Foshan Nanhai Plus Medical Co., Ltd.
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Your notice of	Your reference	Date
18-03-2020		01-04-2020

Analysis Report 20.01616.05

Required tests :

EN 14683 (2019) + AC (2019)	**EN 14683 - annex B (2019) + AC (2019)**	**Bacterial filtration efficiency**
EN 14683 (2019) + AC (2019)	**EN 14683 - annex C (2019) + AC (2019)**	**Medical face masks - Breathability (differential pressure)**
EN 14683 (2019) + AC (2019)	**EN 14683 - §5.2.5 (2019) AC (2019)**	**Microbial cleanliness on masks**

Identification number	Information given by the client	Date of receipt
T2006094	SFMW01	18-03-2020

Sylvie Niessen
Order responsible

Reference: **T2006094 - SFMW01**

Bacterial filtration efficiency

Date of ending the test	27-03-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)

Mask description	Nonwoven face mask, 3-ply: blue outside / white inside
Number of tested masks :	5
BFE Area tested :	± 49 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	99.8
2	99.1
3	99.1
4	99.0
5	99.7

Mean particle size of the bacterial challenge aerosol : 2.8 µm

Controls

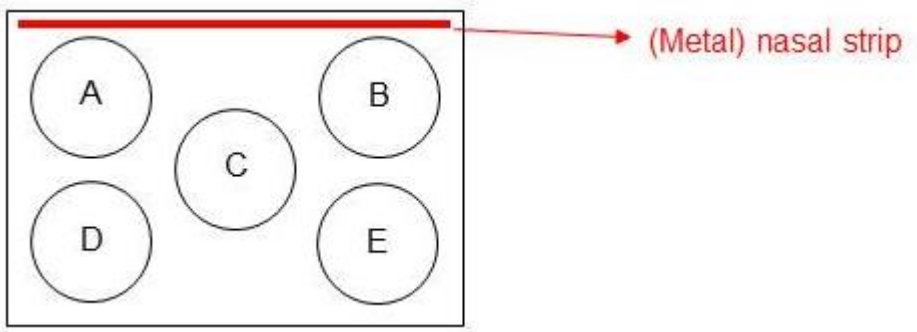
Mean positive controls 2307 CFU
Negative control < 1 CFU

Reference: **T2006094 - SFMW01**

Medical face masks - Breathability (differential pressure)

Date of ending the test	24-03-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Nonwoven face mask, 3-ply: blue outside / white inside
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	45.2	42.0	45.2	41.4	39.7
Area B	37.5	37.5	34.4	37.9	37.7
Area C	28.1	42.0	36.3	48.5	39.7
Area D	26.1	31.4	25.1	24.0	28.3
Area E	26.5	32.2	30.8	44.2	32.2
Average ΔP (Pa/cm²)	**32.7**	**37.0**	**34.4**	**39.2**	**35.5**

Reference: **T2006094 - SFMW01**

Microbial cleanliness on masks

Date of ending the test	30-03-2020
Standard used	EN 14683 - §5.2.5 (2019) AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	300 ml
Extraction time	5 min
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic Soy Agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions	3 days at 30°C (TSA) 7 days at 20-25°C (SDA)

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	3.26	30	<3	<33	<11
2	3.31	21	3	24	8
3	3.34	<3	<3	<6	<2
4	3.30	24	<3	<27	<9
5	3.31	<3	<3	<6	<2