



EUROFINS Medical Device Testing

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FINAL REPORT: Analytical Report for Particulate Filtration Efficiency, N95 Masks

Prepared for:

Breathh, Inc.
9830 Siempre Viva Rd. #15
San Diego CA - 92154
USA

Eurofins Medical Device, Study #: **STUUY20AA0174**



Analytical Report Nr.	AR-20-YL-007675-01
Sample code Nr.	560-2020-00006491
Date	12/11/2020

ANALYTICAL REPORT

Client Information

Eurofins Medical Device Testing
 2425 New Holland Pike
 Lancaster USA
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 KellyConner@eurofins.com
 For the attention of Kelly Conner

Sample Information

Order Code:	EUAA70-00008339
Reception Date:	23-Sep-2020
Analysis Starting Date:	23-Sep-2020
Analysis Ending Date:	12-Nov-2020
Sample code Nr.	560-2020-00006491
Sample described as:	Masks

Requirements and decision rule

Customer requirements:	No requirements
Decision Rule:	Not applicable.

Information provided by the customer*

Client Reference:	EN 14863-19 & ASTM F2100-19
Sample Description:	On behalf of Breathh Inc/ Lutema Products Worldwide
Purchase Order Number:	

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SAMPLE PICTURE





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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
◆ Determination of face mask materials efficiency to penetration by particulates (latex spheres) ASTM F2299 / F2299M - 03(2017)			
A			REFER RESULT

Remark: Test has been performed as per application request

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COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	A	Mask	Pink	---

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
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Analyses on:A

- ◆ **Determination of face mask materials efficiency to penetration by particulates (latex spheres)**

Analysis Ending Date: 12/11/2020

ASTM F2299 / F2299M - 03(2017)

Filtration Efficiency

99.82 %

-

Particle diameter: 0.1 μm \pm 0.015 μm
Complete test data reported at Annex.

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Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Maria Jesus Martinez Puig
Chemical Lab manager

EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
 - Test is subcontracted within Eurofins group and is accredited
 - Test is subcontracted within Eurofins group and is not accredited
 - Test is subcontracted outside Eurofins group and is accredited
 - Test is subcontracted outside Eurofins group and is not accredited
- N/A = Not Applicable

*Eurofins Textile Testing Spain S.L.U is not responsible of the information supplied by the customer and reported as section "Information provided by the customer**".

Eurofins General Sales Terms and Conditions Applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in section "Sample information" and tested in conditions shown in present report.

Test uncertainties not reported are at customer disposal, for those tests in which it is possible to evaluate the test uncertainty.

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%.

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If you happen to have any comments, please do it by sending email to textile_spain@eurofins.com and referring to this report number.

End Of Report



Test report Annex
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DETERMINATION OF THE INITIAL EFFICIENCY OF MATERIALS USED IN MEDICAL FACE MASKS TO PENETRATION BY PARTICULATES USING LATEX SPHERES

Standard: ASTM F2299 / F2299M - 03(2017)

Number of test specimens: 5

Thickness: 1,43 mm

Unit area weight: 228,40 g/m²

Exposed specimen area: 23,8 cm²

Size of test specimen was facing towards the challenge aerosol: Inner

Face velocity: 6 cm/s

Pressure drop: -0,3 mmH₂O

Particle diameter: 0.1 µm ± 0.015 µm

Conditioning and test conditions: T^a between 18°C and 24°C. HR% between 30 and 50 % Hr

Pretreatment techniques used: No

Test duration: Three one-minute counts per specimen

Controls used: Three one-minute control counts were performed, without testing sample, before and after each 5 specimens. Control counts are averaged.

Testing date: 12/11/2020

Deviation from the stated method: Test aerosol is non-neutralized according to the FDA guidance document on surgical face masks.

Test results:

Specimen	Filtration Efficiency (%)
1	99,86
2	99,83
3	99,83
4	99,76
5	99,82
Average	99,82
Standard Deviation	0,04