DIN EN ISO 80369-2:2026-08 (E)

Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO 80369-2:2024, Corrected version 2025-06)

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 *small-bore connectors* ... 3
6.2 R2 *small-bore connectors* ... 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) ***Small-bore connectors* for *respiratory applications*** ... **7**

Annex C (normative) **Reference *connectors* for testing *small-bore connectors* for *respiratory applications*** ... **16**

Annex D (informative) **Assessment of *medical devices* and their attributeswith *connections* within this *application*** ... **31**

Annex E (informative) **Summary of the usability requirements for *small-bore connectors* for *respiratory applications*** ... **37**

Annex F (informative) **Summary of *small-bore connector* design requirementsfor *respiratoryapplications*** ... **39**

Annex G (informative) **Summary of assessment of the design of the *small-bore connectors*for *respiratory applications*** ... **45**

Annex H (informative) **Reference to the IMDRF essential principles** ... **48**

Annex I (informative) **Terminology — Alphabetized index of defined terms** ... **49**

Bibliography ... **50**