

# ISO 80369-2:2024-07 (E)

## Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications

---

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Non-interconnectability requirements	3
5	Material requirements	3
6	Dimensions and tolerances	3
6.1	R1 <i>small-bore connectors</i>	3
6.2	R2 <i>small-bore connectors</i>	3
7	Performance requirements	4
7.1	Leakage by pressure decay	4
7.2	Sub-atmospheric pressure air leakage	4
7.3	Stress cracking	4
7.4	Resistance to separation from axial load	4
7.5	Resistance to separation from unscrewing	4
7.6	Resistance to overriding	5
7.7	Disconnection by unscrewing	5
Annex A (informative)	Rationale and guidance	6
Annex B (normative)	<i>Small-bore connectors for respiratory applications</i>	7
Annex C (normative)	Reference <i>connectors</i> for testing <i>small-bore connectors</i> for respiratory applications	16
Annex D (informative)	Assessment of <i>medical devices</i> and their attributes with <i>connections</i> within this <i>application</i>	31
Annex E (informative)	Summary of the usability requirements for <i>small-bore connectors</i> for <i>respiratory applications</i>	37
Annex F (informative)	Summary of <i>small-bore connector</i> design requirements for <i>respiratory applications</i>	39
Annex G (informative)	Summary of assessment of the design of the <i>small-bore connectors</i> for <i>respiratory applications</i>	45
Annex H (informative)	Reference to the IMDRF essential principles	48
Annex I (informative)	Terminology — Alphabetized index of defined terms	49
Bibliography		50