

# ISO 80369-1:2025-10 (E)

## Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		vi
1	<b>Scope .....</b>	<b>1</b>
2	<b>Normative references .....</b>	<b>1</b>
3	<b>Terms and definitions.....</b>	<b>2</b>
4	<b>Small-bore connector non-interconnectable requirement .....</b>	<b>4</b>
5	<b>Small-bore connectors for clinical applications .....</b>	<b>5</b>
5.1	<b>Small-bore connectors for new clinical applications .....</b>	<b>5</b>
5.2	<b>Small-bore connectors for respiratory applications .....</b>	<b>5</b>
5.3	<b>Small-bore connectors for enteral applications .....</b>	<b>5</b>
5.4	<b>Small-bore connectors for limb cuff inflation applications .....</b>	<b>6</b>
5.5	<b>Small-bore connectors for neural applications .....</b>	<b>6</b>
5.6	<b>Small-bore connectors for intravascular and hypodermic applications .....</b>	<b>6</b>
5.7	<b>Other use cases utilizing an ISO 80369-7 small-bore connector .....</b>	<b>6</b>
6	<b>Alternative small-bore connectors .....</b>	<b>7</b>
Annex A (informative)	<b>Rationale .....</b>	<b>9</b>
Annex B (normative)	<b>Process for demonstrating non-interconnectable characteristics .....</b>	<b>15</b>
Annex C (normative)	<b>Assessment procedures for small-bore connectors .....</b>	<b>30</b>
Annex D (informative)	<b>Applications of small-bore connectors and the relevant standard .....</b>	<b>33</b>
Annex E (informative)	<b>Design assessment summary .....</b>	<b>35</b>
Annex F (informative)	<b>Reference to the IMDRF essential principles .....</b>	<b>38</b>
Annex G (informative)	<b>Alphabetized index of defined terms .....</b>	<b>39</b>
Bibliography .....		41