

DIN EN ISO 10079-4:2022-06 (E)

Medical suction equipment - Part 4: General requirements (ISO 10079-4:2021)

Contents		Page
	European foreword	4
	Foreword	5
	Introduction	6
1	Scope	7
2	Normative references	7
3	Terms and definitions	8
4	General requirements	10
4.1	Risk management	10
4.2	Usability	11
4.3	Clinical studies	11
4.4	Biophysical or modelling research	11
4.5	Test methods	11
5	Materials	11
5.1	Natural rubber latex	11
5.2	Cleaning, disinfection and sterilization	12
6	Design requirements	12
6.1	General	12
6.2	<i>Collection containers</i>	12
6.2.1	Capacity	12
6.2.2	Strength	13
6.3	Connections	13
6.3.1	Tubing connectors	13
6.3.2	<i>Collection container inlet ports</i>	13
6.3.3	<i>Collection container exhaust ports</i>	13
6.4	<i>Suction tubing and intermediate tubing</i>	14
6.5	<i>Vacuum level indicators</i>	14
6.6	Environmental conditions for transport and storage	15
7	Performance requirements	16
7.1	Operating position	16
7.2	Protection devices	16
7.2.1	Contamination protection	16
7.2.2	<i>Overfill protection devices</i>	16
7.2.3	Pressure protection	16
7.3	Noise	17
7.4	Air leakage	17
7.5	<i>Vacuum levels and free air flows</i>	17
7.6	Accuracy	17
7.7	Pharyngeal suction equipment	18
8	Additional/alternative requirements for suction equipment, suction tubing and intermediate tubing designed for field use or transport use	18
8.1	Physical requirements	18
8.2	Strength	18
8.3	Stability	18
8.4	Environmental conditions during operation	18
8.5	<i>Collection container capacity</i>	19

9	Information supplied by the manufacturer	19
9.1	General	19
9.2	Symbols	20
9.3	Marking	20
9.4	Instructions for use	21
Annex A (informative) Rationale		23
Annex B (normative) Test methods		25
Annex C (informative) Schematic of medical <i>suction</i> equipment		40
Bibliography		41