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 Termsanddefinitions 1

4 *General requirements for tracheostomytubes and connectors 3

5 Materials 4

6 Design requirements for tracheostomytubes 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 tracheostomytubes 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)Testmethodforthesecurityofattachmentofafittedconnectorand neck-plate to the tracheostomytube 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)Hazardidentificationforriskassessment 22

Bibliography 25