DIN EN ISO 8836:2015-02 (E)

Suction catheters for use in the respiratory tract (ISO 8836:2014)

Contents

Page

Foreword ... **3**

Introduction ... **4**

1 Scope ... **5**

2 Normative references ... **5**

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

4 *General requirements for open and closed suction catheters ... **9**
4.1 Risk management ... 9
4.2 Safety ... 10

5 Specific requirements for open and closed suction catheters ... **10**
5.1 Size and length designations ... 10
5.2 *Dimensions ... 10

6 Materials ... **11**

7 *Design ... **12**
7.1 Lumen of the suction catheter ... 12
7.2 Suction catheter tip ... 12
7.3 *Suction catheter connector ... 12
7.4 Additional requirements for closed suction catheters ... 14

8 Performance requirements ... **16**
8.1 Security of construction ... 16
8.2 Shaft performance ... 16
8.3 *Vacuum control device performance ... 17
8.4 *Leakage ... 17
8.5 *Resistance to flow ... 17
8.6 *Radiopacity ... 17

9 Requirements for suction catheters supplied sterile ... **17**
9.1 Sterility assurance ... 17
9.2 Packaging of suction catheters supplied sterile ... 18

10 Marking ... **18**
10.1 Marking on suction catheters ... 18
10.2 Use of symbols ... 19
10.3 Labelling of individual packs ... 20
10.4 Labelling of shelf/multi-unit packs ... 20

Annex A (informative) **Rationale** ... **22**

Annex B (normative) **Test method for security of attachment** ... **25**

Annex C (normative) **Measurement of residual vacuum** ... **26**

Annex D (normative) **Method of testing leakage** ... **28**

Annex E (informative) **Hazard identification for risk assessment** ... **29**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC** ... **31**

Bibliography ... **34**