



Your notice of
03-05-2018

Your reference

Date
26-06-2018

Analysis Report 18.02617.02

Required tests :

EN 14683 (2014)	EN 14683 - annex B (2014)	Bacterial filtration efficiency
EN 14683 (2014)	EN 14683 - annex C (2014)	Surgical masks - Breathability (differential pressure)
EN 14683 (2014)	EN 14683 - §5.2.5 (2014)	Microbial cleanliness on masks
EN 14683 (2014)	ISO 22609 (2004)	Surgical masks - Splash Test

Identification number	Information given by the client	Date of receipt
T1810793	Type II R Surgical Mask Lot NR. 181629	02-05-2018



Yvette Rogister

Order responsible

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**Reference: T1810793 - Type II R Surgical Mask
Lot NR. 181629**

Bacterial filtration efficiency

Date of ending the test	31-05-2018
Standard used	EN 14683 - annex B (2014)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks :	5
BFE Area tested :	$\pm 46 \text{ cm}^2$
Masks conditioning :	$21 \pm 5^\circ\text{C}$ and $85 \pm 5\% \text{ RH}$
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	<i>Staphylococcus aureus</i> ATCC6538
Bacterial challenge per test :	$2200 \pm 500 \text{ CFU}$
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 (%)

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

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

# Mask	B (%)
1	> 99.9
2	99.9
3	99.9
4	99.6
5	99.9

Mean particle size of the bacterial challenge aerosol : 3.0 μm

Controls

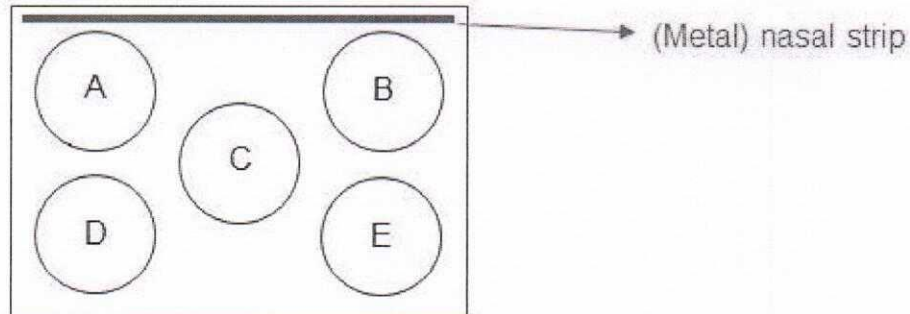
Mean positive controls 2395 CFU
Negative control < 1

Reference: T1810793 - Type II R Surgical Mask
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Surgical masks - Breathability (differential pressure)

Date of ending the test	30-05-2018
Standard used	EN 14683 - annex C (2014)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 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 cm ²
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 ΔP

Performed in the microbiological lab under the responsibility of Yvette Rogister



	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	33.0	39.1	34.0	34.2	37.7
Area B	31.6	34.4	35.4	34.0	36.7
Area C	34.2	33.2	35.2	30.4	34.6
Area D	32.2	33.6	32.2	32.6	30.6
Area E	31.6	32.6	31.6	32.4	30.6
Average ΔP (Pa/cm²)	32.5	34.6	33.7	32.7	34.0



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Microbial cleanliness on masks

Date of ending the test 01-06-2018
 Standard used EN 14683 - §5.2.5 (2014)
 Product standard EN 14683 (2014)

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	3.04	3	<3	< 6	< 2
2	2.99	6	3	9	4
3	3.00	<3	<3	< 6	< 2
4	2.97	3	<3	< 6	< 3
5	3.02	6	<3	< 9	< 3

* CFU : Colony Forming Unit



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Surgical masks - Splash Test

Date of ending the test	30-05-2018
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks :	32
Blood surface tension	42 ± 2 dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	30 ± 1 cm
Side of the mask "impacted"	Outer side
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Results

Blood pressure tested 16.0 kPa

Controls

Blood visualisation on the mask	OK
Calibration procedure	OK
Control of the blood volume delivered (2 ml)	
- before the test :	OK
- after 16 masks :	OK
- after 32 masks :	OK