

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	<i>Particulate matter emissions</i>	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