

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