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 *Collection containers* ... 12
6.2.1 Capacity ... 12
6.2.2 Strength ... 13
6.3 Connections ... 13
6.3.1 Tubing connectors ... 13
6.3.2 *Collection container inlet ports* ... 13
6.3.3 *Collection container exhaust ports* ... 13
6.4 *Suction tubing* and *intermediate tubing* ... 14
6.5 *Vacuum level indicators* ... 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 *Overfill protection devices* ... 16
7.2.3 Pressure protection ... 16
7.3 Noise ... 17
7.4 Air leakage ... 17
7.5 *Vacuum levels* and *free air flows* ... 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 *Collection container* capacity ... 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 *suction* equipment** **40**
Bibliography **41**