

ISO 17510:2015-08 (E)

Medical devices - Sleep apnoea breathing therapy - Masks and application accessories

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Information to be supplied by the manufacturer	3
4.1	General	3
4.2	Marking on the protective packaging	3
4.3	Accompanying document	4
5	Construction requirements	5
5.1	Mask connectors	5
5.2	Biocompatibility	5
5.3	Protection against rebreathing	6
5.3.1	Normal condition protection	6
5.3.2	Single fault condition protection	6
5.4	Cleaning, disinfection, and sterilization	6
5.5	Breathing during single fault condition	7
5.6	Breathing system filter	7
6	Vibration and noise	7
Annex A (informative)	Particular guidance and rationale	8
Annex B (normative)	Exhaustflow test procedure	12
Annex C (normative)	Resistancetoflow(pressuredrop)	14
Annex D (normative)	Anti-asphyxiavalve pressure testing	16
Annex E (normative)	Determination of the inspiratory and expiratory resistance under singlefaultcondition	18
Annex F (normative)	Carbon Dioxide rebreathing	20
Annex G (normative)	Vibration and noise	23
Annex H (informative)	Guide to information to be supplied by the manufacturer	25
Annex I (informative)	Reference to the essential principles	26
Annex J (informative)	Terminology--alphabetizedindexofdefinedterms	28
Bibliography		30