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Your notice of
 31-08-2020

Your reference

Date
 16-09-2020

Analysis Report 20.05224.01

Required tests :

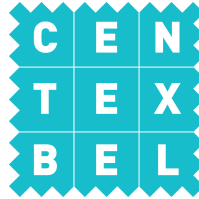
EN 14683 (2019) + AC (2019)	EN 14683 - annex B (2019) + AC (2019)	Bacterial filtration efficiency
EN 14683 (2019) + AC (2019)	EN 14683 - annex C (2019) + AC (2019)	Medical face masks - Breathability (differential pressure)
EN 14683 (2019) + AC (2019)	EN 14683 - §5.2.5 (2019) AC (2019)	Microbial cleanliness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

Sample id	Information given by the client	Date of receipt
T2018512	Ultrafilter 2020082435	31-08-2020



Sylvie Niessen
 Order responsible

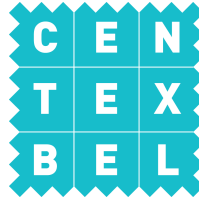
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 The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
 In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.



**Reference: T2018512 - Ultrafilter
2020082435**

Bacterial filtration efficiency

Date of ending the test	09-09-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
BFE Area tested :	$\pm 49 \text{ cm}^2$
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 :	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 (%)

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

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

# Mask	B (%)
1	99.8
2	99.6
3	99.6
4	99.7
5	99.5

Mean particle size of the bacterial challenge aerosol : 2.8 µm

Controls

Mean positive controls 2732 CFU
Negative control < 1 CFU

Note :

The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :

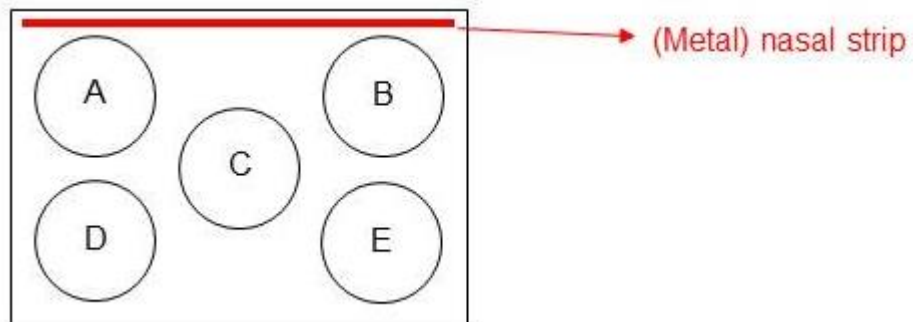
Test	Type I	Type II	Type IIR
<i>(BFE) Bacterial filtration efficiency (%)</i>	≥ 95	≥ 98	≥ 98

Reference: T2018512 - Ultrafilter
 2020082435

Medical face masks - Breathability (differential pressure)

Date of ending the test	03-09-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
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

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	44.2	48.9	43.0	52.2	59.5
Area B	48.5	46.4	51.7	59.7	58.7
Area C	68.2	57.9	52.4	68.2	50.9
Area D	47.7	43.0	51.5	63.2	48.7
Area E	51.3	47.5	39.7	48.7	59.3
Average ΔP (Pa/cm²)	52.0	48.7	47.7	58.4	55.4

Note :

The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :

Test	Type I	Type II	Type IIR
<i>Differential pressure (Pa/cm²)</i>	< 40	< 40	< 60

Reference: T2018512 - Ultrafilter
2020082435

Microbial cleanliness on masks

Date of ending the test 15-09-2020
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)
Deviation from the standard Test result based on 3 instead of 5 samples

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		<i>Aerobic microbial count (bacteria)</i>	<i>Fungi count (SDA)</i>	Σ CFU/mask	Σ CFU/g
1	3.21	6	3	9	3
2	3.30	48	12	60	19
3	3.21	24	< 3	< 27	< 9
4	3.25	15	3	18	6
5	3.28	15	3	18	6

Note :

The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :

Test	Type I	Type II	Type IIR
<i>Microbial cleanliness (cfu/g)</i>	≤ 30	≤ 30	≤ 30