

# ISO 5366:2016-10 (E)

## Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1 *Scope .....		1
2 Normative references .....		1
3 Terms and definitions .....		1
4 *General requirements for tracheostomy tubes and connectors .....		3
5 Materials .....		4
6 Design requirements for tracheostomy tubes and connectors .....		4
6.1 General design requirements .....		4
6.2 Size designation and dimensions .....		4
6.2.1 *Designated size .....		4
6.2.2 Outside dimension .....		5
6.2.3 Nominal length .....		5
6.3 Design .....		5
6.3.1 Connector .....		5
6.3.2 Neck plate .....		6
6.3.3 Inner tube .....		6
6.3.4 *Cuffs .....		7
6.3.5 Inflating tubes for cuffs .....		7
6.3.6 Cuff inflation indicator .....		7
6.3.7 *Inflating tube .....		7
6.3.8 Patient end .....		8
6.3.9 Introducer .....		8
6.3.10 *Radiopaque marker .....		8
6.3.11 *Kink resistance .....		8
7 Requirements for tracheostomy tubes supplied sterile .....		8
7.1 Sterility assurance .....		8
7.2 Packaging for tracheostomy tubes supplied sterile .....		9
8 Information supplied by the manufacturer .....		9
8.1 General .....		9
8.2 Marking of neck-plate .....		9
8.3 Marking on the inflation indicator .....		9
8.4 Marking of tracheostomy tube connectors .....		10
8.5 Additional labelling of unit packs .....		10
8.6 Labelling of inner tube unit packs .....		10
8.7 Labelling of tracheostomy tube inserts .....		10
Annex A (informative) Rationale .....		12
Annex B (normative) Test method for the security of attachment of a fitted connector and neck-plate to the tracheostomy tube .....		14
Annex C (normative) Test method for determining the diameter of the cuff .....		16

<b>Annex D (normative) Test method for cuff herniation .....</b>	<b>17</b>
<b>Annex E (normative) Test method for determining kink resistance .....</b>	<b>19</b>
<b>Annex F (informative) Guidance on materials and design .....</b>	<b>21</b>
<b>Annex G (informative) Hazard identification for risk assessment .....</b>	<b>22</b>
<b>Bibliography .....</b>	<b>25</b>