

# ISO 10079-4:2021-08 (E)

## Medical suction equipment - Part 4: General requirements

---

<b>Contents</b>		<b>Page</b>
Foreword		v
Introduction		vi
<b>1</b>	<b>Scope</b>	<b>1</b>
<b>2</b>	<b>Normative references</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions</b>	<b>2</b>
<b>4</b>	<b>General requirements</b>	<b>4</b>
4.1	Risk management	4
4.2	Usability	5
4.3	Clinical studies	5
4.4	Biophysical or modelling research	5
4.5	Test methods	5
<b>5</b>	<b>Materials</b>	<b>5</b>
5.1	Natural rubber latex	5
5.2	Cleaning, disinfection and sterilization	6
<b>6</b>	<b>Design requirements</b>	<b>6</b>
6.1	General	6
6.2	<i>Collection containers</i>	6
6.2.1	Capacity	6
6.2.2	Strength	7
6.3	Connections	7
6.3.1	Tubing connectors	7
6.3.2	<i>Collection container inlet ports</i>	7
6.3.3	<i>Collection container exhaust ports</i>	7
6.4	<i>Suction tubing and intermediate tubing</i>	8
6.5	<i>Vacuum level indicators</i>	8
6.6	Environmental conditions for transport and storage	9
<b>7</b>	<b>Performance requirements</b>	<b>10</b>
7.1	Operating position	10
7.2	Protection devices	10
7.2.1	Contamination protection	10
7.2.2	<i>Overfill protection devices</i>	10
7.2.3	Pressure protection	10
7.3	Noise	11
7.4	Air leakage	11
7.5	<i>Vacuum levels and free air flows</i>	11
7.6	Accuracy	11
7.7	Pharyngeal suction equipment	12
<b>8</b>	<b>Additional/alternative requirements for suction equipment, suction tubing and intermediate tubing designed for field use or transport use</b>	<b>12</b>
8.1	Physical requirements	12
8.2	Strength	12
8.3	Stability	12
8.4	Environmental conditions during operation	12
8.5	<i>Collection container capacity</i>	13

<b>9</b>	<b>Information supplied by the manufacturer</b> .....	<b>13</b>
9.1	General .....	13
9.2	Symbols .....	14
9.3	Marking .....	14
9.4	Instructions for use .....	15
	<b>Annex A (informative) Rationale</b> .....	<b>17</b>
	<b>Annex B (normative) Test methods</b> .....	<b>19</b>
	<b>Annex C (informative) Schematic of medical <i>suction</i> equipment</b> .....	<b>34</b>
	<b>Bibliography</b> .....	<b>35</b>