

ISO 11712:2023-11 (E)

Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	3
4.1	General	3
4.2	Test methods	3
5	Materials	3
5.1	General	3
5.2	Biological safety testing	3
5.3	Guidance on materials specific to supralaryngeal airways and connectors	3
6	Design requirements	3
6.1	General	3
6.2	Ventilation positions of use	3
6.3	Size designation	4
6.4	Ventilatory openings	4
6.5	Safeguards against collapse of the ventilatory pathway	4
6.6	Seating mechanisms	4
6.7	Cuff inflation/deflation system	5
6.8	Internal volume	5
6.9	Maximum device size	5
6.10	Supralaryngeal airway connectors	6
6.11	Cleaning, disinfection and sterilization	6
7	Requirements for supralaryngeal airways and connectors supplied sterile	6
8	Packaging	6
9	Information supplied by the manufacturer	6
9.1	General	6
9.2	Marking on the supralaryngeal airway	6
9.3	Marking on supralaryngeal airway individual packs	7
9.4	Instructions for use	7
Annex A (informative)	Rationale	10
Annex B (informative)	Evaluation and documentation of the clinical performance in human subjects	16
Annex C (normative)	Test methods to determine kink resistance	18
Annex D (informative)	Hazard identification for risk management	23
Annex E (informative)	Guidance on materials and design	27
Bibliography		29