LGAI Technological Center, S.A. (APPLUS)
Campus UAB
Ronda de la Font del Carme, s/n
E - 08193 Bellaterra (Barcelona - Spain)
T +34 93 567 20 00
www.appluslaboratories.com

Bellaterra,	7th October, 2020
File number:	**20 / 23120 - 1722**
Applicant:	Sonderegger Engineering AG Fulachstrasse 30 8200 Schaffhausen Switzerland

Date of material delivery:	10th September, 2020
Date of testing:	17th September to 7th October, 2020

TEST REPORT

corresponding to *Medical face masks*

ISSUE REQUESTED

Partial 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 **6** pages of which **0** is annex, this being page number 1.

SAMPLES (information reported by the Applicant)

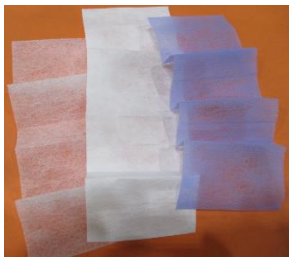
Sampling

Date: September 2020

Responsible: SONDEREGGER

Sample description

REFERENCE	ID NUMBER	SAMPLE DESCRIPTION	Identification A+
SONDIA	07649993794089/ser/ 2009071401	Medical face mask – 3 layers	1722



PACKAGING	Box of 50 units

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

Standard EN 14683	Sample ref. **SONDIA**	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: Microbial cleanliness (bioburden)	--	--

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

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. **SONDIA**
Clause 5.2.2	Bacterial filtration efficiency (BFE)	[%]	**> 99.9**
Clause 5.2.3	Breathability (Differential pressure)	[Pa/cm^2]	**51.4**
Clause 5.2.4	Splash resistance	[to 17 kPa]	**OK**
Clause 5.2.5	Microbial cleanliness (bioburden)	[CFU/g]	--

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 [%]				
SONDIA	>99.9	>99.9	>99.9	>99.9	>99.9

B) Breathability (Differential pressure)

Sample ref.: **SONDIA**		Sample nm.1	Sample nm.2	Sample nm.3	Sample nm.4	Sample nm.5
		[Pa]				
Breathability	(1)	225	205	237	250	234
	(2)	237	243	231	248	256
	(3)	288	251	236	278	241
	(4)	230	302	233	267	248
	(5)	258	298	295	256	251
	MEDIA	248	260	246	260	246
ΔP	[Pa/cm^2]	50,5	53,0	50,3	53,0	50,2

C) Splash resistance test

Sample nº	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
FAIL									X							

Sample nº	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
FAIL			X													

Remark.- Result is not conform if more than 3 samples fail

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 and 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 test

Number of samples	32 units
Dimension 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 parameters (pressure)	10,6 kPa; 16,0 KPa; 21,3 kPa
Synthetic blood volume	2,0 mℓ

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 3 of this report), the resulting classification of the samples tested, taking into account that not all the requirements have been verified, 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)