

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