25

7 Information to be supplied by the manufacturer ... 25

Annex A (informative) Rationale ... 27

Annex B (informative) Environmental aspects ... 28

Annex C (informative) Reported regional and national deviations of colour coding and nomenclature for medical gases ... 29

Bibliography ... 31