## 5. Full Analysis Report

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

**3A Medical Products Co. Ltd, Yu An Industrial Park, 230001 Liu An. PR China**

| Your notice of | Your reference | Date |
|---|---|---|
| 17-03-2020 | | 03-04-2020 |

# Analysis Report 20.01605.03

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** |

| Identification number | Information given by the client | Date of receipt |
|---|---|---|
| T2006058 | REF 2001<br>Lot 202001202 | 17-03-2020 |

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.

ISO 17025 BELAC 056-TEST
ilac-MRA
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INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947



**Reference:** **T2006058 - REF 2001**
**Lot 202001202**

***Bacterial filtration efficiency***

| | |
|---|---|
| Date of ending the test | 25-03-2020 |
| Standard used | EN 14683 - annex B (2019) + AC (2019) |
| Product standard | EN 14683 (2019) + AC (2019) |
| Mask description | 3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue |
| 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 |

Performed in the microbiological lab under the responsibility of Yvette Rogister

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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 | 99.9 |
| 2 | 99.2 |
| 3 | 99.8 |
| 4 | 99.9 |
| 5 | 99.8 |

Mean particle size of the bacterial challenge aerosol : 2.9 µm

*Controls*

Mean positive controls 2636 CFU
Negative control < 1 CFU

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**Reference:** **T2006058 - REF 2001**
**Lot 202001202**

***Medical face masks - Splash Test***

| | |
|---|---|
| Date of ending the test | 26-03-2020 |
| Standard used | ISO 22609 (2004) |
| Product standard | EN 14683 (2019) + AC (2019) |
| Mask description | 3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue |
| 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 | 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 |

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*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.

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**Reference:** **T2006058 - REF 2001**
**Lot 202001202**

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

| | |
|---|---|
| Date of ending the test | 24-03-2020 |
| Standard used | EN 14683 - annex C (2019) + AC (2019) |
| Product standard | EN 14683 (2019) + AC (2019) |
| Mask description | 3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue |
| 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 | 52.6 | 23.0 | 52.6 | 35.2 | 40.3 |
| Area B | 51.1 | 30.6 | 59.1 | 39.7 | 39.7 |
| Area C | 53.0 | 34.8 | 45.4 | 43.4 | 38.3 |
| Area D | 46.7 | 35.7 | 48.1 | 44.2 | 41.4 |
| Area E | 44.2 | 29.7 | 39.5 | 39.7 | 41.4 |
| **Average ΔP (Pa/cm²)** | **49.5** | **30.8** | **48.9** | **40.4** | **40.2** |

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**Reference:** **T2006058 - REF 2001**
**Lot 202001202**

***Microbial cleanliness on masks***

| | |
|---|---|
| Date of ending the test | 30-03-2020 |
| 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)<br>SDA (Sabouraud Dextrose Agar with chloramphenicol) |
| Incubation conditions | 3 days at 30°C (TSA)<br>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 | 4.25 | 33 | <3 | < 36 | < 9 |
| 2 | 4.22 | 3 | <3 | < 6 | < 2 |
| 3 | 4.33 | 3 | <3 | < 6 | < 2 |
| 4 | 4.35 | 36 | <3 | < 39 | < 9 |
| 5 | 4.37 | 3 | <3 | < 6 | < 2 |

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