TEST REPORT N°

ITAT20016345/E1 - Amendment of 20/11/2020

START DATE 28/10/2020
END DATE 20/11/2020

intertek
Total Quality. Assured.

APPLICANT

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

SAMPLE DESCRIPTION	Quotation No. 1451/IR Sample Received 28/10/2020 Reference: K-1 Colour: WHITE Batch number: K-11/2020 Fiber composition POLYPROPYLENE Buyer's Name: Opharm Sp. z o.o.

Sample 01

Test	Rating	Failure result
Bacterial Filtration Efficiency EN 14683: 2019 + AC 2019	P	
Differencial Pressure (BREATHABILITY) EN 14683:2019 + AC 2019	P	
Splash Resistance Pressure ISO 22609:2004	P	
Microbial Cleanliness/Bioburden EN 14683:2019/ EN ISO 11737-1:2018	P	

P = MEETS REQUIREMENT / A = ACCEPTABLE / F = DOES NOT MEET REQUIREMENT / NR = NO REQUIREMENT / SC = STILL CONTINUES / X = NOT PERFORMED
Values in brackets represent the limits

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TEST METHOD	SAMPLE DESCRIPTION	PARAMETERS	RESULT	U.M.	LIMITS	NOTES	LAB
Bacterial Filtration Efficiency EN 14683: 2019 + AC 2019 Operating Conditions Test Conditions: Temperature: 21±5ºC Humidity: 85± 5% Dimensions of the test specimens: 49cm2 (5 test specimens) Side of the test specimen facing the challenge aerossol: intern Air flow rate: 28.3 l/min. MPS 2.9 The expanded uncertainty at a confidence level of 95%, k=2: 1.8%	01						
		Specimen 1	98,7	%			PT
		Specimen 2	98,7	%			PT
		Specimen 3	98,8	%			PT
		Specimen 4	99,0	%			PT
		Specimen 5	98,5	%			PT
		Result	98,7	%	>=95		PT
Differencial Pressure (BREATHABILITY) EN 14683:2019 + AC 2019 Operating Conditions Test Conditions: Temperature: 21±5ºC Humidity: 85± 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: 8L/min Dimensions of the test specimens: 4.9cm2 (5 test specimens) The expanded uncertainty at a confidence level of 95%, k=2: 8.7%	01						
		Specimen 1	26,5	Pa/cm²			PT
		Specimen 2	26,5	Pa/cm²			PT
		Specimen 3	26,5	Pa/cm²			PT
		Specimen 4	26,5	Pa/cm²			PT
		Specimen 5	26,5	Pa/cm²			PT
		Result	26,5	Pa/cm²	<40		PT

Laboratory Manager

Ilenia Francioni
ilenia.francioni@intertek.com

Validated by: Ilenia Francioni

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TEST METHOD	SAMPLE DESCRIPTION	PARAMETERS	RESULT	U.M.	LIMITS	NOTES	LAB
Splash Resistance Pressure ISO 22609:2004 Operating Conditions Test Conditions: Samples exposed to a jet of 2mL synthetic blood at pressure (low: 10.6 KPa; medium: 16.0 KPa; high:21.3 KPa) aimed at the centre of the mask. Test performed at laboratory temperature of 21ºC and 45% relative humidity, within 60 seconds after the mask was removed from the conditioning chamber Observation after 10+1 second of blood penetration on the opposite side of the mask. Synthetic blood according to Annex B of ISO 22609: 2004 with surface tension of 42 + 2mN / Number and General location of the áreas: 32 test specimen / center (pass at least Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, acording EN 14683: 2019 mask Type IIR)	01	Result	16	kPa	>=16		PT
Microbial Cleanliness/Bioburden EN 14683:2019/ EN ISO 11737-1:2018 Operating Conditions Test Conditions: 5 min shaker at 250rpm Área of each test specimen: 5 test specimens Mic30ºC (3 days), Molds and yeasts 25ºC (7 days) The expanded uncertainty at a confidence level of 95%, k=2: 20%	01	Specimen 1	19	UFC/g			PT
		Specimen 2	23	UFC/g			PT
		Specimen 3	24	UFC/g			PT
		Specimen 4	20	UFC/g			PT
		Specimen 5	19	UFC/g			PT
		Result	21	UFC/g	<=30		PT

Test performed by:
PT: Intertek Portugal Unipessaol LDA
Rua Antero De Quental 221 S.102
Perafita-Matosinhos

Amendment 1: splash test requirement was added as per applicant request
This Report replaced the report n° ITAT20016345 dated on 13/11/2020 and must be used instead of it.

Laboratory Manager
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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
As received by the customer, the sample was accepted for testing.

RESULTS MARKED IN RED EXCEED LIMITS

END OF TEST REPORT

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