INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Ontex bv
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Your notice of	Your reference	Date
31-08-2020		16-09-2020

Analysis Report 20.05211.01

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)	**ISO 22609 (2004)**	**Medical face masks - Splash Test**
	ISO 10993-5 (2009)	**Cytotoxicity**
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
T2018458	SMtIIR-010	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.

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Reference: **T2018458 - SMtIIR-010**

Bacterial filtration efficiency

Date of ending the test	03-09-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
BFE Area tested :	± 49 cm²
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 :	*Staphylococcus aureus* 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

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Results

B = Bacterial filtration efficiency (%)

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

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	> 99.9
3	99.9
4	99.9
5	99.9

Mean particle size of the bacterial challenge aerosol : 2.7 µm

Controls

Mean positive controls 2276 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
(BFE) Bacterial filtration efficiency (%)	≥ 95	≥ 98	≥ 98

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Reference: **T2018458 - SMtIIR-010**

Medical face masks - Splash Test

Date of ending the test	02-09-2020
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
- *after 16 masks :*	OK
- *after 32 masks :*	OK

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Results obtained on the set of masks

# Mask	Results : pass / fail
1	Fail
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*

* A blood spot is observable but the blood doesn't seem to penetrate the last layer even after the 10 s required by the standard. Nevertheless after more than 10 s a penetration is obtained.

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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.

Note :

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

Test	Type I	Type II	Type IIR
Splash resistance pressure (kPa)	Not required	Not required	≥ 16

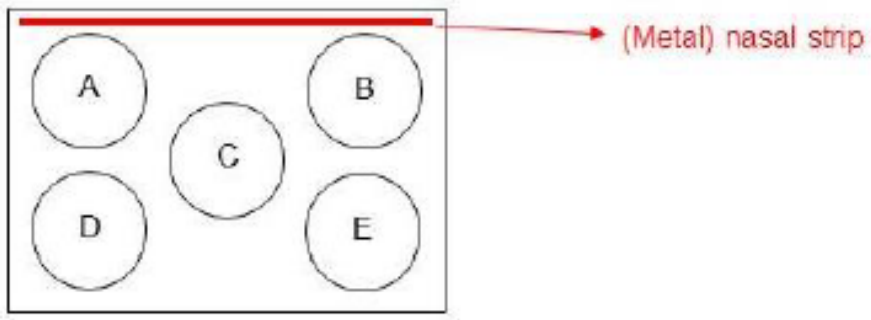
INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Reference: **T2018458 - SMtIIR-010**

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 cm²
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



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Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	60.3	61.3	60.5	65.8	58.1
Area B	64.4	61.7	65.4	59.7	61.9
Area C	50.7	61.9	56.0	59.7	52.2
Area D	55.2	59.5	60.3	55.4	58.9
Area E	56.0	58.9	59.7	58.1	58.3
Average ΔP (Pa/cm²)	**57.3**	**60.7**	**60.4**	**59.7**	**57.9**

Note :

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

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