4. Declaration of Conformity

安徽富美医疗科技有限公司
3A Medical Products Co., Ltd.
地址：安徽省六安市裕安区
Add: Yu An Industrial Park, Liu An City, P.R. China

Declaration of Conformity

Manufacturer: 3A Medical Products Co., Ltd
Address: Yu An Industrial Park, 237100, Liu An, PEOPLE'S REPUBLIC OF CHINA

European Representative:

Name: Shanghai International Holding Corp. GmbH(Hamburg)

Address: Eiffestrasse 80, 20537, Hamburg, Germany

Product name：Medical face mask
Classification: Class 1 Rule 1of Annex IX of MDD 93/42/EEC)
Type：Type IIR
Rule: According to Rule I Annex VII

We here with declare that above mentioned products meet the requirement of the (MDD 93/42/EEC) Medical device directive and the following harmonized standards:

EN14683:2019
ENISO 15223-1:2016
ENISO10993-1:2009/AC: 2010
ENISO10993-10:2013
ENISO 14971:2012
ENISO1041:2008A1:2013
ENISO10993-5:2009

The Medical face mask meets the requirement of EN14683:2019

Signature Billy Zhang 2020.4.17
Name: Billy Zhang
Position: Management Representative
Place：Liu An City
Date: 2020-04-17

CERTIFICATE OF NOTIFICATION

This is to certify that, according to European Council Directive 93/42/EEC, Shanghai International Holding Corp, GmbH (Europe), performed all notification duties and responsibilities as the European authorized Representative:

MANUFACTURER: 3A Medical Products Pty Ltd

Address: Yu An Industrial Park, 230001, Liu An, CN

The manufacturer has provided Shanghai International Holding Corp, GmbH (Europe), with all the appropriate declaration according to the European Council Directive 93/42 EEC including the EC Declaration of Conformity confirming that its medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 93/42/EEC.

Devices: Medical Face Mask

Classification: I

Model: 17.5(±5%)cm*9.5(±5%)cm,14.5(±5%)cm*9.5(±5%)cm

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 93/42/EEC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Germany. The Germany Competent Authority is notified of the manufacture's device and has allocated registration.

EXECUTIVE DIRECTOR

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5. Full Analysis Report

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 Lot 202001202	17-03-2020

Sylvie Niessen
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.

ISO 17025 BELAC 056-TEST

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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

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

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.

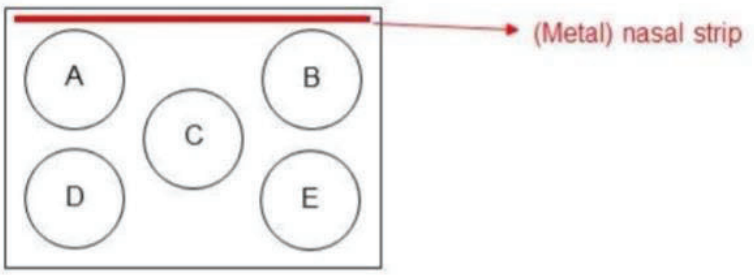
Performed in the microbiological lab under the responsibility of Yvette Rogister

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



Performed in the microbiological lab under the responsibility of Yvette Rogister

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**

Performed in the microbiological lab under the responsibility of Yvette Rogister

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) 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	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