

# ISO 18562-4:2024-03 (E)

## Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

---

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General principles	2
5	<b>Leachables in condensate</b>	3
5.1	Identifying applicable <i>gas pathway</i> surfaces	3
5.2	Determining if testing is required	3
5.3	Test methods	4
5.3.1	General	4
5.3.2	Sample collection	5
5.3.3	Chemical characterization of <i>leachables</i> in condensate	6
5.3.4	Calculation of <i>tolerable exposure</i>	7
5.3.5	Calculation of <i>exposure dose estimate</i>	7
5.3.6	<i>Risk assessment</i>	7
5.3.7	Biological evaluation according to ISO 10993 standards	8
6	Reporting	9
Annex A (informative)	Rationale and guidance	10
Annex B (informative)	Reference to the IMDRF <i>essential principles</i> and labelling guidances	12
Annex C (informative)	Reference to the <i>essential principles</i>	13
Annex D (informative)	Terminology — Alphabetized index of defined terms	14
Bibliography		15