

ISO 5367:2014-10 (E)

Anaesthetic and respiratory equipment - Breathing sets and connectors

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	4
4.1 Risk management	4
4.2 Usability	4
4.3 Clinical evaluation	5
4.4 Biophysical or modelling research	5
4.5 Test methods	5
4.6 Recommended service life	5
5 Specific requirements	5
5.1 Materials	5
5.2 Length	5
5.3 Means of connection	6
5.4 Leakage	7
5.5 Resistance to flow	7
5.6 Compliance	8
6 Prevention of electrostatic charges	9
7 Requirements for breathing sets and breathing tubes supplied sterile	9
7.1 Sterility assurance	9
7.2 Packaging of breathing sets and breathing tubes supplied sterile	9
8 Marking	10
8.1 General	10
8.2 Marking of breathing sets and breathing tubes	10
8.3 Marking of packages	10
8.4 Information to be supplied by the manufacturer	12
Annex A (informative) Rationale	13
Annex B (informative) Hazard identification for risk assessment	23
Annex C (normative) Test for security of attachment of plain end to conical connector	24
Annex D (normative) Test for security of attachment of adaptor to breathing tube	25
Annex E (normative) Test for leakage	26
Annex F (normative) Measurement of resistance to flow	28
Annex G (normative) Test for increase in flow resistance with bending	31

Annex H (normative) Test for compliance	33
Bibliography	35