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Bellaterra, 2nd November, 2020

File number: **20/ 23368 - 1839**

Applicant: American Safety Power Tool (pvt) Ltd.
Plot # 1 and 2, 12 and 13, E-IV, Phase II
Karachi Export Processing Zone Karachi Sind
Pakistan

Date of material delivery:	28th September, 2020	20th October, 2020
Date of testing:	28th September to 7h October, 2020	21th to 31th October, 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 **8** pages of which **0** is annex, this being page number 1.

SAMPLES (information reported by the Applicant)

Sampling

Date: September 2020

Responsible: American Safety Power Tool (pvt)

Sample description

Samples received in September 2020			
REFERENCE	**DESCRIPTION TISSUE / LAYERS**	**RECEIVED FORMAT**	**Identification A+**
Qadri & Qureshi	3 layers	Face mask	1839



Samples received in October 2020

PACKAGING	Box of 50 units

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

Standard EN 14683	Sample ref. **Qadri & Qureshi**	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. **Qadri & Qureshi**
Clause 5.2.2	Bacterial filtration efficiency (BFE)	[%]	**>99.9**
Clause 5.2.3	Breathability (Differential pressure)	[Pa/cm^2]	**50.2**
Clause 5.2.4	Splash resistance	[to 17 kPa]	**OK**
Clause 5.2.5	Microbial cleanliness (bioburden)	[CFU/g]	(Obs1)

(Obs1) See results in page 6.

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 [%]				
Qadri & Qureshi	>99.9	>99.9	>99.9	>99.9	>99.9

B) Breathability (Differential pressure)

Sample ref.: **Qadri & Qureshi**		Sample nm.1	Sample nm.2	Sample nm.3	Sample nm.4	Sample nm.5
		[Pa]				
Breathability	(1)	252	258	248	240	267
	(2)	221	247	234	224	273
	(3)	250	260	231	256	264
	(4)	273	227	232	244	238
	(5)	247	273	223	243	228
	MEDIA	249	253	234	241	254
ΔP	[Pa/cm^2]	50.7	51.6	47.7	49.3	51.8

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.: **Qadri & Qureshi**	**Position inside packaging**	**Sample weight** [g]	**TSA plate** [CFU]	**SDA plate** [CFU]	**Total** [CFU]	**Total by weight** [CFU/g]
Sample nm.1	Top	3.18	300	7	307	96.54 (Obs1)
Sample nm.2	Randomly	3.23	18	4	22	6.81
Sample nm.3		3.22	56	4	60	18.63
Sample nm.4		3.12	19	2	21	6.73
Sample nm.5	Bottom	3.15	49	6	55	17.46

Remark (Obs1)- All the results, except for sample number 1 (the first one when opening the package) are compliant. Due to the quite degraded state in which the packaging was received, this result could be a consequence of contamination produced in the shipment.

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 °C / 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)°C
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)° 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 °C
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 30°C SDA plate: 7 days to 25°C

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" (if the result of bioburden test is considered compliant; see remark in page 6).

Laboratory Technician: Marc Parera

Signed by

Firmado digitalmente por BELEN BAILERA PALOMERO

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