

BACTERIAL FILTRATION EFFICIENCY (BFE)

REPORT N. 5030-20 Rev. 00

Customer: **Balerina-Czech, s.r.o.**
Prestavlicka 1447 - Mnichovo Hradiste 295 01 - Czech Republic

TIME SCHEDULE

Acceptance N.: 20-4746
Samples receiving date: 09/07/2020
Start test date: 10/07/2020
End test date: 15/07/2020
Coronati Consulting Operator: Dr. C. Pellegrini

TEST MANAGEMENT

Coronati Consulting S.r.l Via L. Gavioli, 3 I-41037 Mirandola (MO) Certified ISO 9001/ ISO 13485

The test was performed at Eurofins Cosmetics & Personal Care Italy Srl Via Bruno Buozzi, 2 I-20090 – Vimodrone (Italia)

REFERENCE DOCUMENTS

UNI EN 14683:2019 "Medical face masks - Requirements and test methods" - Annex B

PROCEDURES

All procedures used during this study are recorded in the Laboratory Coronati Consulting s.r.l.

TEST SAMPLE IDENTIFICATION

Name: **Disposable Face Mask BFE 99 Balerina**
Sample Typology: medical face mask
Composition: 3 layers medical face mask
For additional information see in the next page
Quantity tested: 5
Code (REF): DFM3-2020
Batch: 2020-29-06-49
Manufacturing date: 2020-29-06
Expiry date: 2023-29-06
Sterilization Method: Not sterile
Sterilization Batch: N/A
Sterilization Date: N/A
Sterilization Unit: N/A

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of the Customer and have not been verified by the test laboratory.

Issue Date	Rev.	Change Description	Prepared by: Dr. D. Cattabriga (Laboratory Technician)	Verified and Approved by: Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
17/07/2020	00	First Issue	<i>Devis Cottalupo</i>	<i>Renzo Coronati</i>

This test report is digitally signed by Dr. Renzo Giovanni Coronati.
The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.

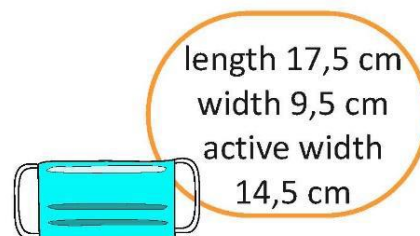
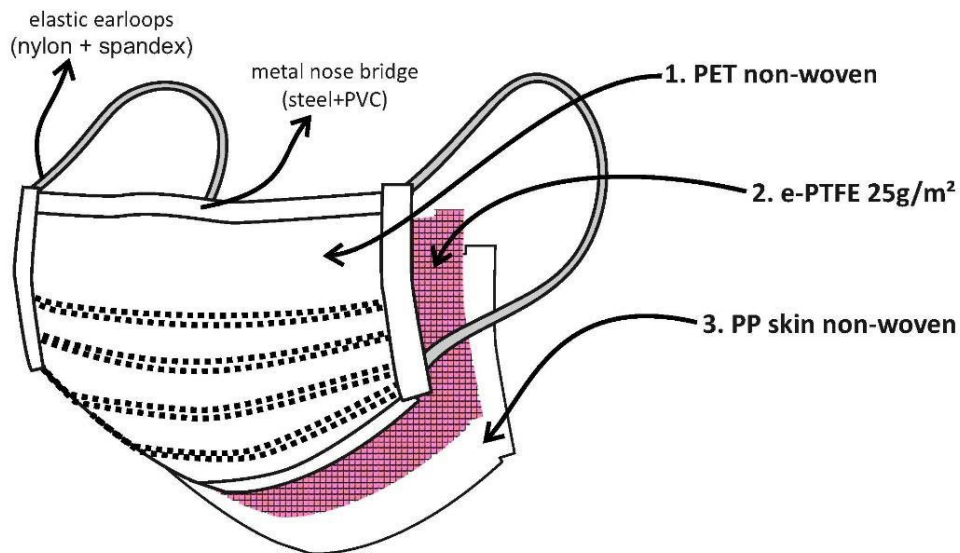
*The sampling is performed by the Customer. The test results are related only to the test samples as received.
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Drawing and component list of the sample

Disposable Face Mask BFE 99 *Balerina*

3 layers

Material and Design:



Manufacturer: Balerina-Czech, s.r.o., Mnichovo Hradiště

PROCEDURE

All procedure is reported in Annex 01.

ACCEPTANCE CRITERIA (according to UNI EN 14683:2019 par. 5.2.7, table 1)

	Type I (a)	Type II	Type IIR
Bacterial filtration efficiency (BFE)	≥ 95 %	≥ 98%	≥ 98%
(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 health care professionals in an operating room or in other medical settings with similar requirements.			

RESULTS

The results are reported in Annex 01 and summarized below:

Bacterial filtration efficiency (BFE) UNI EN 14683:2019 +AC:2019 Annex B			
Aliquot 1		100.00	%
Aliquot 2		99.86	%
Aliquot 3		99.70	%
Aliquot 4		100.00	%
Aliquot 5		99.97	%

RECORD FILING

An original copy of Test Report Eurolab S.r.l. Analytical Report: AAI78462 is available at Coronati Consulting.

ANNEX

Annex 01: Test Report Eurolab S.r.l. Analytical Report: AAI78462

-----End of Report-----

ANNEX 01

Report n. 5030-20 Rev.00 dated 17/07/2020

Coronati Consulting S.r.l.
Via Luigi Gavioli, 3
Mirandola (MO)
IT

Client Account Number: APH008934
Eurofins Quote Number: N3OPPH20018101

Eurofins Sample Number LV20AB1302-1	
Original Received Date:	13-Jul-2020
Description:	DFM3-2020 - Disposable Face Mask BFE 99 Balerina (20-4746)
Lot Number:	2020-29-06-49
Protocol Reference: Bacterial Filtration Efficiency (BFE) - EN 14683:2019+AC:2019 Annex B	
General Method Reference: Bacterial Filtration Efficiency (BFE) - EN 14683:2019+AC:2019 Annex B	

Analysis	Result	Unit
Bacterial Filtration Efficiency (BFE) - EN 14683:2019+AC:2019 Annex B		
Aliquot 1	100.00	%
Aliquot 2	99.86	%
Aliquot 3	99.70	%
Aliquot 4	100.00	%
Aliquot 5	99.97	%

Sample description and experimental conditions: see Addendum 1

Detailed Results: see Addendum 2

Analysis Date: 14-Jul-2020 to 15-Jul-2020

Contracted Company: Eurofins Biolab Srl (Vimodrone)
Via Bruno Buozzi, 2, Vimodrone, MI 20090 Italy InfoFarma@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Employee
for Eurofins Biolab Srl, on 15-Jul-2020 14:49:37 UTC+02:00

LV20AB1302-1




Dimension of the test specimen: 170 mm x 100 mm

Size of the area tested: 49 cm²

Flow rate during testing: 28,3 l/min

Inner side of the mask to the aerosol challenge.

 eurofins	Bacterial Filtration Efficiency (BFE) - EN 14683	EDR: 1-P-QM-TEM-9087392
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 Started on: 14/07/2020

 Batch: LV20AB1302

 Sample description: DFM3-2020 - Disposable Face Mask BFE 99 Balerina (20-4746)

 Lot Number: 2020-29-06-49
Negative Control Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Mean
Negative Control (CFU)	0	0	0	0	0	0	0

*number of colonies adjusted with positive-hole correction table

Positive Controls Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
Size of particle (μm)	7,00	4,70	3,30	2,10	1,10	0,65	
Positive Control N.1 (CFU)	224	306	1010	675	465	239	2919
Positive Control N.2 (CFU)	208	297	986	703	499	295	2988

*number of colonies adjusted with positive-hole correction table

 Mean of the total plate counts of the two positive controls (CFU): 2954
Mean Particle Size (MPS)

	MPS
Positive Control N.1 (μm)	2,89
Positive Control N.2 (μm)	2,79
Mean (μm)	2,84

Test specimens Plate Counts


	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
LV20AB1302-1 - Aliquot 1	0	0	0	0	0	0	0
LV20AB1302-1 - Aliquot 2	0	0	0	0	1	3	4
LV20AB1302-1 - Aliquot 3	0	0	0	0	3	6	9
LV20AB1302-1 - Aliquot 4	0	0	0	0	0	0	0
LV20AB1302-1 - Aliquot 5	0	0	0	0	0	1	1

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
LV20AB1302-1 - Aliquot 1	100,00
LV20AB1302-1 - Aliquot 2	99,86
LV20AB1302-1 - Aliquot 3	99,70
LV20AB1302-1 - Aliquot 4	100,00
LV20AB1302-1 - Aliquot 5	99,97

 Date: 15. 07. 20

 Technician sign: 

 Date: 15. 07. 20

 Approval sign: 

Revision: 1	Local Reference : Mod. PS/MIC/122.B	Page 1 of 1
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