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Your notice of	Your reference	Date
27-07-2020		20-08-2020

Analysis Report 20.04684.01

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)	**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**
	ISO 10993-5 (2009)	**Cytotoxicity**

Sample id	Information given by the client	Date of receipt
T2016347	Protective mask MK1 CE	27-07-2020

Christine Remi
Order responsible

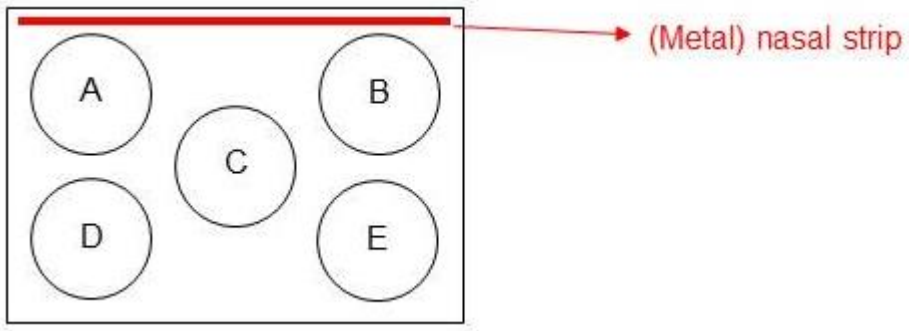
The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

Reference: **T2016347 - Protective mask MK1 CE**

Medical face masks - Breathability (differential pressure)

Date of ending the test	31-07-2020
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



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	33.6	35.2	30.6	42.4	44.0
Area B	36.1	41.2	34.0	37.7	37.3
Area C	37.1	28.1	33.8	36.9	39.3
Area D	31.0	45.2	34.8	38.5	34.4
Area E	37.1	40.7	38.3	36.3	39.3
Average ΔP (Pa/cm²)	**35.0**	**38.1**	**34.3**	**38.3**	**38.9**

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

Reference: **T2016347 - Protective mask MK1 CE**

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 :	2
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
Deviation from the standard	Test result based on 2 instead of 5 samples

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	99.7

Mean particle size of the bacterial challenge aerosol : 2.7 µm

Controls

Mean positive controls 2064 CFU
Negative control < 1 CFU

This test report is valid for products used in relation to the current Covid-19 health crisis and for products which are not entering the regular distribution channels. Cfr Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat"

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

Reference: **T2016347 - Protective mask MK1 CE**

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	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	2.69	9	<3	<12	<5
2	2.66	27	<3	<30	<12
3	2.72	<3	<3	<6	<3
4	2.71	<3	<3	<6	<3
5	2.68	<3	<3	<6	<3

Note :

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

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

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister

Reference: **T2016347 - Protective mask MK1 CE**

Cytotoxicity

Date of ending the test	31-07-2020
Standard used	ISO 10993-5 (2009)

1. Method

ISO 10993-5: 2009 – Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity

Test method used : Test on extracts and Measurement of cell viability by XTT Assay

Principle :

Monolayers of *in vitro* cultured cells are incubated for 24 hours at 37°C and 5 % CO_2 in the presence of the device or material extract. After incubation , the cytotoxic effect of the device or material is determined by assessing the cell viability using the XTT assay.
Next to the device or material under investigation, negative and positive controls are simultaneously checked.
If the sample extract shows a mean cell viability ≥70 %, the sample is considered as non-cytotoxic.

2. Results

The test has been performed by GD from 29.07.2020 to 31.07.2020

General information

Cells :	Mouse fibroblasts
Strain :	*L929 (ATCC CCL-1, NCTC Clone 929)*
Passage :	*585*
Sample description :	green/white Nonwoven mask
Sterilisation of the sample :	UV (10 min. each side)
Extraction medium :	Complete Dulbeccos' Modified Eagle's Medium (Dulbeccos' Modified Eagle's Medium (Lonza, lot 718751) supplemented with 10%FBS (VWR, Lot S18092S181H) and 1% Penicillin/ Streptomycin /Amphotericin B (Lonza, lot 19B135304)

Extraction ratio *(according to ISO 10993-12)*	0.1 g/ ml (ratio recommended for textiles)
Extraction conditions :	24 hours under agitation at 37°C
Test procedure :	Incubation of the cells in the presence of the extract(s) and controls for 24h at 37°C
Reagent control :	Extraction medium (without test material) that has been subjected to the same extraction conditions as for the sample.
Positive control	Solution of Triton X100 (in complete DMEM)
Negative control	HDPE film

Cytotoxicity assessment:

After the 24 h incubation of the cells with the extract (or control), the XTT (2,3-Bis-(2-methoxy-4-nitro-5-sulfophenyl]-2H-tetrazolium-5-carboxyanilide salt) solution is added. After incubation for 2 hours at 37°C (5% CO_2), the resulting solution is measured at the spectrophotometer (OD_{450nm}).
XTT is a salt that is cleaved to formazan by the succinate dehydrogenase system of the mitochondrial respiratory chain of the cells.
An increase or decrease in cells number results in a concomitant change in the amount of formazan formed, indicating the degree of cytotoxicity caused by the test material. The cell viability is expressed as a percentage of the reagent control.

samples	cell viavibility % (± Std Dev)
Reagent control (100% viability)	100.00 ± 4.70
T2016347 (100 %)	**84.53 ± 4.03**
T2016347 - 50 % (= diluted 2 times)	86.53 ± 2.59
T2016347 - 25 % (= diluted 4 times)	94.93 ± 17.41
T2016347 - 13 % (= diluted 8 times)	88.71 ± 4.43
T2016347 - 6 % (= diluted 16 times)	90.21 ± 5.17
T2016347 - 3 % (= diluted 32 times)	90.14 ± 3.28

The reagent control, positive control and negative control performed as anticipated.

3. Conclusions

According to ISO 10993-5, a cell viability equal or higher than 70% is considered as non-cytotoxic.
Under the conditions of the assay, the tested sample **T2016347** has therefore to be considered as non-**cytotoxic**.