

DIN EN ISO 5361:2017-01 (E)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)

Contents

Page

European foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [O] L 169]	5
Foreword	9
Introduction	10
1 Scope	11
2 Normative references	11
3 Terms and definitions	12
4 *General requirements for tracheal tubes and tracheal tube connectors	15
4.1 Risk assessment	15
4.2 Safety	16
5 Specific requirements for tracheal tubes and tracheal tube connectors	16
5.1 Size designation	16
5.2 Dimensions	16
5.2.1 Tracheal tubes	16
5.2.2 Tracheal tube connectors	20
5.3 *Materials	23
5.4 Tracheal tube bevel	23
5.5 *Tracheal tube cuffs	23
5.6 Inflating system for cuffs	24
5.7 Curvature of the tube	24
5.8 *Radiopaque marker	26
5.9 *Kink resistance	26
6 Additional requirement for tracheal tubes with a Murphy eye	27
6.1 Size of the Murphy eye	27
6.2 Location of the Murphy eye	27
6.3 Resistance to kinking or collapse of the Murphy eye	27
6.4 Surface characteristics of the Murphy eye	27
7 Requirements for tracheal tubes with tracheal tube connectors supplied sterile	27
7.1 Sterility assurance	27
7.2 Packaging for tracheal tubes and tracheal tube connectors supplied sterile	28
8 Marking	28
8.1 Use of symbols	28
8.2 Marking on the tracheal tube	28
8.3 Marking on the tracheal tube individual pack or any insert	29
8.4 Marking on tracheal tube connectors	31
Annex A (informative) Rationale	32
Annex B (normative) Determination of cuff diameter	36
Annex C (normative) Test method for cuffed tube collapse	37
Annex D (normative) *Test method for cuff herniation	40
Annex E (informative) Guidance on design of tracheal tube connectors	42
Annex F (informative) Hazard identification for risk assessment	43
Annex G (normative) *Test method for tracheal seal	46
Annex H (normative) Test method to determine kink resistance	49
Bibliography	51