TEST REPORT

2020TM0361

DATE OF RECEPTION
19/03/2020

DATE TESTS
Starting: 19/03/2020
Ending: 28/03/2020

APPLICANT

[redacted]

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
MASK REF: **PTXMASKV2_HOSP**

TESTS CARRIED OUT

- CARRIED OUT ON THE FOLLOWING REFERENCE:.
- IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)*.
- DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)*.
- DETERMINATION OF PRESSURE OF SPLASH RESISTANCE*.
- DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS.
- TEST FOR CYTOTOXICITY*.

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

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RESULTS

Carried out on the following reference:

MASK REF: PTXMASKV2_HOSP

With the performance requirements of EN 14683: 2019 + AC: 2019 standard for surgical masks points 5.2.2, 5.2.3 and 5.2.4 for types I, II and IIR.

Having obtained the following results:

Operating requirements:					**RESULTS (Average ± SD)**
		Type I	**Type II**	**Type IIR**	
5.2.2.	Bacterial Filtration Efficiency (BFE) (%)	≥ 95	≥ 98	≥ 98	**99,81 ± 0,19**
5.2.3.	Breathability: Differential pressure (Pa/cm^2)	< 40	< 40	< 60	**54**
5.2.4.	Splash resistance pressure (kPa)	Not required	Not required	≥ 16	**0 de 32 at 21.3 kPa**

Notes:

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

RESULTS

IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)*

Standard

EN 14683:2019+AC:2019

Test date

18/03/2020 – 20/03/2020

Batch n°(1)

Sample reference

MASK REF: PTXMASKV2_HOSP

Number of test specimen

5

Size of test specimen

10 cm x 10 cm

Tested area of the test specimen

50 cm^2

Description of the test specimen

Inner side to the aerosol challenge

Test environmental conditions

Tª 20 ºC Hr 30 %

Test control unit

Six stage Andersen Sampler

Flow of air

28.3 l/min

Test microorganism

Staphylococcus aureus ATCC 6538

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RESULTS

Incubation conditions

48 h at 36 ± 1 ºC

Test time

2 min / test specimen

Results

Control values							
	Level 1 (cfu/plate)	Level 2 (cfu/plate)	Level 3 (cfu/plate)	Level 4 (cfu/plate)	Level 5 (cfu/plate)	Level 6 (cfu/plate)	Total count (ufc)
C.P.	66	64	272	196	144	29	771
C.N.	0	0	0	0	0	0	0

Test sample values							
	Level 1 (cfu/plate)	Level 2 (cfu/plate)	Level 3 (cfu/plate)	Level 4 (cfu/plate)	Level 5 (cfu/plate)	Level 6 (cfu/plate)	Total count (ufc)
1	0	0	0	0	0	0	0
2	1	0	0	0	0	0	1
3	1	0	0	0	1	1	3
4	0	0	0	0	0	0	0
5	1	0	0	1	0	1	3

Legend meaning:

cfu: colony forming units
C.P.: positive control (test run without test specimen).
C.N.: negative control (test run without bacterial suspension).

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RESULTS

Calculation of bacterial filtration efficiency:

Equation: B=(C-T)/Cx100
:

C: Mean of the total plate counts for the two positive control runs

T: Total plate count for the test specimen

Test	Filtration efficiency
1	99,99
2	99,87
3	99,61
4	99,99
5	99,61
Mean	**99,81 ± 0,19** [2]

Notes

- The performance requirement for surgical mask according with EN 14683:2019+AC:2019, is:

Test	Type I	Type II	Type IIR
(BFE) % Bacterial filtration efficiency	≥ 95	≥ 98	≥ 98

- Tested samples were supplied by the customer.

- [1]Data provided by the customer.

- [2] 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

20/03/2020 – 21/03/2020

Batch nº(1)

Sample reference

MASK REF: PTXMASKV2_HOSP

Number of test specimen

5

Size of test specimen

4.9 cm^2

Tested area of the test specimen

Circular, diameter 2.5 cm

Test environmental conditions

Tª 21 ºC Hr 30 %

Flow of air

(8 ± 0.2) l/min

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RESULTS

Results

Test specimen	Pos1 Pa	Pos2 Pa	Pos3 Pa	Pos4 Pa	Pos5 Pa	Average Pa	ΔP (Pa/cm^2)
1	268	268	259	263	241	260	53
2	261	253	276	264	263	263	54
3	262	254	270	275	264	265	54
4	262	226	272	266	292	264	54
5	276	265	256	265	250	262	54
					Average	263	**54**

Notes

- The performance requirement for surgical mask according with EN 14683:2019+AC:2019, is:

Test	Type I	Type II	Type IIR
Differential pressure (Pa/cm^2)	< 40	< 40	< 60

- Tested samples were supplied by the customer.

- (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 speeds and the selected volume correspond to a certain blood pressure, which spurts out by a defined opening size. The test could be 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 barrier is the liquid resistance.

Test date
19/03/2020 – 20/03/2020

Batch n°(1)

Sample reference
MASK REF: PTXMASKV2_HOSP

Number of test specimen
32

Size of test specimen
Circular diameter 5 cm

Tested area of the test specimen
19.6 cm^2

Conditioning	Tª 22 ºC Hr 80 %	**Test environmental conditions**	Tª 20 ºC Hr 32 %
Test parameters	21,3 kPa (160 mm de Hg)	**Volume of synthetical blood**	2.0 mL

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RESULTS

Results

Pressure 21,3 kPa (160 mm de Hg)		
Replica	**Passed**	**Fail**
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 samples at each pressure may fail.

- The performance requirement for surgical mask according with EN 14683:2019+AC:2019, is:

Test	Type I	Type II	Type IIR
Pressure of splash resistance (kPa)	Not required	Not required	≥ 16

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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

MASK REF: PTXMASKV2_HOSP

Batch number [1]

Sample size

3,29 g

Replica number

5

Test date

20/03/2020 – 27/03/2020

Test equipments

Incubator (03068E05) and Incubator (03202E05)

Results

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

RESULTS

Notes

(1) Data provided from customer

The total count of microorganisms in the sample is <2 cfu/g

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

Parameter	Units	Requirement
Cleanliness microbial	cfu/g	≤ 30

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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
23/03/2020 – 25/03/2020

Reference

MASK REF: PTXMASKV2_HOSP

Quatitative evaluation

- Sample
99 % Viable cells (Vital stain: Trypan Blue)

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

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RESULTS

Qualitative evaluation

After the contact period are not observed structural alterations in the cell monolayer under or around the sample. The cells maintain cell membrane integrates and there is no evidence or other alteration cytoplasmic vacuolization suggestive of cell damage.

Conclusion **Grade 0**

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.

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

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