

DIN EN ISO 5361:2026-10 (E)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2023, Corrected version 2023-11 + Amd 1:2026) (includes Amendment :2026)

Contents

Page

Foreword	v
Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	3
4.1 General	3
4.2 Safety	3
5 Materials	3
5.1 General	3
5.2 Biological safety testing	3
5.3 Reuse requirements	3
5.4 Flexibility	3
6 Design requirements	4
6.1 General	4
6.2 Size designation	4
6.3 Dimensions	4
6.3.1 Tracheal tubes	4
6.3.2 Tracheal tube connectors	8
6.4 Tracheal tube bevel	10
6.5 Tracheal tube cuffs	10
6.6 Cuff inflating system	11
6.7 Tracheal tube curvature	12
6.8 Surface finish	12
6.9 Radiopaque marker	14
6.10 Kink resistance	14
6.11 Additional requirements for tracheal tubes with a Murphy eye	14
7 Requirements for tracheal tubes with tracheal tube connectors supplied sterile	15
8 Packaging for tracheal tubes and tracheal tube connectors supplied sterile	15
9 Information supplied by the manufacturer on the tracheal tube, individual pack or the instructions for use	15
9.1 General	15
9.2 Durability of tracheal tube markings	15
9.3 Marking	16
9.3.1 Tracheal tubes shall be clearly and legibly marked with:	16
9.3.2 Marking on tracheal tube connectors	16
9.4 Placement of marking	16
9.5 Instructions for use	17
Annex A (informative) Rationale	19
Annex B (informative) Guidance on the design of tracheal tubes and tracheal tube connectors	25
Annex C (normative) Determination of cuff diameter	30

Annex D (normative) Test method for cuffed tube collapse.....	31
Annex E (normative) Test method for <i>cuff</i> herniation.....	34
Annex F (normative) Test method for tracheal seal	36
Annex G (informative) Hazard identification for <i>risk</i> assessment.....	39
Annex H (normative) Test method to determine kink resistance	42
Bibliography	44