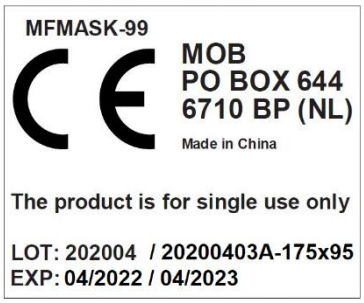
EU Declaration of Conformity (DOC)

Company name:	*Mid Ocean (Brands) BV (MOB)*
Postal address:	*PO BOX 644*
Postcode and City:	*6710 BP* *Ede (NL)*
Telephone number:	*0031 (0)342 426992*
E-mail address:	*DOC@reclamond.com*

We declare that DOC issued under our sole responsibility and belongs to the following product:

Unique Number & Description:	*MFMASK-99* *3ply disposable face mask*
Classification and Type	*Medical device Class 1* | *Surgical mask ≥ Type I*
Country of Origin:	*China*
Product/serial number:	*LOTS:202004 / 20200403A-175x95*

Object of the declaration (identification of MD allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):



The object of the declaration described above is in conformity with the relevant Union harmonization legislation: Medical device 1993/42/EC replaced by (EU) 2017/745 on 26-10-2020

Medical devices (EU) 2017/745
Medical devices 1993/42/EC (till 26-10-2020)
REACH Directive 1907/2006/EC

The following harmonized standards and technical specifications have been applied:

Title, date of standard/specification:

EN14683 annex B (Bacterial Filtration Efficiency)
EN14683 annex C (Breathing Resistance)
*EN14683 (Splash Resistance)**
ANNEX XVII 1907/2006/EC

Notified body (where applicable):

N/A

4 digit notified body number:

Additional information:

**EN14683 (Splash Resistance) not applicable for chirurgical masks Type I and II.*

Signed for and on behalf of:

Ede (NL) *17-04-2020*

R.M. Sillessen
Manager Operations
midocean

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Mid Ocean Brands B.V.**
CLIENT ADDRESS	7/F., Kings Tower, 111 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong
TEST PERIOD	05-Apr -2020~09-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	3ply face mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	202004
Specification	:	MFMASK-99
Size	:	/
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass

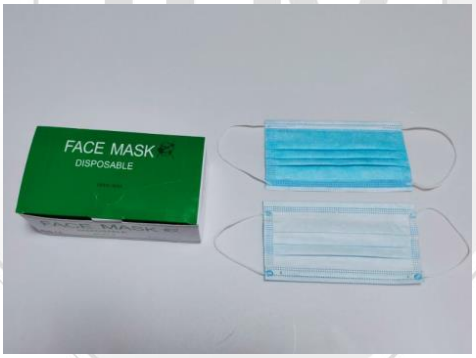
Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment;

N.D. = Not detected.

Photo of Samples



Restults

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.8% Specimen 2#: 99.6% Specimen 3#: 99.8% Specimen 4#: 99.7% Specimen 5#: 99.6%

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : 3ply face mask
Specification : MFMASK-99
Lot Number : 202004
Sample Receiving Date : 2020-04-05

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.

6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

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

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	23	24	0	0	0	0	0	0
2	81	77	0	0	1	0	0	0
3	292	129	0	0	0	0	0	0
4	260	285	0	0	0	2	1	0
5	1518	1438	0	4	4	3	5	6
6	686	692	0	3	6	1	2	4
Total (*T*), CFU	2860	2645	<1	7	11	6	8	10
Average (C), CFU	$2.8x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.8	99.6	99.8	99.7	99.6
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

EN 14683:2005

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.
This standard is intended to help facilitate the choice of surgical face masks in the European Market by standardizing the information and performance data required for the masks.
There are three test methods used to classify surgical masks:

1. Bacterial Filtration Efficiency in vitro (BFE) (ASTM F2101-07**)**
This test is used to determine the amount of infective agent that is retained by the surgical facemask, which is directly related to the amount of bacteria released through the mask into the air of the surgical theatre.
Classification:
BFE => 95% TYPE I
BFE => 98% TYPE II

2. Breathing Resistance (Delta P)
This test is used to determine the resistance airflow of the facemask.
Classification:
TYPE I & II (non splash resistant) = < 29.4 Pa/cm2
TYPE IR & IIR (splash resistant) = < 49.0 Pa/cm2

3. Splash Resistance (ASTM F1862-07**)**
This test is used to determine the resistance penetration of potentially contaminated fluid splashes.
Classification:
TYPE I & TYPE II not applicable
TYPE IR & TYPE IIR >120 mmHg
120 mmHg is a minimum value. It corresponds to the average systolic arterial blood pressure, and intends to protect against ruptures in small arteries causing small sprays of blood. Some products off protection even in excess of the 120 mmHg.

Minimum Performance Requirements According to the New Facemask Standard EN14683

EU Standard Class	Bacterial Filtration Efficiency	Breathing Resistance (Pa/cm2)	Splash Resistance (mmHg)
Type I	95%	< 29.4	NA
Type IR	95%	< 49.0	> 120
Type II	98%	< 29.4	NA
Type IIR	98%	< 49.0	> 120