



**Medprotex by  
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**Your notice of**  
03-03-2021

**Your reference**

**Date**  
17-03-2021

## Analysis Report 21.01355.01

Required tests :

EN 14683 (2019) + AC (2019)	EN 14683 - annex B (2019) + AC (2019)	Bacterial filtration efficiency
EN 14683 (2019) + AC (2019)	ISO 22609 (2004)	Medical face masks - Splash Test
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
T2104730	Lot nummer: 2021/007 #0024	03-03-2021

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: T2104730 - Lot nummer: 2021/007 #0024**

**Bacterial filtration efficiency**

Date of ending the test	10-03-2021
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	White nonwoven masks
Number of tested masks :	5
Dimensions of the test specimen :	17 cm x 14 cm
BFE Area tested :	± 49 cm <sup>2</sup>
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 :	<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	99.9
2	99.8
3	99.8
4	99.8
5	> 99.9

Mean particle size of the bacterial challenge aerosol : 2.7 µm

**Controls**

Mean positive controls 2480 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:** T2104730 - Lot number: 2021/007 #0024

**Medical face masks - Splash Test**

Date of ending the test	05-03-2021
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	White non-woven
Number of tested masks :	32
Blood surface tension	$42 \pm 2$ dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	$30 \pm 1$ cm
Side of the mask "impacted"	Outer side
Masks conditioning :	$21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ 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

Results obtained on the set of masks

<u># Mask</u>	<u>Results : pass / fail</u>
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass
11	Pass
12	Pass
13	Pass
14	Pass
15	Pass
16	Pass
17	Pass
18	Pass
19	Pass
20	Pass
21	Pass
22	Pass
23	Pass
24	Pass
25	Pass
26	Pass
27	Pass
28	Pass
29	Pass
30	Pass
31	Pass
32	Pass



Summary P = 16.0 kPa

Number of "Pass" masks	Number of "Fail" masks
32	0

Pass = no blood detected on the observed side

Fail = blood detected on the observed side

In agreement with the customer the number of tested mask has been determined based on a single sampling plan providing an AQL of 4 % (acceptable quality limit).

If 29 masks or more over 32 obtain a "Pass" result the 4% AQL is reached.

**Note :**

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

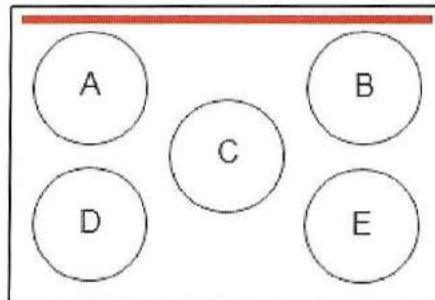
Test	Type I	Type II	Type IIR
<i>Splash resistance pressure (kPa)</i>	Not required	Not required	$\geq 16$

**Reference: T2104730 - Lot nummer: 2021/007 #0024**

**Medical face masks - Breathability (differential pressure)**

Date of ending the test	04-03-2021
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 <sup>2</sup>
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**       $\Delta P$

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	35.4	43.2	41.4	39.1	34.8
Area B	44.2	43.2	41.8	39.9	35.0
Area C	43.2	36.3	33.8	45.4	38.5
Area D	33.4	39.3	40.1	32.2	36.1
Area E	39.1	44.8	38.7	37.9	37.1
<b>Average <math>\Delta P</math> (Pa/cm<sup>2</sup>)</b>	<b>39.1</b>	<b>41.4</b>	<b>39.2</b>	<b>38.9</b>	<b>36.3</b>

**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/cm<sup>2</sup>)</i>	< 40	< 40	< 60

**Reference:** T2104730 - Lot nummer: 2021/007 #0024

**Microbial cleanliness on masks**

Date of ending the test 16-03-2021  
 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	
		<i>Aerobic microbial count (bacteria)</i>	<i>Fungi count (SDA)</i>	$\Sigma$ CFU/mask	$\Sigma$ CFU/g
1	3.55	39	9	48	14
2	3.59	21	3	24	7
3	3.57	3	6	9	3
4	3.55	21	3	24	7
5	3.57	21	39	60	17

**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