

## TEST REPORT

**2020TM4576**

### DATE OF RECEPTION

15/09/2020

### DATE TESTS

Starting: 16/09/2020

Ending: 29/09/2020

### APPLICANT

HOLIK INTERNATIONAL S.R.O.

ZA DVOREM 612, 763 14

CZ-12 ZLÍN

ZLÍN

Att. Marcela Mlcková

### IDENTIFICATION AND DESCRIPTION OF SAMPLES

#### REFERENCES

SURGICAL FACE MASK M8001

### 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.



## SAMPLE DESCRIPTION

### FOTOGRAFÍA PHOTOGRAPHY



### Referencia <sup>(1)</sup>

### Reference <sup>(1)</sup>

SURGICAL FACE MASK M8001

### Nº lote <sup>(1)</sup>

### LOT number <sup>(1)</sup>

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<sup>(1)</sup> Dato proporcionado por el cliente

<sup>(1)</sup> Data provided for the customer

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## RESUMEN / SUMMARY

Of the tests carried out on the following reference:

### **SURGICAL FACE MASK M8001**

**ORIGINAL. No pretreatment has been performed.**

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

Having obtained the following results:

TESTS	RESULTS (Average $\pm$ SD)
Pto 5.2.2 Bacterial Filtration Efficiency (BFE)* (%)	<b>99,51 <math>\pm</math> 0,16</b>
Pto 5.2.3 Breathability: Differential pressure* (Pa/cm <sup>2</sup> )	<b>59,8 <math>\pm</math> 1</b>
Pto 5.2.4 Splash resistance pressure* (kPa)	<b>Failure 0 of 32 at 17 kPa</b>

#### **Notes**

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

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## RESULTS

### IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)\*

**Standard**

EN 14683:2019+AC:2019

**Test date**

24/09/2020 - 25/09/2020

**Batch n<sup>o</sup>(1)**

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**Sample reference**

SURGICAL FACE MASK M8001

**Number of test specimen**

5

**Size of test specimen**

10 cm x 10 cm

**Tested area of the test specimen**

50 cm<sup>2</sup>

**Description of the test specimen**

Inner side to the aerosol challenge

**Test control unit**

Six stage Andersen Sampler

**Flow of air**

28.3 l/min

**Test germ**

Staphylococcus aureus ATCC 6538

**Incubation conditions**

24 h at 36 ± 1 °C

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## 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	0	1	1	12	14
2	0	0	1	4	18	4	27
3	0	0	0	0	14	4	18
4	0	0	1	1	6	5	13
5	0	0	0	2	2	12	16

**Legend meaning:** cfu: colony forming units

**Pre-treatment** Original. No pretreatment has been performed.

**Calculation of bacterial filtration efficiency:**

Test	Filtration efficiency (%)
1	99,61
2	99,24
3	99,49
4	99,63
5	99,55
<b>Mean</b>	<b>99,51 ± 0,16<sup>(2)</sup></b>

**Remark**

- 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.

**Notes**

- Tested samples were supplied by the customer.
- Total plate count for blanks are available upon request.
- <sup>(1)</sup>Data provided by the customer.
- <sup>(2)</sup>Standard Deviation of the results.

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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 surgical mask.

**Test date**

29/09/2020 - 30/09/2020

**Batch n<sup>o(1)</sup>**

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**Sample reference**

SURGICAL FACE MASK M8001

**Number of test specimen**

5

**Size of test specimen**

4.9 cm<sup>2</sup>

**Tested area of the test specimen**

Circular, diameter 2.5 cm

**Test environmental conditions**

T<sup>a</sup> 22 °C Hr 30 %

**Flow of air**

(8 ± 0.2) l/min

**Pre-treatment**

Original. No pretreatment has been performed.

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## RESULTS

### Results

Test specimen	Pos1 Pa	Pos2 Pa	Pos3 Pa	Pos4 Pa	Pos5 Pa	Average Pa	$\Delta P$ (Pa/cm <sup>2</sup> )
1	286	298	309	288	274	291	60
2	280	287	294	279	302	288,4	59
3	279	282	284	298	321	292,8	60
4	318	295	289	277	307	297,2	61
5	285	287	279	297	288	287,2	59
					<b>Average</b>	291,32	59,8 ± 1 <sup>(2)</sup>

### Notes

- Tested samples were supplied by the customer.

- <sup>(1)</sup>Data provided by the customer.

- <sup>(2)</sup>Standard Deviation of the results.

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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 speeds and the selected volume correspond to a certain blood pressure, which spurts out by a defined opening size. The test is performed with a pressure of 80, 120 and 160 mmHg. The back of the mask is examined by means of visual inspection and swab on penetrating liquid.

120 mmHg corresponds to the average systolic arterial blood pressure. The more the resistance against liquid splashes, the more merrier is the liquid resistance.

**Test date**

24/09/2020 - 25/09/2020

**Batch n<sup>o(1)</sup>**

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**Sample reference**

SURGICAL FACE MASK M8001

**Number of test specimen**

32

**Size of test specimen**

Circular diameter 5 cm

**Tested area of the test specimen**

19.6 cm<sup>2</sup>

**Conditioning** T<sup>a</sup> 22 °C Hr 80 %      **Test environmental conditions** T<sup>a</sup> 20 °C Hr 36 %  
**Test parameters** 21,3 kPa (160 mm de Hg)      **Volume of synthetical blood** 2.0 mL

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## RESULTS

### Pre-treatment

Original. No pretreatment has been performed.

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	

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## RESULTS

### Remarks

- To pass the test no more than 3 samples at each pressure may fail.

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## RESULTS

### DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

**Standard**

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

**Reference**

SURGICAL FACE MASK M8001

**Batch number** <sup>(1)</sup>

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**Sample size (SIP)**

g

**Replica number**

5

**Test date**

16/09/2020 – 22/09/2020

**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	41	14	38	17	15	25
Moulds and yeasts to 22 ± 2°C	3	2	2	1	1	2



## RESULTS

### Notes

<sup>(1)</sup> Data provided from customer

The total count of microorganisms in the sample is 27 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

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**Judit Sisternes**  
**Head of Health & Hygiene Products Division**

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