

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

Executive Directo

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 notifed of the manufacture's device and has allocated registration. The registration number is RPS/686/2020

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



Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

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: $17.5(\pm 5\%)$ cm* $9.5(\pm 5\%)$ cm, $14.5(\pm 5\%)$ cm* $9.5(\pm 5\%)$ 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

CE

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

hangzhou, 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

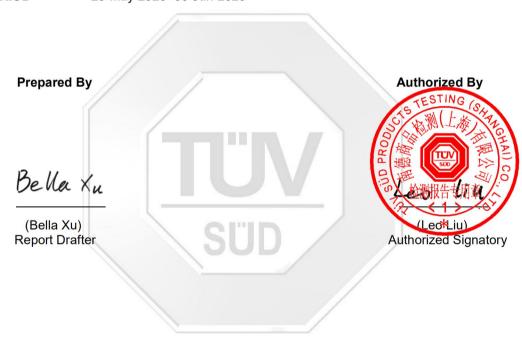
Shanghai 201108, P.R. China

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



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.



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	EN 14683:2019+AC:2019(E)	≥ 98	Pass
1	(BFE), %	Annex B	2 90	F 455
2	Differential Pressure Test	EN 14683:2019+AC:2019(E)	100 Bara	
2	(Pa/cm²)	Annex C	< 60	Pass
3	Synthetic Blood Penetration Test	EN 14683:2019+AC:2019(E)	≥ 16.0	Doos
3	(kPa)	ISO 22609:2004	2 16.0	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E)	< 30	Pass
4	(CFU/g)	FU/g) Annex D ≤ 30		F d 5 5

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment; N.D. = Not detected.

Photo of Samples





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





Results

0	
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49.4 Pa/cm ²	
Specimen 1#~32#: None seen	
I/g	
J/g	
J/g	
J/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.

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6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10⁵ 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 specime 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. Immediaterly 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 ran, 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±2)°C for (20 to 52) h.
- 6.10 Count each of the six-stage plates of the Anderson sampler.

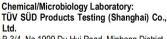
7. Calculation

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:

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

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	Positive	Positive	Negative	Specimen	Specimen	Specimen	Specimen	Specimen
Stage Number	Control (A)	Control (B)	Control	1#	2#	3#	4#	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 x10 ³ =	(P _A +P _B) / 2						
BFE ,%		_//_	1	99.8	99.9	99.9	99.9	99.8
Requirements	≥ 98							
Remarks	P is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. T is the total of P value for the test specimen. C is the mean of the total of P value of the two positive controls.							





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:

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Specimen	Test Results* (Pa/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	51.5			
2#	45.4			
3#	41.0	49.4	< 60	Pass
4#	55.2			
5#	53.8			

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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±5)°C and (85±5) % relative humidity.

6.Procedure

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- 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).

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- 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 $+2 \% \sim -5 \%$ 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.) $t = 0.5 + (2 \times p - q)$ at 0.5 s) / (q at 1.5 s - q at 0.5 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
- 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.

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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	Pass
17#	None Seen	(120mmHg)	Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen	ID /	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	1	Pass
31#	None Seen]	Pass
32#	None Seen]	Pass

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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

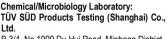
- 5.1 As requested by client, take a total of 5 mask samples.
- 5.2 Mask samples for testing are provided in the original primary packaging.
- 5.3 Condition at (18 to 26)°C and (45 to 65)% relative humidity during testing.

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.



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Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	2	2	ENIA 4000 0040 (A O 0040 (E)	
2#	0	1	1	EN14683:2019+AC:2019(E) Annex D	
3#	0	2	2	EN ISO 11737-1:2018	Pass
4#	0	2	2	≤ 30 CFU/g	
5#	0	2	2		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

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Email: food.chem@tuv-sud.cn

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.



70*50mm

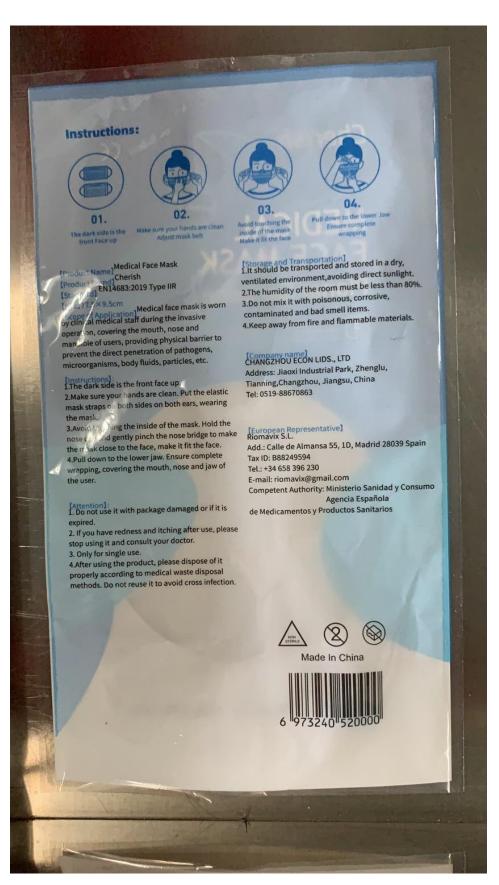
	合格证 Certificate of Approval
产品名称	一次性使用医用口罩
Name	Medical Face Mask
规格型号	平面形耳挂式 175*95mm
Specification	Planar Earloop 175*95 mm
主要成分	无纺布65%,熔喷布30%,氨纶5%
Main Components	Nonwovens 65%, Melt blown fabric 30% ,Spandex 5%
包装数量	25只/包
Quantity	25PCS/Bag
检验员 Inspector	202
生产批号 Lot No.	20200701
生产日期 Mfg date	2020.07.22
有效期至 Valid Until	2022.07.21 检验专用章
执行标准 Standard	EN14683-2019 TYPE IIR
生产商	常州怡康盖业有限公司
Manufacturer	CHANGZHOU ECON LIDS CO., LTD.
地 址	江苏省常州市天宁区郑陆镇焦溪工业集中区
Add	Jiaoxi Industrial Park, Zhenglu, Tianning Changzhou, Jiangsu, China

70*50mm

	合格证 Certificate of Approval
产品名称	一次性使用医用口罩
Name	Medical Face Mask
规格型号	平面形耳挂式 175*95mm
Specification	Planar Earloop 175*95 mm
主要成分	无纺布65%, 熔喷布30%, 氨纶5%
Main Components	Nonwovens 65%, Melt blown fabric 30%, Spandex 5%
包装数量	25只/包
Quantity	25PCS/Bag
检验员 Inspector	202
生产批号 Lot No.	20200701
生产日期 Mfg date	2020.07.23
有效期至 Valid Until	2022.07.22 检验专用章
执行标准 Standard	EN14683-2019 TYPE IIR
生产商	常州怡康盖业有限公司
Manufacturer	CHANGZHOU ECON LIDS CO., LTD.
地 址	江苏省常州市天宁区郑陆镇焦溪工业集中区
Add	Jiaoxi Industrial Park, Zhenglu, Tianning Changzhou, Jiangsu, China

合格证 Certificate of Approval





25pc/bag 彩袋 color bag





中盒正面 Middle box front picture





中盒侧面 Middle box side picture







外箱 Outer carton