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Analytical Report Nr.
Sample code Nr.
Date

AR-20-YL-005289-01 560-2020-00005800 08/09/2020

ANALYTICAL REPORT

Client Information

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

For the attention of Kelly Conner

Sample Information

Order Code: EUAA70-0008016

Reception Date:2-Sep-2020Analysis Starting Date:2-Sep-2020Analysis Ending Date:8-Sep-2020

Sample described as: Masks

Information provided by the customer:

Client Reference:

Sample Description:

Customer requirements: N

Purchase Order Number:

No requirements

DFM3L

Decision ruleNot applicable.BatchNot provided







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SAMPLE PICTURE





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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Breathability (Differential Pressure)			
EN 14683:2019+AC:2019 Annex C	1 1	1 1 1	
		, ,	
A - Mask		1 1 1	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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MASKS TESTING CAS No. RESULTS UNC. LOQ GUIDELINES

Analyses on: A - Mask

Breathability (Differential Pressure)

EN 14683:2019+AC:2019 Annex C

Differential pressure

49.4 Pa/cm²

Complete test data reported at Annex.





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Signed for and on behalf of Eurofins Textile Testing Spain:



Report electronically validated by

Axel Ferrando

Physical-Mechanical 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





METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Test Method: EN 14683: 2019+AC: 2019 Annex C

Number of test specimens: 5

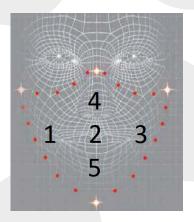
Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

Tested area of the test sample: 4,9 cm²

Flow rate during testing: 8±0,25 l/min

General location of measurement areas: Representative of the overall surface.



Results

Units (Pa)							
Specimen	Position	Position	Position	Position	Position	Mean value	ΔP (Do/om ²)
	1	2	3	4	5	(Pa)	(Pa/cm ²)
1	262	265	271	285	215	260	53,0
2	218	238	205	232	217	222	45,3
3	236	268	275	225	205	242	49,3
4	246	275	219	294	203	247	50,5
5	267	235	208	276	207	239	48,7
			Mean Value	49,4			
						Uncertainty	± 2,7

Observation:

For thick and rigid masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.



Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30