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**Your notice of**  
 05-02-2020

**Your reference**

**Date**  
 20-03-2020

## Analysis Report 20.00718.02

**Translation of analysis report 20.00718.01, made on 27-02-2020**

Required tests :

<b>EN 14683 (2019) + AC (2019)</b>	<b>EN 14683 - annex B (2019) + AC (2019)</b>	<b>Bacterial filtration efficiency</b>
<b>EN 14683 (2019) + AC (2019)</b>	<b>EN 14683 - annex C (2019) + AC (2019)</b>	<b>Medical face masks - Breathability (differential pressure)</b>
<b>EN 14683 (2019) + AC (2019)</b>	<b>ISO 22609 (2004)</b>	<b>Medical face masks - Splash Test</b>

Identification number	Information given by the client	Date of receipt
T2002718	#25 Respiratory Face Mask, FFP, Type IIR	05-02-2020

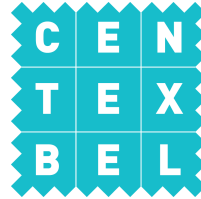
Sylvie Niessen  
 Order responsible

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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: T2002718 - #25 Respiratory Face Mask, FFP, Type IIR**

**Bacterial filtration efficiency**

Date of ending the test	13-02-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Type IIR, 2 layers, white, elastic
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	> 99.9*
2	> 99.9*
3	> 99.9*
4	> 99.9*
5	> 99.9*

\* no detected colonie on any of the Andersen sampler plates

Mean particle size of the bacterial challenge aerosol : 3.0 µm

**Controls**

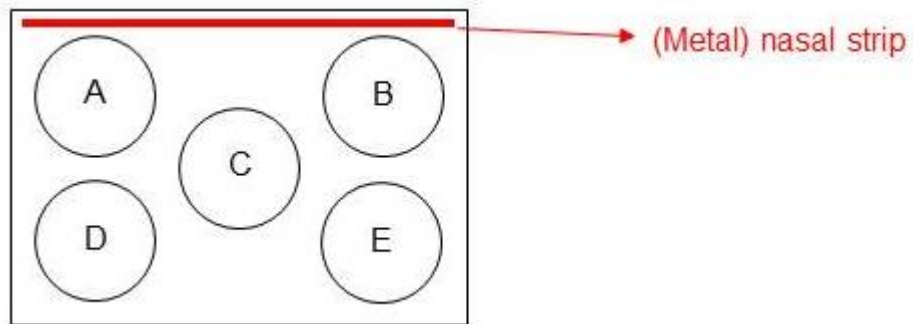
Mean positive controls 2387 CFU  
 Negative control < 1 CFU

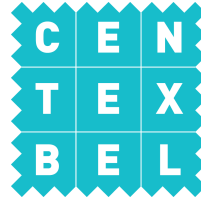
**Reference: T2002718 - #25 Respiratory Face Mask, FFP, Type IIR**

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

Date of ending the test	12-02-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Type IIR, 2 layers, white, elastic
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

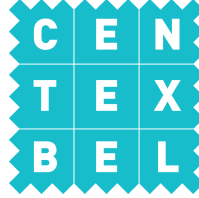
Figure : Distribution of the areas in the mask





**Results**       $\Delta P$

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	43.4	45.8	48.5	45.6	48.5
Area B	43.4	43.6	44.0	46.9	46.4
Area C	41.8	37.9	44.0	42.6	41.4
Area D	45.4	46.4	48.3	48.5	47.5
Area E	44.2	47.9	46.7	45.8	47.1
<b>Average <math>\Delta P</math> (Pa/cm<sup>2</sup>)</b>	<b>43.6</b>	<b>44.3</b>	<b>46.3</b>	<b>45.9</b>	<b>46.2</b>



**Reference: T2002718 - #25 Respiratory Face Mask, FFP, Type IIR**

**Medical face masks - Splash Test**

Date of ending the test	12-02-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Type IIR, 2 layers, white, elastic
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**

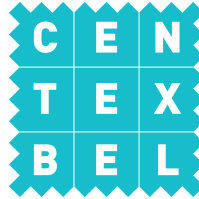
**Controls**

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



Results obtained on the set of masks

<b># Mask</b>	<b>Results : pass / fail</b>
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass
11	Fail
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
31	1

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.