

# DIN EN ISO 5361:2024-11 (E)

## Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2023, Corrected version 2023-11)

---

Contents	Page
European foreword.....	4
Foreword.....	5
Introduction.....	6
<b>1 Scope.....</b>	<b>7</b>
<b>2 Normative references.....</b>	<b>7</b>
<b>3 Terms and definitions.....</b>	<b>7</b>
<b>4 General requirements.....</b>	<b>9</b>
4.1 General.....	9
4.2 Safety.....	9
<b>5 Materials.....</b>	<b>9</b>
5.1 General.....	9
5.2 Biological safety testing.....	9
5.3 Reuse requirements.....	9
5.4 Flexibility.....	9
<b>6 Design requirements.....</b>	<b>10</b>
6.1 General.....	10
6.2 Size designation.....	10
6.3 Dimensions.....	10
6.3.1 <i>Tracheal tubes</i> .....	10
6.3.2 <i>Tracheal tube connectors</i> .....	14
6.4 <i>Tracheal tube bevel</i> .....	16
6.5 <i>Tracheal tube cuffs</i> .....	16
6.6 <i>Cuff inflating system</i> .....	17
6.7 <i>Tracheal tube curvature</i> .....	18
6.8 Surface finish.....	18
6.9 Radiopaque marker.....	20
6.10 Kink resistance.....	20
6.11 Additional requirements for <i>tracheal tubes</i> with a <i>Murphy eye</i> .....	20
<b>7 Requirements for <i>tracheal tubes</i> with <i>tracheal tube connectors</i> supplied sterile.....</b>	<b>21</b>
<b>8 Packaging for <i>tracheal tubes</i> and <i>tracheal tube connectors</i> supplied sterile.....</b>	<b>21</b>
<b>9 Information supplied by the manufacturer on the <i>tracheal tube</i>, individual pack or the instructions for use.....</b>	<b>21</b>
9.1 General.....	21
9.2 Durability of <i>tracheal tube</i> markings.....	21
9.3 Marking.....	22
9.3.1 <i>Tracheal tubes</i> shall be clearly and legibly marked with:.....	22
9.3.2 Marking on <i>tracheal tube connectors</i> .....	22
9.4 Placement of marking.....	22
9.5 Instructions for use.....	23
<b>Annex A (informative) Rationale.....</b>	<b>25</b>
<b>Annex B (informative) Guidance on the design of <i>tracheal tubes</i> and <i>tracheal tube connectors</i>.....</b>	<b>31</b>

<b>Annex C (normative) Determination of <i>cuff</i> diameter</b> .....	<b>36</b>
<b>Annex D (normative) Test method for cuffed tube collapse</b> .....	<b>37</b>
<b>Annex E (normative) Test method for <i>cuff</i> herniation</b> .....	<b>40</b>
<b>Annex F (normative) Test method for tracheal seal</b> .....	<b>42</b>
<b>Annex G (informative) Hazard identification for <i>risk</i> assessment</b> .....	<b>45</b>
<b>Annex H (normative) Test method to determine kink resistance</b> .....	<b>48</b>
<b>Bibliography</b> .....	<b>50</b>