DIN EN ISO 10079-2:2014-09 (E)

Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2014)

Contents

Page

Foreword 3

1 Scope 4

2 Normative references 4

3 Termsanddefinitions 4

4 General requirements 6
4.1 Risk management 6
4.2 Usability 7
4.3 Clinical investigation 7
4.4 Biophysical or modelling research 7

5 Cleaning, disinfection and sterilization 7

6 Design requirements 7
6.1 Collection container 7
6.2 Connections 8
6.3 Suction tubing 8
6.4 Vacuum level indicators 9

7 Operational requirements 9
7.1 Ease of operation 9
7.2 Dismantling and reassembly 9
7.3 Mechanical shock 9
7.4 Stability 9
7.5 Protection devices 10
7.6 Immersion in water 10

8 Physicalrequirementsforfieldandtransportusesuctionequipment 10
8.1 (*)Dimensions 10
8.2 Mass 10

9 Performancerequirementsforvacuumlevelandflowrate 11
9.1 Vacuum level 11
9.2 Free air flowrate 11
9.3 Pharyngeal suction 11

10 (*)Resistancetoenvironmentofsuctionequipmentforfieldand/ortransportuse 11
10.1 Operating conditions 11
10.2 Storage 11

11 Marking 11
11.1 Use of symbols 11
11.2 Equipment 11
11.3 Equipment or carrying case 12

12 Information to be supplied by the manufacturer 12

Annex A (normative) Test methods 14

Annex B (informative) Rationale statement 20

Annex C (informative)Lumensizeanditseffectonflowrate 21

Annex D (informative) Schematic of suction equipment 22

Bibliography 25

Annex ZA RelationshipbetweenthisEuropeanStandardandtheEssential RequirementsofEUDirective93/42/EEC 23 .....