Messrs ROBUL CARE OOD
EIK 206176587,115G,Tsarigradsko Shose blvd.,Megapark,fl.2 office A
1784 SOFIA (BULGARIA)()

Sample Identification: (#)FACE MASK PTOTOTYPE BATCH
Sampling: Customer
Sampling site: (#)Customer Site
Transport: External Representate - Room Temperature
Storage: Room Termperature

Recording Date: 18/12/2020
Beginning Test Date: 18/12/2020
End Test Date: 28/12/2020

MEDICAL FACE MASKS. REQUIREMENTS AND TEST METHODS

Scope

Evaluation of performance requirements of the medical face mask according to UNI EN 14683:2019

Performance requirements for medical face masks (UNI EN 14683:2019, § 5.2.7):

Table 1

Test	Type I [a)]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a)] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Summary of the test results:

Table 2

Test	Result
Bacterial filtration efficiency (BFE), (%)	99,8
Differential pressure (Pa/cm2)	34,7
Microbial cleanliness (cfu/g)	6

Bacterial filtration efficiency (BFE)

Principle and Normative References

Scope	Evaluation of efficiency of the medical face mask material(s) as a barrier to bacterial penetration
Normative References	UNI EN 14683:2019 Annex B

Experimental conditions

N° of medical face masks tested	5
Dimensions of the test specimens	100 mm x 100 mm
Size of tested area	49 cm^2
Side of the test specimen facing the aerosol	Outside
Air flow rate during testing	28,3 L/min
Test strain	*Staphylococcus aureus* ATCC 6538
Culture mean:	
Inoculum	TSB (Tryptic Soy Broth)
Aerosol	Peptonated Water
Growth medium	TSA (Tryptic Soy Agar)
Specimen conditioning	21 ± 5 °C e 85 ± 5 % HR per 4h
Cascade impactor	Six-stage Andersen impactor
Incubation conditions	37 ± 2 °C per 20-52 h

Procedure:

Following procedures are performed for each of the five tested masks.

A representative test specimen of at least 100 mm x 100 mm is obtained from each mask. The specimen is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* ATCC 6538 is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (B) of each test specimen is calculated, as percentage using the following formula:

$$B = (C - T) / C \times 100$$

Where:

C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

Results

Table 3 summarizes results obtained with the Bacterial filtration efficiency (BFE) test.

Table 3

Parameter *Test Method*	M.U.	Result
Positive control (mean)	cfu	2923
Negative control	cfu	0
Bacterial filtration efficiency (BFE), Sample 1 *UNI EN 14683:2019 Annex B*	%	99,7
Bacterial filtration efficiency (BFE), Sample 2 *UNI EN 14683:2019 Annex B*	%	99,9
Bacterial filtration efficiency (BFE), Sample 3 *UNI EN 14683:2019 Annex B*	%	99,9
Bacterial filtration efficiency (BFE), Sample 4 *UNI EN 14683:2019 Annex B*	%	99,9
Bacterial filtration efficiency (BFE), Sample 5 *UNI EN 14683:2019 Annex B*	%	99,8
Bacterial filtration efficiency (BFE), Mean *UNI EN 14683:2019 Annex B*	%	99,8

cfu: colony forming units; Positive control: test run without test specimen; Negative control: test run without bacterial suspension.

Breathabiliy (Differential Pressure)

Principle and Normative References

Scope	Evaluation of efficiency of the air permeability of the mask.
Normative References	UNI EN 14683:2019 Annex C

Experimental conditions

N° of medical face masks tested	5
Tested area location	Front and Side
Size of each tested area	4,9 cm^2
Side of the test specimen facing the airflow	Outside
Air flow rate during testing	8 L/min
Specimen conditioning	21 ± 5 °C e 85 ± 5 % HR per 4h

Procedure:

Following procedures are performed for each of the five tested masks.
A device, which measures the differential pressure required to draw air through a specimen surface area of 4,9 cm^2 at a constant air flow rate of 8 L/min, is used to measure the air exchange pressure of the medical face mask material. A differential manometer is used to measure the differential pressure required to move air through the specimen surface area.

Results

Table 4 summarizes results obtained with the differential pressure test.

Table 4

Parameter *Test Method*	M.U.	Results Area 1	Results Area 2	Results Area 3	Results Area 4	Results Area 5	Results (Mean)
Breathabiliy (Differential Pressure), Area 1 *UNI EN 14683:2019 Annex C*	Pa/cm2	28,3	35,6	32,4	36,9	38,9	34,4
Breathabiliy (Differential Pressure), Area 2 *UNI EN 14683:2019 Annex C*	Pa/cm2	33,4	32,7	35,3	41,0	35,7	35,6
Breathabiliy (Differential Pressure), Area 3 *UNI EN 14683:2019 Annex C*	Pa/cm2	37,9	35,9	32,6	30,8	32,6	34,0
Breathabiliy (Differential Pressure), Area 4 *UNI EN 14683:2019 Annex C*	Pa/cm2	34,2	39,9	35,4	33,7	35,0	35,6
Breathabiliy (Differential Pressure), Area 5 *UNI EN 14683:2019 Annex C*	Pa/cm2	30,5	36,1	33,3	31,7	38,1	33,9
Breathabiliy (Differential Pressure), Mean per areas *UNI EN 14683:2019 Annex C*	Pa/cm2						34,7

Determination of a population of microorganisms (Bioburden)

Principle and Normative References

Scope	Evaluation of microbial cleanliness performance requirements in medical face mask.
Normative References	UNI EN 14683:2019 Annex D + ISO 11737-1:2018

Experimental conditions

N° of medical face masks tested	5
Culture media:	
Extraction liquid (used volume)	1g/L Peptone, 5g/L NaCl, 2g/L Polysorbate 20 (300 mL)
Total viable aerobic microbial count	TSA (Tryptic Soy Agar)
Total yeasts and moulds count	SDCA (Sabouraud Dextrose Agar with Chloramphenicol)
Extraction method	Orbital shaker for 5 min at 250 rpm
Analytical Technique	Membrane filtration (pore size 0,45 µm)
Incubation conditions:	
Total viable aerobic microbial count	30 ± 1 °C for 3 days
Total yeasts and moulds count	25 ± 1 °C for 7 days
Correction factor determined by the bioburden recovery efficiency	1,12

Procedure:

Following procedures are performed for each of the five tested masks.

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDCA for yeasts and moulds enumeration. The plates are incubated for 3 days at 30 °C and 7 days at 25 °C for TSA and SDCA plates respectively.

The total bioburden is expressed by addition of the TSA and SDCA counts adjusted by a correction factor calculated from the bioburden recovery efficiency.

Results

Table 6 summarizes results obtained with the microbial cleanliness (bioburden) tests.

Table 6

Parameter *Test Method*	Results *cfu/mask*[§]	Mask weight *g*	Results *cfu/g*[§]
Determination of a population of microorganisms (Bioburden), Sample 1 *UNI EN 14683:2019 Annex D + ISO 11737-1:2018*	24	3,43	7
Determination of a population of microorganisms (Bioburden), Sample 2 *UNI EN 14683:2019 Annex D + ISO 11737-1:2018*	13	3,39	4
Determination of a population of microorganisms (Bioburden), Sample 3 *UNI EN 14683:2019 Annex D + ISO 11737-1:2018*	13	3,4	4
Determination of a population of microorganisms (Bioburden), Sample 4 *UNI EN 14683:2019 Annex D + ISO 11737-1:2018*	20	3,48	6
Determination of a population of microorganisms (Bioburden), Sample 5 *UNI EN 14683:2019 Annex D + ISO 11737-1:2018*	34	3,37	10
Determination of a population of microorganisms (Bioburden), Total cfu per g UNI EN 14683:2019 Annex D + ISO 11737-1:2018			6

[§] **Values adjusted by the bioburden correction factor.**

Test notes:

(*): Prova non accreditata da ACCREDIA
(#) The information after the # symbol is provided by the customer
MP: Laboratory-developed method
M.U.: Measurement Unit
Parameter Note: parameter information

N.R.: Not Detectable
The "Limits" column shows: the limits of quantification or detectability indicated with "LDQ or LDR", the legal limits and / or guide values agreed with the client (The value indicated, if expressed in round brackets (), is to be considered "Guide Value" - Otherwise it is to be considered "Law Limit").

The result of the quantitative evidence on surfaces is obtained by recalculation performed on the basis of the measure declared by the person who performed the sampling.

Uncertainty of measurement (I.D.M.):

For microbiological parameters the extended uncertainty of measurement is expressed as confidence interval (lower limit-upper limit) with coverage factor K = 2 and with confidence level of 95%. Quantitative tests are performed in a single replica in accordance with ISO 7218: 2007 / Amd 1: 2013.

For chemical parameters the extended uncertainty values refer to a 95% confidence interval and a coverage factor K = 2

Documentation traceability:

The description of Laboratory-developed methods (MP), test procedures (PP) methods normed and Operating Procedures (P.O.) are at your disposal in the laboratory.

In laboratory are available all the documentation to trace the technicians who carried out the tests, as well as the sampling and transport.