DIN EN ISO 80369-1:2026-10 (E)

Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2025)

Contents

Page

Foreword ... **iv**

Introduction ... **vi**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 *Small-bore connector non-interconnectable* requirement ... **4**

5 *Small-bore connectors* for clinical *applications* ... **5**

5.1 *Small-bore connectors* for new clinical *applications* ... 5

5.2 *Small-bore connectors* for respiratory *applications* ... 5

5.3 *Small-bore connectors* for enteral *applications* ... 5

5.4 *Small-bore connectors* for limb cuff inflation *applications* ... 6

5.5 *Small-bore connectors* for neural *applications* ... 6

5.6 *Small-bore connectors* for intravascular and hypodermic *applications* ... 6

5.7 Other use cases utilizing an ISO 80369-7 *small-bore connector* ... 6

6 Alternative *small-bore connectors* ... **7**

Annex A (informative) **Rationale** ... **9**

Annex B (normative) ***Process* for demonstrating *non-interconnectable* characteristics** ... **15**

Annex C (normative) **Assessment *procedures* for *small-bore connectors*** ... **30**

Annex D (informative) ***Applications* of *small-bore connectors* and the relevant standard** ... **33**

Annex E (informative) **Design assessment summary** ... **35**

Annex F (informative) **Reference to the IMDRF essential principles** ... **38**

Annex G (informative) **Alphabetized index of defined terms** ... **39**

Bibliography ... **41**