

ISO 5366:2016-10 (E)

Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors

Contents		Page
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

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