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Bellaterra, 30th November, 2020

File number: **20/ 23467 - 2168**

Applicant: BODY ONE
47 Rue Cartier Bresson
93500 Pantin
France

Date of material delivery: 28th October, 2020

Date of testing: 29th October to 24h November, 2020

TEST REPORT

corresponding to *Medical face masks*

ISSUE REQUESTED

Tests indicated in the application form, according to prescriptions of standard cited below:

- EN 14683: 2019 + AC: 2019 "Medical face masks. Requirements and tests methods"

This document has **7** pages of which **0** is annex, this being page number 1.

SAMPLES (information reported by the Applicant)

Sampling

Date: October 2020

Responsible: BODY ONE

Sample description

REFERENCE	DESCRIPTION TISSUE / LAYERS	RECEIVED FORMAT	Identification A+
BODY ONE	3 layers	Face mask	20/ 2168
			
PACKAGING	Box of 50 units, with bags of 10 units inside		

SCHEDULE OF THE TESTS (only the requested tests are indicated)

Standard EN 14683	Sample ref. **BODY ONE**	Number of samples used in tests
Clause 5.2.2 & Annex B: [1] Bacterial filtration efficiency (BFE)	X	5
Clause. 5.2.3 & Annex C: Breathability (Differential pressure)	X	5
Clause. 5.2.4 & standard ISO 22609: [1] Splash resistance	X	32
Clause 5.2.5 & Annex D: [2] Microbial cleanliness (bioburden)	X	5

Note.- Test carried out in a collaborating centre: [1] AQUIMISA; [2] EURECAT

REQUIRED REQUIREMENTS

According to table 1 of the standard EN 14683, the classification of medical face masks is determined based on the limits established for each of the tests.

Test	**Classification**	**Type I**	**Type II**	**Type IIR**
BFE	(%)	≥ 95	≥ 98	≥ 98
Differential pressure	Pa/cm^2	< 40	< 40	< 60
Splash resistance	kPa	NR	NR	≥ 16
Microbial cleanliness	CFU/g	≤ 30	≤ 30	≤ 30

NR: not required

TEST RESULTS

The result obtained in the samples tested is indicated below, as the average value of the partial values in each of the tests.

Standard EN 14683			Sample ref. **BODY ONE**
Clause 5.2.2	Bacterial filtration efficiency (BFE)	[%]	**>99.9**
Clause 5.2.3	Breathability (Differential pressure)	[Pa/cm^2]	**59.4**
Clause 5.2.4	Splash resistance	[to 17 kPa]	**OK**
Clause 5.2.5	Microbial cleanliness (bioburden)	[CFU/g]	**5.8**

Primary results

A) Bacterial filtration efficiency (BFE)

Sample ref.:	Sample nm.1	Sample nm.2	Sample nm.3	Sample nm.4	Sample nm.5
	BFE [%]				
BODY ONE	>99.9	>99.9	>99.9	>99.9	>99.9

B) Breathability (Differential pressure)

Sample ref.: **BODY ONE**		Sample nm.1	Sample nm.2	Sample nm.3	Sample nm.4	Sample nm.5
		[Pa]				
Breathability	(1)	334	317	252	276	323
	(2)	302	295	289	329	262
	(3)	268	264	268	334	302
	(4)	284	287	234	255	286
	(5)	277	301	348	293	301
	MEDIA	293	293	278	297	295
ΔP	[Pa/cm^2]	59.8	59.8	56.8	60.7	60.2

C) Splash resistance

Sample nm.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
PASS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
NO PASS																

Sample nm.	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
PASS	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
NO PASS											X					

Remark.- Result non conform if more than 3 samples fail

D) Microbial cleanliness (bioburden)

Sample ref.: **BODY ONE**	**Position inside packaging**	**Sample weight** [g]	**TSA plate** [CFU]	**SDA plate** [CFU]	**Total** [CFU]	**Total by weight** [CFU/g]
Sample nm.1	Top	3.17	16	5	21	6.62
Sample nm.2	Randomly	3.24	10	1	11	3.40
Sample nm.3		3.13	10	3	13	4.15
Sample nm.4		3.16	16	4	20	6.33
Sample nm.5	Bottom	3.17	24	3	27	8.52

Test conditions

A) Bacterial filtration efficiency (BFE)

Number of samples	5 units
Dimensions of test sample	10 cm x 10 cm
Size of the area under test	50 cm^2
Position of test sample	Internal face towards the inoculating spray
Environmental test conditions	T= 21 ºC / RH= 80 %
Test control unit	Andersen Cascade Impactor of 6-steps
Air flow	28.3 ℓ/min
Test microorganism	Staphyloccoccus aureus ATTC6538
Bacterial suspension (inoculum)	1.7 x 10^3 y 3 x 10^3 CFU/ml
Incubation conditions	20-52 h a (37 ± 2)ºC
Test duration	2 min / test sample

B) Breathability (Differential pressure)

Number of samples	5 units
Number of repetitions per sample	5
Size of the area under test	Ø 25 mm
Environmental temperature	(22 ± 2)º C
Test control unit	Mass flow meter
Air flow	(8 ± 0.2) ℓ/min

C) Splash resistance

Number of samples	32 units
Dimensions of test sample	Ø 5 cm
Size of the area under test	19.6 cm^2
Test method	ISO 22609: 2004
Environmental temperature	21 ºC
Test parameter (pressure)	127.5 mmHg (17 kPa)
Synthetic blood volume	2.0 mℓ

D) Microbial cleanliness (bioburden)

Number of samples	5 units
Test method	EN ISO 11737-1:2018
Extraction liquid	Peptone, NaCl and Tween 20, dissolved in Milli-Q water
Soluciones TSA: SDA:	Tryptic Soy Agar, pH 7.3±0.2 Sabouraud Dextrose Cloramphenicol Agar, 5.6±0.2
Sterile Cellulose Nitrate Membrane Filter	Size grid 0.45µm
Incubation	TSA plate: 3 days to 30ºC SDA plate: 7 days to 25ºC

GENERAL REMARKS

Based on the results obtained from the requested tests and the limits indicated in Table 1 of the EN 14683 standard (see page 4 of this report), the resulting classification of the samples tested could be: "type IIR".

Laboratory Technician: Marc Parera

Signed by

Firmado digitalmente por BELEN BAILERA PALOMERO

Technical Manager
Product Conformity B.U.
LGAI Technological Center, S.A.(APPLUS)

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