

Analytical Report Nr.

AR-20-YL-008943-01

Sample code Nr.

560-2020-00009590

Date

21/12/2020

**ANALYTICAL REPORT****Client Information**

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Eurofins Medical Device Testing  
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For the attention of Aditi Anand

**Sample Information**

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**Order Code:** EUAA70-00009654  
**Reception Date:** 9-Dec-2020  
**Analysis Starting Date:** 9-Dec-2020  
**Analysis Ending Date:** 21-Dec-2020  
**Sample code Nr.** 560-2020-00009590  
**Sample described as:** Masks

**Requirements and decision rule**

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**Customer requirements:** No requirements  
**Decision Rule:** Not applicable.

**Information provided by the customer\***

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**Client Reference:** DMF4L  
**Sample Description:** On behalf of: Breathh Inc./Lutema  
**Purchase Order Number:**

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**Batch** BLR156

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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	Pink	---

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MASKS TESTING

CAS No.

RESULTS

UNC.

LOQ

GUIDELINES

**Analyses on:A - Mask****◆ Determination of face mask materials efficiency to penetration by particulates (latex spheres)**

Analysis Ending Date: 21/12/2020

ASTM F2299 / F2299M - 03(2017)

Filtration Efficiency

99.86 %

-

Particle diameter: 0.1  $\mu\text{m}$   $\pm$  0.015  $\mu\text{m}$   
Complete test data reported at Annex.

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**Signed for and on behalf of Eurofins Textile Testing Spain:**

eurofins  
Eurofins Textile Testing Spain, S.L.U.  
C/ Constantino Barrio (Alicante)  
E-03074099

Report electronically validated by

**Maria Jesus Martinez Puig**

Chemical Lab manager

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**EXPLANATORY NOTE**

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- ◆ 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

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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](mailto:textile_spain@eurofins.com) and referring to this report number.

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**End Of Report**

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

**Test Method:** ASTM F2299 / F2299M - 03(2017)

**Number of test specimens:** 5

**Thickness:** 0.58 mm

**Unit area weight:** 106.2 g/m<sup>2</sup>

**Exposed specimen area:** 78.5 cm<sup>2</sup>

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

**Face velocity:** 6 cm/s

**Pressure drop:** 0.0 mmH<sub>2</sub>O

**Particle diameter:** 0.1 μm ± 0.015 μm

**Conditioning and test conditions:** T<sup>a</sup> 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:** 09/12/2020

**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	99,84
2	99,87
3	99,89
4	99,87
5	99,83
<b>Average</b>	<b>99,86</b>
Standard Deviation	0,02