

DIN EN ISO 5366:2017-04 (E)

Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors (ISO 5366:2016)

Contents

	Page
European foreword	3
Foreword	4
Introduction	5
1 *Scope	6
2 Normative references	6
3 Terms and definitions	6
4 *General requirements for TRACHEOSTOMY TUBES and connectors	8
5 Materials	9
6 Design requirements for TRACHEOSTOMY TUBES and connectors	9
6.1 General design requirements	9
6.2 Size designation and dimensions	9
6.2.1 *Designated size	9
6.2.2 Outside dimension	10
6.2.3 NOMINAL LENGTH	10
6.3 Design	10
6.3.1 Connector	10
6.3.2 NECK PLATE	11
6.3.3 INNER TUBE	11
6.3.4 *CUFFS	12
6.3.5 INFLATING TUBES for CUFFS	12
6.3.6 CUFF INFLATION INDICATOR	12
6.3.7 *INFLATING TUBE	12
6.3.8 PATIENT END	13
6.3.9 INTRODUCER	13
6.3.10 *Radiopaque marker	13
6.3.11 *Kink resistance	13
7 Requirements for TRACHEOSTOMY TUBES supplied sterile	13
7.1 Sterility assurance	13
7.2 Packaging for TRACHEOSTOMY TUBES supplied sterile	14
8 Information supplied by the manufacturer	14
8.1 General	14
8.2 Marking of NECK-PLATE	14
8.3 Marking on the INFLATION INDICATOR	14
8.4 Marking of TRACHEOSTOMY TUBE connectors	15
8.5 Additional labelling of unit packs	15
8.6 Labelling of INNER TUBE unit packs	15
8.7 Labelling of TRACHEOSTOMY TUBE inserts	15
Annex A (informative) Rationale	17
Annex B (normative) Test method for the security of attachment of a fitted connector and NECK-PLATE to the TRACHEOSTOMY TUBE	19
Annex C (normative) Test method for determining the diameter of the CUFF	21
Annex D (normative) Test method for CUFF herniation	22
Annex E (normative) Test method for determining kink resistance	24
Annex F (informative) Guidance on materials and design	26
Annex G (informative) Hazard identification for risk assessment	27
Bibliography	30