

NYLSTAR, S.L.
AVDA. DE L'ESTACIÓ, 53
17300 - BLANES
GIRONA (ESPAÑA)

TECHNICAL REPORT

Report Nr: IN-00643/2020-2
Total pages: 7

SAMPLE PRESENTED

Description of the sample:

According to the information provided by applicant:

Description of the product:
Reference: 28H_ 46330_SLF_KIT (2 LAYERS)

Date arrival: 25/04/2020

REQUESTED DETERMINATIONS

➤ Test(s) according UNE-EN 14683:2019+AC (EN 14683:2019+AC)

5.2.2 METHOD FOR IN VITRO DETERMINATION OF BACTERIAL FILTRATION
(Anexo B) EFFICIENCY (BFE).

5.2.3 METHOD FOR THE DETERMINATION OF BREATHABILITY
(Anexo C) (DIFFERENTIAL PRESSURE).

Terrassa, 28th April, 2020

METHOD FOR IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE).

According to: UNE-EN 14683:2019+AC (EN 14683:2019+AC), paragraph 5.2.2 and annex B

Scope: The purpose of this test is to verify the bacterial filtration efficiency (BFE) of the masks, by determining the number of colonies forming units that pass through the material, expressed as a percentage of the number of colonies forming units present in the inoculation spray.

Testing equipment: Six Stage Cascade Impactor
 Nebulizer
 Spray chamber
 Flowmeters
 Manometer
 Peristaltic pump
 Vacuum pump
 Erlenmeyer flasks (250 ml, 500 ml)

Pre-conditioning of the samples: ≥ 4 hours / 21°C ± 5°C / 85% RH. ± 5% RH.

Test conditions

Identification of the material tested: According to the information provided by applicant

- *Reference 28H_46330_SLF_KIT (2 LAYERS)*

Test conditions: 23°C ± 2°C / 50% HR. ± 5% HR.

Number of samples: 5

Test sample dimensions: 100 cm² (10 cm x 10 cm)

Area under test: 50 cm²

Face in direct contact with the inoculating spray: Indistinct

Flow during the test: 28,3 ml/min.

Test microorganism: Staphylococcus aureus ATCC 6538

Bacterial suspension (inoculum): 1,5 x 10⁵ cfu/ml

Incubation conditions: 24 hours at 36°C ± 1°C

Date of performance: 22 - 23 April, 2020

Results:

CONTROL VALUES							
Control	Level 1 (cfu/pl)	Level 2 (cfu/pl)	Level 3 (cfu/pl)	Level 4 (cfu/pl)	Level 5 (cfu/pl)	Level 6 (cfu/pl)	Total count (cfu)
Positive	564	620	688	756	908	462	3998
Negative	0	0	0	0	0	0	0

VALUES OF TEST SAMPLE							
Sample	Level 1 (cfu/pl)	Level 2 (cfu/pl)	Level 3 (cfu/pl)	Level 4 (cfu/pl)	Level 5 (cfu/pl)	Level 6 (cfu/pl)	Total count (cfu)
#1	1	0	0	13	189	74	277
#2	5	0	26	52	153	92	328
#3	10	17	34	38	171	79	349
#4	7	13	22	17	134	82	275
#5	9	9	16	27	146	47	254

CALCULATION OF BACTERIAL FILTRATION EFFICACY (BFE)	
According to equation: $B = (C - T) / C \times 100$	
Where,	
C: Mean total plate count for the two positive controls	
T: Total count for the sample tested	
Test #1	93,07%
Test #2	91,80%
Test #3	91,27%
Test #4	93,12%
Test #5	93,65%
Middle value	92,58%

Conclusions:

Requirement (UNE 0065:2020)	Result	Test OK	Test NOK	NA/ NR
BFE ≥ 90%	92,58%			

METHOD FOR THE DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE).

According to: UNE-EN 14683:2019+AC (EN 14683:2019+AC), paragraph 5.2.3 and annex C

Scope: The purpose of this test is to determine the differential pressure of a mask or a material intended for a mask, understanding air permeability as such, measured by determining the pressure difference through the material under specified conditions of flow, temperature and humidity of the air. Differential pressure is an indicator of the “breathability” of the mask.

Testing equipment: Permeability air, TEXTEST FX 3300-III, nº EQ189

Pre-conditioning of the samples ≥ 4 hours / 21°C ± 5°C / 85% RH. ± 5% RH.

Test conditions:

Identification of the material tested: According to the information provided by applicant

- Reference: 28H_46330_SLF_KIT (2 LAYERS)

Test conditions: 20°C ± 2°C / 65% HR. ± 4% HR.

Number of samples: 1 (minimum 5 measurements)

Test surface: 4,9 cm²

Flow during test: 8 l/min.

Face tested in contact with the head: Indistinct

Date of performance: 22nd April 2020

Results:

	#1	#2	#3	#4	#5
Differential pressure (Pa)	284	289	279	289	284
Differential pressure (Pa/cm ²)	58	59	57	59	58
Mean value (Pa/cm ²)	58				
Uncertainty ⁽²⁾	± 3%				

⁽²⁾ This value corresponds to the relative method uncertainty (%) obtained by multiplying the standard method uncertainty by the coverage factor $k = 2$, which, for a normal distribution, corresponds to a coverage probability of approximately 95%.

Conclusions:

Requirement (UNE 0065:2020)	Results	Test OK	Test NOK	NA/ NR
Breathability ≤ 60 Pa/cm ²	58 Pa/cm ² ± 3%			

METHOD FOR IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE).

According to: UNE-EN 14683:2019+AC (EN 14683:2019+AC), paragraph 5.2.2 and annex B

Scope: The purpose of this test is to verify the bacterial filtration efficiency (BFE) of the masks, by determining the number of colonies forming units that pass through the material, expressed as a percentage of the number of colonies forming units present in the inoculation spray.

Testing equipment: Six Stage Cascade Impactor
 Nebulizer
 Spray chamber
 Flowmeters
 Manometer
 Peristaltic pump
 Vacuum pump
 Erlenmeyer flasks (250 ml, 500 ml)

Pre-conditioning of the samples: ≥ 4 hours / 21°C ± 5°C / 85% RH. ± 5% RH.

Test conditions

Identification of the material tested: According to the information provided by applicant
• <i>Reference 28H_46330_SLF_KIT (2 LAYERS)</i>
Test conditions: 23°C ± 2°C / 50% HR. ± 5% HR.
Number of samples: 5
Test sample dimensions: 100 cm ² (10 cm x 10 cm)
Area under test: 50 cm ²
Face in direct contact with the inoculating spray: Indistinct
Flow during the test: 28,3 ml/min.
Test microorganism: Staphylococcus aureus ATCC 6538
Bacterial suspension (inoculum): 1,5 x 10 ⁵ cfu/ml
Incubation conditions: 24 hours at 36°C ± 1°C
Pre-treatment: 5 cycles washing at 60 °C (UNE-EN ISO 6330 program 6N) and air dried (UNE-EN ISO 6330:2012, type A)
Date of performance: 22 - 23 April, 2020

Results:

CONTROL VALUES							
Control	Level 1 (cfu/pl)	Level 2 (cfu/pl)	Level 3 (cfu/pl)	Level 4 (cfu/pl)	Level 5 (cfu/pl)	Level 6 (cfu/pl)	Total count (cfu)
Positive	487	512	609	683	715	437	3443
Negative	0	0	0	0	0	0	0

VALUES OF TEST SAMPLE							
Sample	Level 1 (cfu/pl)	Level 2 (cfu/pl)	Level 3 (cfu/pl)	Level 4 (cfu/pl)	Level 5 (cfu/pl)	Level 6 (cfu/pl)	Total count (cfu)
#1	8	12	5	35	201	79	340
#2	11	2	17	44	132	107	313
#3	17	19	23	44	150	86	339
#4	10	21	31	36	148	97	343
#5	12	17	28	43	175	58	333

CALCULATION OF BACTERIAL FILTRATION EFFICACY (BFE)	
According to equation: $B = (C - T) / C \times 100$	
Where,	
C: Mean total plate count for the two positive controls	
T: Total count for the sample tested	
Test #1	90,12%
Test #2	90,91%
Test #3	90,15%
Test #4	90,04%
Test #5	90,33%
Middle value	90,31%

Conclusions:

Requirement (UNE 0065:2020)	Result	Test OK	Test NOK	NA/ NR
BFE ≥ 90%	90,31%			

METHOD FOR THE DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE).

According to: UNE-EN 14683:2019+AC (EN 14683:2019+AC), paragraph 5.2.3 and annex C

Scope: The purpose of this test is to determine the differential pressure of a mask or a material intended for a mask, understanding air permeability as such, measured by determining the pressure difference through the material under specified conditions of flow, temperature and humidity of the air. Differential pressure is an indicator of the “breathability” of the mask.

Testing equipment: Permeability air, TEXTEST FX 3300-III, nº EQ189

Pre-conditioning of the samples ≥ 4 hours / 21°C ± 5°C / 85% RH. ± 5% RH.

Test conditions:

Identification of the material tested: According to the information provided by applicant
• <i>Reference: 28H_46330_SLF_KIT (2 LAYERS)</i>
Test conditions: 20°C ± 2°C / 65% HR. ± 4% HR.
Number of samples: 1 (minimum 5 measurements)
Test surface: 4,9 cm ²
Flow during test: 8 l/min.
Face tested in contact with the head: Indistinct
Pre-treatment: 5 cycles washing at 60 °C (UNE-EN ISO 6330 program 6N) and air dried (UNE-EN ISO 6330:2012, type A)
Date of performance: 22nd April 2020

Results:

	#1	#2	#3	#4	#5
Differential pressure (Pa)	274	250	279	245	270
Differential pressure (Pa/cm ²)	56	51	57	50	55
Mean value (Pa/cm ²)	54				
Uncertainty ⁽²⁾	± 3%				

⁽²⁾ This value corresponds to the relative method uncertainty (%) obtained by multiplying the standard method uncertainty by the coverage factor $k = 2$, which, for a normal distribution, corresponds to a coverage probability of approximately 95%.

Conclusions:

Requirement (UNE 0065:2020)	Results	Test OK	Test NOK	NA/ NR
Breathability ≤ 60 Pa/cm ²	54 Pa/cm ² ± 3%			