

START DATE 23/06/2020
END DATE 08/07/2020

APPLICANT

Opharm Sp. z o.o.
POKRZYWNICA 62
99-120 Piatek .

SAMPLE
DESCRIPTION

Sample Received 23/06/2020
Reference: SANI - DM - 01
Colour: BLUE
Batch number: S001
Fiber composition POLYPROPYLENE
Buyer's Name: Opharm Sp. z o.o.



TEST METHOD	SAMPLE DESCRIPTION	PARAMETERS	RESULT	U.M.	LIMITS	NOTES	LAB
Bacterial Filtration Efficiency EN 14683: 2019 <u>Operating Conditions</u> Temperature: 21±5°C Humidity: 75±5% Dimensions of the test specimens: 4.9cm ² (5 test specimens) Side of the test specimen facing the challenge aerosol: intern Air flow rate: 13 l/min. MPS 3.0 Expanded uncertainty = 0.16% (based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%)	01	Specimen 1	99,7	%			PT
		Specimen 2	98,7	%			PT
		Specimen 3	98,0	%			PT
		Specimen 4	98,7	%			PT
		Specimen 5	98,2	%			PT
		Result	98,6	%		>=95	
Differential Pressure (BREATHABILITY) EN 14683:2019 <u>Operating Conditions</u> Test Conditions: Temperature: 21±5°C Humidity: 75±5% Number and general location of the areas of the mask the differential measurements were taken: Test performed with the direction of flow from the inside to the outside. Side and central location. Air flow rate: 5.5L/min Dimensions of the test specimens: 4.9cm ² (5 test specimens)	01	Result	<20	Pa/cm ²	<40		PT
		Result	>=16	kPa			PT
Splash Resistance Pressure ISO 22609:2004 <u>Operating Conditions</u> Test Conditions: Temperature: 21±5°C Humidity: 75±5% Number and general location of the areas: center /32 test specimens AQL < 4%	01	Result	>=16	kPa			PT

Laboratory Manager


 Ilenia Francioni
 ilenia.francioni@intertek.com

TEST METHOD	SAMPLE DESCRIPTION	PARAMETERS	RESULT	U.M.	LIMITS	NOTES	LAB
Microbial Cleanliness/Bioburden EN 14683:2019/ EN ISO 11737-1:2018 <u>Operating Conditions</u> Test Conditions: Temperature: 21±5°C Humidity: 75±5% 5 min shaker at 250rpm Area of each test specimen: 5 test specimens Mic30°C (3 days), Molds and yeasts 25°C (7 days)	01		Result	11	UFC/g	<=30	PT

Test performed by:

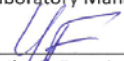
PT: Intertek Portugal Unipessoal LDA
 Rua Antero De Quental 221 S.102
 Perafita-Matosinhos

The partial reproduction of the present Test Report is not allowed without written authorization of the General Manager.
 The content of the present document refers exclusively to the submitted samples and not to the batch that they want to represent.
 A representative portion of the sample is kept for 60 days. Specimen are kept for 30 days.
 Samples are drawn by customer.
 UM: unit of measurement
 Limits are based on Customer's Manual in force available at Intertek Italia S.p.a. - Via di Stagno 17 F/G - 50055 Lastra a Signa (FI)
 Uncertainty is the extended uncertainty calculated using a coverage factor of 2 which gives a level of confidence of approximately 95%.
 All the results are reported without considering the uncertainty.
 LQ: Quantification Limit

RESULTS MARKED IN RED EXCEED LIMITS

END OF TEST REPORT

Laboratory Manager


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