ISO 18190:2016-11 (E)

Anaesthetic and respiratory equipment - General requirements for airways and related equipment

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 2

4 General requirements for airwaysandrelatedequipment 3
4.1 * Risk management 3
4.2 Usability 3
4.3 Clinical evaluation 4
4.4 Biophysical or modelling research 4

5 Materials 4
5.1 Biological safety testing 4
5.2 Intended use and environmental conditions 4
5.3 Leaching 4
5.4 Cleaning, disinfecting or sterilizing agents 4
5.5 Phthalates 5
5.6 Natural rubber (latex) 5
5.7 Gas compatibility 5
5.8 * Durability of marking 6
5.9 Resistance to deterioration 6
5.10 Magnetic resonance imaging (MRI) compatibility 6

6 Design requirements for airwaysandrelatedequipment 6
6.1 Mechanical safety 6
6.2 Medical electrical equipment safety 7
6.3 Pneumatic safety 7
6.4 Protection against inadvertent adjustments 7
6.5 * Prevention of electrostatic charges 7
6.6 Device lifetime 7

7 Requirements for airwaysandrelatedequipment supplied sterile 8
7.1 Sterility assurance 8

8 Packaging 8

9 Information supplied by the manufacturer 8
9.1 Marking 8
9.1.1 General 8
9.1.2 Marking on controls and instruments 10
9.2 Instructions for use 10

Annex A (informative) Rationale 13

Annex B (informative)Hazardidentificationforriskassessment 16

Bibliography 21