

ISO 18562-2:2024-03 (E)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

Contents		Page
Foreword.....		iv
Introduction.....		v
1 Scope		1
2 Normative references		2
3 Terms and definitions		2
4 General principles		2
5 Particulate matter emissions		2
5.1 General.....		2
5.2 Testing methods overview.....		3
5.3 Single filter test setup.....		4
5.4 Double filter test setup.....		5
5.5 Test method.....		6
5.6 Measuring <i>particulate matter</i> emissions according to particle size.....		7
5.7 Measuring <i>particulate matter</i> emissions by particle counter.....		7
5.8 <i>Medical devices</i> with time-varying emissions.....		7
6 Reporting		8
Annex A (informative) Rationale and guidance		9
Annex B (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances		13
Annex C (informative) Reference to the <i>essential principles</i>		14
Annex D (informative) Terminology — Alphabetized index of defined terms		15
Bibliography		16