

Midocean
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Your notice of
 23-07-2020

Your reference

Date
 20-08-2020

Analysis Report 20.04613.01

Required tests :

EN 14683 (2019) + AC (2019)	EN 14683 - annex C (2019) + AC (2019)	Medical face masks - Breathability (differential pressure)
EN 14683 (2019) + AC (2019)	ISO 22609 (2004)	Medical face masks - Splash Test
EN 14683 (2019) + AC (2019)	EN 14683 - annex B (2019) + AC (2019)	Bacterial filtration efficiency
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
T2016170	MFMASK-99 (30023130) Face masks MOB batch Midocean 8	23-07-2020



Christine Remi
Order responsible

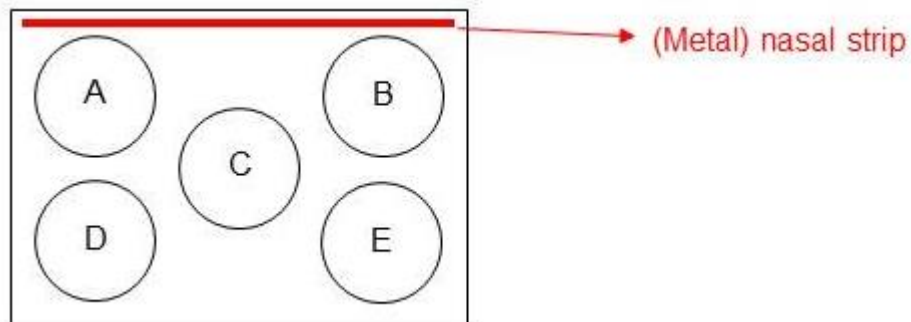
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 The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
 In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

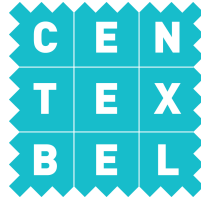
Reference: T2016170 - MFMASK-99 (30023130)
Face masks MOB batch Midocean 8

Medical face masks - Breathability (differential pressure)

Date of ending the test	18-08-2020
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





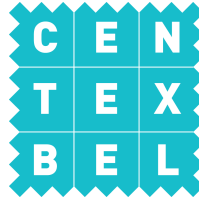
Results ΔP

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	23.2	23.0	23.4	19.6	18.1
Area B	21.8	23.6	22.6	21.8	18.9
Area C	22.0	19.6	20.6	18.1	20.2
Area D	17.9	21.2	21.2	18.9	19.6
Area E	19.4	20.0	22.4	17.3	17.7
Average ΔP (Pa/cm²)	20.9	21.5	22.0	19.1	18.9

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: T2016170 - MFMASK-99 (30023130)
Face masks MOB batch Midocean 8

Medical face masks - Splash Test

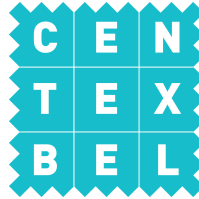
Date of ending the test	14-08-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	32
Blood surface tension	42 ± 2 dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	30 ± 1 cm
Side of the mask "impacted"	Outer side
Masks conditioning :	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



Results obtained on the set of masks

# Mask	Results : pass / fail
1	Fail
2	Fail
3	Fail
4	Fail
5	Fail

As mentioned 32 specimens are prepared for testing.

Nevertheless and due to the current Covid-19 health crisis as soon as 5 "Fail" results are obtained the test is stopped.

The number of 32 tested masks 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.

Consequently if more than 4 masks obtain a "Fail" result the 4% AQL is **not** reached.

Summary

P =
16.0
kPa

Number of "Pass" masks	Number of "Fail" masks
0	5

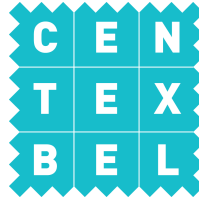
Pass = no blood detected on the observed side

Fail = blood detected on the observed side

Note :

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

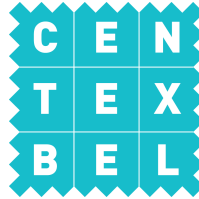
Test	Type I	Type II	Type IIR
<i>Splash resistance pressure (kPa)</i>	Not required	Not required	≥ 16



Reference: T2016170 - MFMASK-99 (30023130)
Face masks MOB batch Midocean 8

Bacterial filtration efficiency

Date of ending the test	17-08-2020
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	98.5
2	98.6
3	98.7
4	97.9
5	98.3

Mean particle size of the bacterial challenge aerosol : 2.7 µm

Controls

Mean positive controls 2064 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: T2016170 - MFMASK-99 (30023130)
Face masks MOB batch Midocean 8

Microbial cleanliness on masks

Date of ending the test 18-08-2020
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	
		<i>Aerobic microbial count (bacteria)</i>	<i>Fungi count (SDA)</i>	Σ CFU/mask	Σ CFU/g
1	3.46	21	6	27	8
2	3.43	9	9	18	6
3	3.42	9	3	12	4
4	3.43	9	12	21	7
5	3.42	18	3	21	7

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