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TEST REPORT

2021TM0674

DATE OF RECEPTION
10/03/2021

DATE TESTS
Starting: 10/03/2021
Ending: 25/03/2021

APPLICANT

HOLIK INTERNATIONAL S.R.O.
ZA DVOREM 612, 763 14
CZ-12 ZLÍN
ZLÍN

Att. Hana Kováčová

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
Medical face mask NANO M8002

TESTS CARRIED OUT

- IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE) / *STANDARD.*
- DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE) / *STANDARD.*
- DETERMINATION OF PRESSURE OF SPLASH RESISTANCE.
- DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS.
- TEST FOR CYTOTOXICITY.

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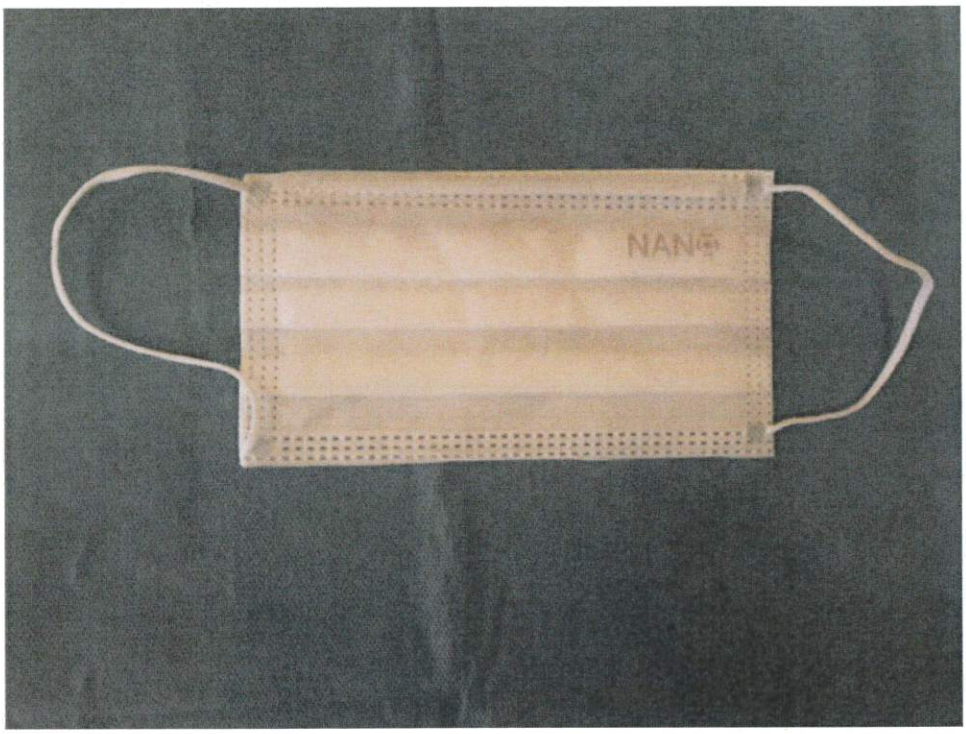
*Tests marked with * are not included within the scope of the ENAC accreditation*

ilac-MRA ENAC ENSAYOS Nº12 / LE025 Nº12 / LE427

SAMPLE DESCRIPTION

FOTOGRAFÍA
PHOTOGRAPHY



Referencia [1]
Reference [1]

Medical face mask NANO M8002

Nº lote [1]
LOT number [1]

-

[1] Dato proporcionado por el cliente
[1] *Data provided for the customer*

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RESUMEN / *SUMMARY*

Of the tests carried out on the following reference:

Medical face mask NANO M8002

ORIGINAL. No pretreatment has been performed.

Tests according to the standard EN 14683:2019+AC: 2019.

Having obtained the following results:

TESTS	RESULTS
Pto 5.2.2 Bacterial Filtration Efficiency (BFE) (%)	**99,94**
Pto 5.2.3 Breathability: Differential pressure (Pa/cm^2)	**59,5**
Pto 5.2.4 Splash resistance pressure (kPa)	**Failure 0 of 32 at 21,3 kPa**

Notes

- The rest of the standard tests not indicated in this report, have not been evaluated.

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RESULTS

IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Standard
EN 14683:2019+AC:2019

Test date
23/03/2021 - 24/03/2021

Batch n°[1]

Reference
Medical face mask NANO M8002

Number of test specimen
5

Size of test specimen
10 cm x 10 cm

Tested area of the test specimen
50 cm^2

Sample side was oriented toward the challenge aerosol
Inner side

Equipment
Six stage Andersen Sampler (03285E12)

Flow of air
28.3 l/min

Test germ
Staphylococcus aureus ATCC 6538

Incubation conditions
24 h at 37 ± 2 °C

Uncertainty of the test
The relative expanded uncertainty of the test is ± 5 % assay value of the measured.

>>>

RESULTS

Test sample values							
	Level1 (cfu/plate)	Level2 (cfu/plate)	Level3 (cfu/plate)	Level4 (cfu/plate)	Level5 (cfu/plate)	Level6 (cfu/plate)	Total count (ufc)
1	0	0	1	0	1	0	**2**
2	0	0	0	1	0	0	**1**
3	0	0	0	1	0	0	**1**
4	0	0	0	1	0	0	**1**
5	0	0	0	1	1	0	**2**

Legend meaning: cfu: colony forming units

Pre-treatment Original. No pretreatment has been performed.

Calculation of bacterial filtration efficiency:

Test	Filtration efficiency (%)
1	99,91
2	99,96
3	99,96
4	99,96
5	99,91
Mean	**99,94**

Notes

- The "positive hole" conversion factor described by A. Andersen has been applied to the number of CFU colony forming units collected by the cascade impactor for the sample and positive control.
- Tested samples were supplied by the customer.
- Mean of the plate counts of the negative controls: 0 ufc.
- Mean of the total plate counts of the two positive controls: 2249 cfu.

- [1] Data provided by the customer.

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RESULTS

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Standard
EN 14683:2019+AC:2019

Principle
It is measure the differential pressure required to move air through a measured surface area at a constant flow of air, with the aim of measuring the pressure of air exchange of the material of the mask.

Test date
19/03/2021 - 22/03/2021

Batch n°(1)

Reference
Medical face mask NANO M8002

Number of test specimen
5

Size of test specimen
4.9 cm^2

Tested area of the test specimen
Circular, diameter 2.5 cm

Sample conditioning
T^a 21 ± 5 °C Hr 85 ± 5 %

Flow of air
(8 ± 0,3) l/min

Pre-treatment
Original. No pretreatment has been performed.

Uncertainty of the test
The relative expanded uncertainty of the test is ± 6 % assay value of the measured

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RESULTS

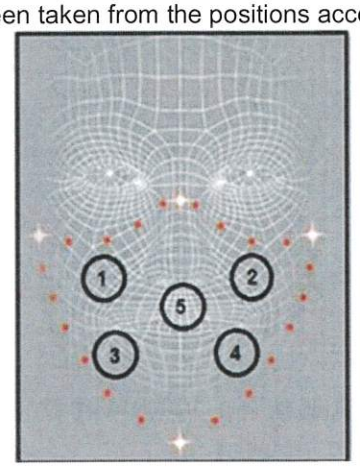
Results

Test specimen	Pos1 Pa	Pos2 Pa	Pos3 Pa	Pos4 Pa	Pos5 Pa	Average Pa	ΔP (Pa/cm²)
1	294,2	303,8	292,3	301,2	292,0	296,7	60,6
2	292,1	289,6	301,7	281,3	302,7	293,5	59,9
3	285,3	275,6	302,8	286,7	304,2	290,9	59,4
4	290,6	278,6	301,7	274,6	272,0	283,5	57,9
5	304,6	300,7	281,3	289,6	287,3	292,7	59,7
					Average	291,5	59,5

Notes

- Tested samples were supplied by the customer.

- The specimens of each mask have been taken from the positions according to the image:



- [1]Data provided by the customer.

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RESULTS

DETERMINATION OF PRESSURE OF SPLASH RESISTANCE

Standard EN 14683:2019+AC:2019 **Test method** ISO 22609:2004

Principle:

A defined volume of synthetic blood is shot with defined speeds of a pneumatically checked valve at the test specimen, in order to simulate a squirting of blood and other body fluids for the sample material. The back of the mask is examined by means of visual inspection and swab on penetrating liquid. The more the resistance against liquid splashes, the more merrier is the liquid resistance.

Test date

24/03/2021 - 25/03/2021

Batch n°(1)

Reference

Medical face mask NANO M8002

Material of test sample

Fabric

Tested area of the test specimen

19.6 cm^2

Sample Conditioning

Tª 21 ± 5 ºC

Hr 85 ± 5 %

Test environmental test conditions

Tª 21 ± 5 ºC

Hr 36 ± 5 %

Test parameters 21,3 kPa (160 mm de Hg) **Volume of synthetical blood** 2.0 mL

Pre-treatment

Original. No pretreatment has been performed.

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RESULTS

Results Pressure 21,3 kPa (160 mm de Hg)		
Replica	**Passed**	**Failed**
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26	X	
27	X	
28	X	
29	X	
30	X	
31	X	
32	X	

>>>

RESULTS

Remarks

- To pass the test no more than 3 of 32 samples may fail.
- [1]Data provided by the customer.

///

RESULTS

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Standard

EN 14683:2019+AC:2019; EN ISO 11737-1:2018

Reference
Medical face mask NANO M8002

Batch number [1]

Sample size (SIP)
3,48 g

Replica number
5

Test date
16/03/2021 – 21/03/2021

Test equipments

Incubator (03068E05) and Incubator (03202E05)

Results

Parameter	Replica 1 (ufc/g)	Replica 2 (ufc/g)	Replica 3 (ufc/g)	Replica 4 (ufc/g)	Replica 5 (ufc/g)	Average (ufc/g)
Aerobic bacteria to 33 ± 2°C	<1	2	<1	1	2	1
Moulds and yeasts to 22 ± 2°C	<1	<1	<1	<1	<1	<1

RESULTS

Notes

(1) Data provided from customer

The total count of microorganisms in the sample is 1 cfu/g

In accordance with the standard EN 14683:2019+AC:2019, the results must be in the values of the following table:

Parameter		
Cleanliness microbial	ufc/g	≤ 30

///

RESULTS

TEST FOR CYTOTOXICITY

Standard
EN ISO 10993-5:2009

Test method
Direct contact

Exposure period
24 h.

Culture plates
EMEM

Celular line
NCTC-L-929

Test date
11/03/2021 – 13/03/2020.

Reference

Medical face mask NANO M8002

Quatitative evaluation

- Sample
95,50 % Viable cells (Vital stain: Trypan Blue)

- Negative control
100 % Viable cells (Vital stain: Trypan Blue)

RESULTS

Qualitative evaluation

After the contact period a slight cell monolayer detachment is observed below the sample. The cells maintain cell membrane integrity and cytoplasmic vacuolization is not evidence or other alteration suggestive of cell damage. It is not observed a decreased cell growth during the incubation time in the presence of the device.

Conclusion Grade 1

TABLE 1. Evaluation of the cytotoxicity grade for the qualitative evaluation of the direct contact test.

Cytotoxicity grade	Reactivity	Description of the reactivity zone
0	Non reactivity	Zone non detectable around or under the sample.
1	Light	Some malformed or degenerated cells below the sample.
2	Slight	Zone limited to area under sample.
3	Moderate	Zone extending up to 1 cm from the edge of the sample size.
4	Severe	Zone extending more than 1 cm from the edge of the sample size.

Remarks

- In the quantitative assessment, a value of less than 70% of viable cells was considered cytotoxic effect.
- En la valoración cualitativa, se considera efecto citotóxico un grado superior a 2 en la Tabla 1.

In the qualitative assessment is considered like cytotoxic effect, grade higher to 2 in Table 1.

Judit Sisternes
Head of Health & Hygiene Products Division

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