

DIN EN 14683:2019-06 (E)

Medical face masks - Requirements and test methods

Contents	Page
European foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Classification	8
5 Requirements	8
5.1 General	8
5.1.1 Materials and construction	8
5.1.2 Design	8
5.2 Performance requirements	8
5.2.1 General	8
5.2.2 Bacterial filtration efficiency (BFE)	8
5.2.3 Breathability	8
5.2.4 Splash resistance	8
5.2.5 Microbial cleanliness (Bioburden)	9
5.2.6 Biocompatibility	9
5.2.7 Summary of performance requirements	9
6 Marking, labelling and packaging	9
Annex A (informative) Information for users	10
Annex B (normative) Method for in vitro determination of bacterial filtration efficiency (BFE)	11
B.1 General	11
B.2 Principle	11
B.3 Reagents and materials	11
B.3.1 General	11
B.3.2 Tryptic soy agar	11
B.3.3 Tryptic soy broth	11
B.3.4 Peptone water	12
B.3.5 Culture of <i>Staphylococcus aureus</i> ATCC 6538, growing on tryptic soy agar slants	12
B.4 Test apparatus	12
B.4.1 Six stage cascade impactor, the arrangement is specified in Table B.1	12
B.4.2 Nebulizer, capable of delivering particles with a mean size of $(3,0 \pm 0,3)$ μm when in contact with the cascade impactor	12
B.4.3 Aerosol chamber, glass, 600 mm long and 80 mm in external diameter	12
B.4.4 Flow meters, capable of measuring a flow rate of 28,3 l/min	12
B.4.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa	12
B.4.6 Erlenmeyer flasks, 250 ml and 500 ml capacity	12
B.4.7 Peristaltic or syringe pump, capable of delivering 0,01 ml/min	12
B.4.8 Vacuum pump, capable of maintaining a flow rate of 57 l/min	12
B.5 Test specimens	12
B.6 Preparation of bacterial challenge	12
B.7 Procedure	13

B.8	Calculation of bacterial filtration efficiency (BFE)	15
B.9	Test report	15
Annex C (normative) Method for determination of breathability (differential pressure)		17
C.1	Principle	17
C.2	Test apparatus	18
C.2.1	Mass flow meter(s) capable of measuring an airflow of 8 l/min	18
C.2.2	Manometer, a differential manometer (water or digital). Individual manometers can also be used. M1 is for the upstream pressure measurement and M2 is for the downstream pressure measurement	18
C.2.3	Electric vacuum pump including a pressure buffer tank	18
C.2.4	Valve permitting the adjustment of the flow rate	18
C.2.5	Sample holder	18
C.3	Test specimens	18
C.4	Procedure	19
C.5	Calculation of differential pressure	19
C.6	Test report	19
Annex D (informative) Microbial cleanliness		20
D.1	Sampling	20
D.2	Testing	20
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered		21
Bibliography		22