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25/09/2020

ANALYTICAL REPORT

Client Information

Eurofins Medical Device Testing 2425 New Holland Pike Lancaster USA +1 717 725 8250 KellyConner@eurofins.com

For the attention of Kelly Conner

Sample Information

Order Code: EUAA70-00008283

Reception Date:21-Sep-2020Analysis Starting Date:21-Sep-2020Analysis Ending Date:25-Sep-2020

Sample described as: Masks

Information provided by the customer:

Client Reference: EN 14863 -19 & ASTM F2100-19

Sample Description: On behalf of Breathh Inc./ Lutema Products Worldwide

Customer requirements: No requirements

Purchase Order Number:

Decision rule Not applicable.





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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 - Mask			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	Mask	Green	



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CHEMICAL TESTS CAS No. **RESULTS** UNC. LOQ **GUIDELINES**

Analyses on: A - Mask

• Determination of face mask materials efficiency to penetration by particulates (latex

ASTM F2299 / F2299M - 03(2017)

Filtration Efficiency 99.93 %

Particle diameter: 0.1 µm ± 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 General Sales Terms and Conditions applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in point related to sample description, and tested in conditions shown in present report.

Test uncertainties not reported are at customer disposal.

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

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End Of Report



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: 0,42 mm

Unit area weight: 84,5 g/m²

Exposed specimen area: 78,5 cm²

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

Face velocity: 6 cm/s

Pressure drop: 0,0 mmH₂O

Particle diameter: 0.1 µm ± 0.015 µm

Conditioning and test conditions: Ta 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: 22/09/2020

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	99,90		
2	99,92		
3	99,94		
4	99,96		
5	99,93		
Average	99,93		
Standard Deviation	0,02		