

# DIN EN ISO 18562-3:2025-02 (E)

## Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)

---

### Contents

Page

European foreword .....	3
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered .....	4
Foreword.....	8
Introduction .....	9
1 Scope .....	10
2 Normative references .....	10
3 Terms and definitions .....	11
4 General principles .....	11
5 <i>Volatile organic substance emissions</i> .....	11
5.1 General.....	12
5.2 Test method.....	12
5.3 Assessment of <i>inhalation dose</i> .....	16
6 Reporting .....	17
Annex A (informative) Rationale and guidance .....	18
Annex B (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances .....	21
Annex C (informative) Reference to the <i>essential principles</i> .....	22
Annex D (informative) Terminology — Alphabetized index of defined terms.....	23
Bibliography.....	24