

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the European Council Directive 93/42/EEC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: CHANGZHOU ECON LIDS CO., LTD.

ADDRESS: JIAOXI INDUSTRIAL PARK, ZHENGLU, TIANNING, CHANGZHOU213115, JIANGSU, CHINA

The manufacturer has provided Riomavix S.L. 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 Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is RPS/686/2020


Executive Director



Issue date: 6/MAY/2020
Cert. No.: R20200507



EC Declaration of Conformity

Manufacturer:

Name: CHANGZHOU ECON LIDS CO., LTD.

Add.: JIAOXI INDUSTRIAL PARK, ZHENGLU, TIANNING, CHANGZHOU 213115,
JIANGSU, CHINA

Email: sales@team-long.com

European Representative:

Name: Riomavix S.L.

Add: Calle de Almansa 55, 1D, Madrid 28039 Spain

Tel.: +34 658 396 230

E-mail: riomavix@gmail.com

Product Name: Medical face mask

Classification and relevant Rule of MDD: I, MDD 93/42/EEC Annex IX, Rule 1

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

GMDN: 35177

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Standard: EN 14683:2019 Type II R



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mention declaration of conformity is exclusively under the responsibility of

Company: CHANGZHOU ECON LIDS CO., LTD.

Address: JIAOXI INDUSTRIAL PARK, ZHENGLU, TIANNING, CHANGZHOU 213115,
JIANGSU, CHINA

Changzhou, 2020-04-30.
Place, date

Yaozhuo, General Manager
Legally binding signature, Function



SUBJECT Physical & Microbiological Test

TEST LOCATION TÜV SÜD China
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME CHANGZHOU ECON LIDS CO., LTD

CLIENT ADDRESS JIAOXI INDUSTRIAL PARK, ZHENGLU, TIANNING, CHANGZHOU,
JIANGSU, CHINA

TEST PERIOD 29-May-2020~06-Jun-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By



(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co.,
Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing
(China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TUV®

TEST REPORT

Sample Description : Medical Face Mask
Sample Quantity : 80 pieces
Lot Number/Batch Code : 20200501
Specification : Planar Ear Loop
Size : /
Brand Name : /

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type II R	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm ²)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	EN 14683:2019+AC:2019(E) ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment;

N.D. = Not detected.

Photo of Samples



Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.8% Specimen 2#: 99.9% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.8%
2	Differential Pressure Test	49.4 Pa/cm ²
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 2 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: 2 CFU/g Specimen 4#: 2 CFU/g Specimen 5#: 2 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of masks.

2. Sample description was given by client

Sample description : Medical Face Mask
Specification : Planar Ear Loop
Lot Number : 20200501
Sample Receiving Date : 2020-05-29

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

- 4.1 *Staphylococcus aureus* ATCC 6538 (Particle Diameter 3.0±0.3µm).
- 4.2 Peptone water.
- 4.3 Tryptic Soy Broth(TSB).
- 4.4 Tryptic Soy Agar(TSA).
- 4.5 Bacterial filtration efficiency test apparatus.
- 4.6 Six-stage viable particle Anderson sampler.
- 4.7 Flow meters.

5. Test specimen

- 5.1 As requested by client, take a total of 5 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
- 6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
- 6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
- 6.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
 - 6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the Anderson sampler.
 - 6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
 - 6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
 - 6.4.4 At the conclusion of the positive control run, remove plates from the Anderson sampler.
- 6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm²).
- 6.6 Repeat the challenge procedure for each test specimen.
- 6.7 Repeat a positive control after completion of the sample set.
- 6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
- 6.9 Incubate agar plates at $(37 \pm 2)^\circ\text{C}$ for (20 to 52) h.
- 6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$\text{BFE} = (C - T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.



8. Test results*

P Value Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	31	22	0	0	0	0	0	0
2	79	108	0	0	0	0	0	0
3	86	177	0	0	0	0	0	0
4	130	349	0	0	0	0	0	0
5	1408	1518	0	3	1	2	3	4
6	377	437	0	1	1	1	0	0
Total (T), CFU	2111	2611	<1	4	2	3	3	4
Average (C), CFU	$2.4 \times 10^3 = (P_A + P_B) / 2$							
BFE, %				99.8	99.9	99.9	99.9	99.8
Requirements	≥ 98							
Remarks	<p><i>P</i> is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. <i>T</i> is the total of <i>P</i> value for the test specimen. <i>C</i> is the mean of the total of <i>P</i> value of the two positive controls.</p>							

Differential pressure Test

1. Purpose

The purpose of the test was to measure the differential pressure of masks.

2. Sample description was given by client

Sample description : Medical Face Mask
Specification : Planar Ear Loop
Lot Number : 20200501
Sample Receiving Date : 2020-05-29

3. Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5. Test specimen

- 5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

- 6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm, airflow direction from the inside of the mask to the outside of the mask) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm ²)	Average (Pa/cm ²)	Requirements	Judgement
1#	51.5	49.4	< 60	Pass
2#	45.4			
3#	41.0			
4#	55.2			
5#	53.8			

Synthetic Blood Penetration Test

1. Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2. Sample description was given by client

Sample description : Medical Face Mask
Specification : Planar Ear Loop
Lot Number : 20200501
Sample Receiving Date : 2020-05-29

3. Test Method

EN 14683:2019+AC:2019(E).
ISO 22609:2004.

4. Apparatus and materials

- 4.1 Synthetic blood.
- 4.2 Tensiometer.
- 4.3 Synthetic blood penetration test apparatus;
- 4.4 Targeting plate.
- 4.5 Air pressure source.
- 4.6 Ruler.
- 4.7 Balance.
- 4.8 Controlled temperature and humidity chamber.

5. Test specimen

- 5.1 As requested by client, take a total of 32 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4h at $(21\pm 5)^{\circ}\text{C}$ and $(85\pm 5)\%$ relative humidity.

6. Procedure

- 6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
- 6.2 Determine the density of the synthetic blood.
- 6.3 Fill the reservoir with new synthetic blood.
- 6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
- 6.5 Set the reservoir pressure to the approximate pressure.
- 6.6 Place the targeting plate approximately 1 cm away from the mask.
- 6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

- 6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

- 6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.
- 6.11 Record the weight difference for the spurts exiting the nozzle.
- 6.12 Record the pressure in the reservoir.
- 6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.
- 6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.
- 6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).
- 6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2 \times p - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$.
- 6.19 Record the timer setting to use as the starting point for subsequent testing.
- 6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.
- 6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.
- 6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.
- 6.23 Report the results (none / penetration) for each test specimen at the test pressure.



Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen		Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Medical Face Mask
Specification : Planar Ear Loop
Lot Number : 20200501
Sample Receiving Date : 2020-05-29

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

- 4.1 Orbital shaker.
- 4.2 0.45 um filter.
- 4.3 Tryptic Soy Agar (TSA).
- 4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
- 4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
- 4.6 Extraction apparatus.

5. Test specimen

- 5.1 As requested by client, take a total of 5 mask samples.
- 5.2 Mask samples for testing are provided in the original primary packaging.
- 5.3 Condition at (18 to 26)°C and (45 to 65)% relative humidity during testing.

6. Procedure

- 6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
- 6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
- 6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
- 6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
- 6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
- 6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.



Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	2	2	EN14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	0	1	1		
3#	0	2	2		
4#	0	2	2		
5#	0	2	2		

Note:

- 1.*denotes this test was carried out by external laboratory assessed as competent.
- 2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-



1 SAFE **CE**
 MASCHERINA CHIRURGICA
 TIPO IIR BFE > 98%

100% polipropilene idrofobo

10 PEZZI

ISTRUZIONI PER L'USO
 Istruzioni per l'uso di mascherine chirurgiche e respiratori filtranti
 Prima di indossare la mascherina è consigliabile lavarsi le mani

Asciuga la mascherina.	Prendila e mettila sulla tua faccia coprendo il naso e la bocca.	Aggirare gli elasti dietro la testa e assicurarsi che non tocchi il viso e la mascherina.	Prima di toglierla, evita di toccare la mascherina e il viso. Toglila dalla parte posteriore.

Rimuovere la mascherina evitando il contatto con la parte interna

Data produzione: 2020/10/09
 Scadenza: 2025/10/08



1

SAFE

MASCHERINA CHIRURGICA
TIPO NR. 100 - 98%

100% polipropilene idrofobo



10
PEZZI

ISTRUZIONI PER L'USO

Istruzioni per l'uso di mascherine chirurgiche e respiratori filtranti
Prima di indossare la mascherina è consigliabile lavarsi le mani



Aprire la mascherina.



Indossare la mascherina appoggiandola prima sul naso



Appoggiare gli elastici dietro alle orecchie. Coordinare la stringitura facendola aderire al contorno



Premere leggermente per ottenere la migliore aderenza possibile anche sulle guance e sotto il mento

Rimuovere la mascherina evitando il contatto con la parte interna

Data produzione: 2020/10/09
Scadenza: 2025/10/08

1

SAFE

MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%

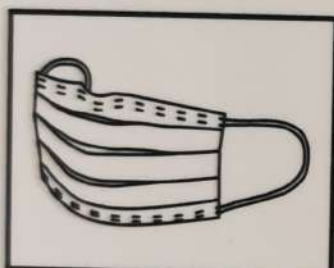


MASCHERINA MEDICA DI TIPO IIR
MASCHERINA FIRSTSAFE



ISTRUZIONI PER L'USO

Istruzioni per l'uso di mascherine chirurgiche e respiratori filtranti
Prima di indossare la mascherina è consigliabile lavarsi le mani



Aprire la mascherina.



Indossare la mascherina appoggiandola prima sul naso



Agganciare gli elastici dietro alle orecchie. Conformare lo stringinaso facendolo aderire ai contorni



Premere leggermente per ottenere la migliore aderenza possibile anche sulle guance e sotto il mento

Rimuovere la mascherina evitando il contatto con la parte interna

AVVERTENZE GENERALI RELATIVE ALL'UTILIZZO

La maschera deve essere sostituita dopo ogni utilizzo e si sconsiglia l'uso prolungato per oltre 4 ore;
Interrompere l'utilizzo se le condizioni di rischio rendono non idoneo un dispositivo di prima classe;
Questo prodotto non è lavabile, assicurarsi che venga utilizzato entro il periodo di validità;
Conservare in luogo asciutto e ventilato al riparo da calore diretto



AVVERTENZE GENERALI RELATIVE ALL'UTILIZZO

La maschera deve essere sostituita dopo ogni utilizzo e si sconsiglia l'uso prolungato per oltre 4 ore;
Interrompere l'utilizzo se le condizioni di rischio rendono non idoneo un dispositivo di prima classe;
Questo prodotto non è lavabile, assicurarsi che venga utilizzato entro il periodo di validità;
Conservare in luogo asciutto e ventilato al riparo da calore diretto

MASCHERINA CHIRURGICA DI TIPO IIR

MASCHERINA FIRSTSAFE

DISPOSITIVO DI CLASSE IIR



Composizione: 100% polipropilene idrofobo

Destinazione d'uso: MASCHERINA FIRSTSAFE è un dispositivo medico monouso non sterile di Tipo IIR, pertanto dovrebbe essere utilizzato solo per i pazienti e per altre persone per ridurre il rischio di diffusione delle infezioni, in particolare in situazioni epidemiche o pandemiche. Le maschere di Tipo IIR non sono destinate all'uso da parte di operatori sanitari in sala operatoria o in altre attività mediche con requisiti simili.

Istruzioni: 1. Lava accuratamente le mani con acqua e sapone o con un disinfettante a base di alcol prima di indossare la mascherina 2. Indossa la mascherina impugnandola dagli elastici laterali. 3. Nel coprire la bocca e il naso, assicurati che non ci siano spazi tra il viso e la mascherina in modo che aderisca bene al volto. 4. Evita di toccare la mascherina durante l'uso e sostituiscila con una nuova non appena è umida. 5. Rimuovi la mascherina dalle estremità laterali senza toccare la parte anteriore. 6. Subito dopo l'uso buttila in un apposito contenitore. 7. Lava subito le mani con acqua e sapone o gel igienizzante.

Manutenzione: non necessaria in quanto prodotto monouso.

Conservazione: Conservare in luogo fresco e asciutto senza esporre a calore diretto.

Scadenza: 5 anni dalla produzione (vedi data di produzione, prime 8 cifre del numero di lotto)

LOTTO: YH20200805

REGOLAMENTO (UE) 2017/745
CLASSIFICAZIONE: IIR
MATERIE PLASTICHE
MATERIE PLASTICHE
MATERIE PLASTICHE

Data produzione: 2020/10/09
Scadenza: 2025/10/08

MADE IN CHINA

1 SAFE
MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%



1 SAFE
MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%



1 SAFE
MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%



1 SAFE
MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%



1 SAFE
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TIPO IIR BFE > 98%



1 SAFE
MASCHERINA CHIRURGICA
TIPO IIR BFE > 98%

