

ISO 16628:2022-06 (E)

Anaesthetic and respiratory equipment - Tracheobronchial tubes

| Contents | | Page |
|------------------------------|---|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | General requirements | 2 |
| 4.1 | General | 2 |
| 4.2 | Safety | 2 |
| 5 | Materials | 2 |
| 5.1 | General | 2 |
| 5.2 | Biological safety testing | 2 |
| 6 | Design requirements | 3 |
| 6.1 | General | 3 |
| 6.2 | Designated size | 3 |
| 6.3 | Dimensions | 3 |
| 6.4 | Connectors | 3 |
| 6.5 | Cuffs | 3 |
| 6.6 | Cuff inflation system | 4 |
| 6.7 | Bronchial segment | 4 |
| 7 | Requirements for tracheobronchial tubes supplied sterile | 5 |
| 8 | Packaging | 5 |
| 9 | Information supplied by the manufacturer | 6 |
| 9.1 | General | 6 |
| 9.2 | Marking | 6 |
| 9.2.1 | Durability and legibility | 6 |
| 9.2.2 | Marking on the tracheobronchial tube | 6 |
| 9.3 | Colour coding | 7 |
| 9.4 | Marking on the individual packaging or insert | 7 |
| Annex A (informative) | Rationale | 8 |
| Annex B (normative) | Test method to determine the outside diameter of the bronchial segment | 10 |
| Annex C (normative) | Test method to determine the effective inside diameters | 11 |
| Bibliography | | 13 |