

DIN EN ISO 5367:2015-02 (E)

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

Contents	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 General requirements	8
4.1 Risk management	8
4.2 Usability	8
4.3 Clinical evaluation	9
4.4 Biophysical or modelling research	9
4.5 Test methods	9
4.6 Recommended service life	9
5 Specific requirements	9
5.1 Materials	9
5.2 Length	9
5.3 Means of connection	10
5.4 Leakage	11
5.5 Resistance to flow	11
5.6 Compliance	12
6 Prevention of electrostatic charges	13
7 Requirements for breathing sets and breathing tubes supplied sterile	13
7.1 Sterility assurance	13
7.2 Packaging of breathing sets and breathing tubes supplied sterile	13
8 Marking	14
8.1 General	14
8.2 Marking of breathing sets and breathing tubes	14
8.3 Marking of packages	14
8.4 Information to be supplied by the manufacturer	16
Annex A (informative) Rationale	17
Annex B (informative) Hazard identification for risk assessment	27
Annex C (normative) Test for security of attachment of plain end to conical connector	28
Annex D (normative) Test for security of attachment of adaptor to breathing tube	29
Annex E (normative) Test for leakage	30
Annex F (normative) Measurement of resistance to flow	32
Annex G (normative) Test for increase in flow resistance with bending	35

Annex H (normative) Test for compliance	37
Bibliography	42
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	39