COVID-19
PPE & Medical Equipment

Certified. Reliable. Trusted.

Surgical Face Mask - Type IIR

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT
www.shieldworksppe.com

Shield Works PPE

With 15 years of China manufacturing experience and a team of over 50 project managers and engineers, we have the infrastructure and knowledge to ensure that all medical products are supplied by approved manufacturers to required national standards. This eliminates the risk of bulk shipments being impounded by customs at port of entry.

The SW PPE Logistics Department is here to ensure your supply gets to where it needs to be with zero unnecessary delays. Our Planning & Ops coordinators are highly experienced and knowledgeable in customs regulations in China and all major overseas markets including the USA and the EU, especially in those related to PPE such as face masks.

The close relationships we have with customs agents and brokers built over 15 years of supply chain management in China means we always stay on top of the ever-changing customs rules. Nothing catches us by surprise.

We can charter entire cargo planes, converted passenger planes and organize regular air freight and sea freight.

Take the hassle, stress and risk out of this vital part of your supply chain by engaging with SW today.

Nick Cunningham QVCS
President & Founder
Major in HM Royal Marines (ret'd)

Mark Jacobs
CEO
1st Class Mechanical Engineer

Mark Clayton FMATT
CFO
Vice-Chairman of British Chamber of Commerce Guangdong;
2019 Peace Laureate

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

- Light & breathable
- Fit & comfortable
- Triple Protection
- Safety and Hygiene

Surgical Face Mask - Type IIR

ASTM Level 2 Mask

SKU: SW-3PLYTYPEIIR

Packaging details
50 pcs per box / 2,000 pcs per carton
Carton Size: 51 x 41 x 35 cm
G.W.: 8.5 KG
CBM: 0.073
V.W.: 12.2 KG

ASTM Level 2

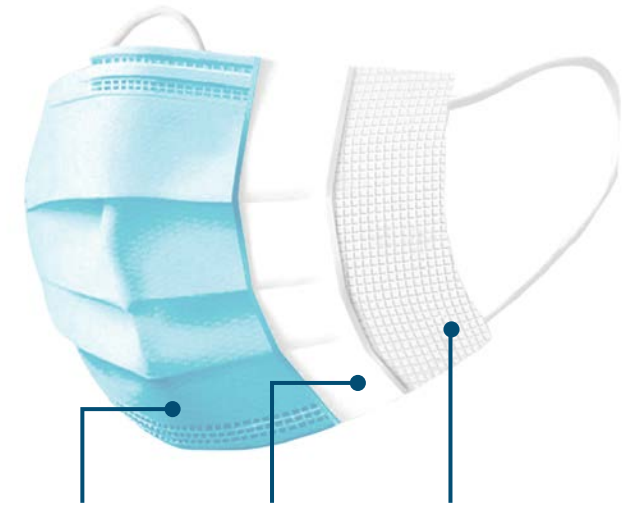
Ideal for procedures where moderate to light amounts offuid, spray and/or aerosols are produced.

Meets EN14683:2019+AC:2019 Standard.

REQUIREMENT	ACCEPTABLE LEVEL
BFE (Bacterial Filtration Efficiency) %	≥ 98%
PFE (Submicron Particle Filtration Efficiency) %	≥ 98% @ 0.1 micron
Delta P - Differential Pressure	< 5.0 mm H_2O/cm^2
Moderate Fluid Resistance	120 mmHg
Flame Spread	Class 1

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR



Certifications

FDA

CE

SGS

Packaging

10 pieces per PP bag

2000 pieces per carton

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

CERTIFICATE

CERTIFICATE OF FDA REGISTRATION

Certification No.: CTCSD20203301

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment: HUNAN TECHRAY MEDICAL TECHNOLOGY CO., LTD
Address: 1F-3F A1 BUILDING, LUGU INTERNATIONAL MEDICAL EQUIPMENT INDUSTRY ZONE, NO. 229, GUYUAN ROAD, CHANGSHA, HUNAN, 410205, CHINA
Owner/operator N0.: 10065491

Listing Number	Premarket Submission Number	Product Code(s)	Device Name	Activities
D381489	EXEMPT	KHA	MASK, SCAVENGING (disposable mask)	Manufacturer
D381492	EXEMPT	LYU	ACCESSORY,SURGICAL APPAREL	Manufacturer

Helen Han

General Manager
CTC REGISTRATION LLC
Email: ctc-086@hotmail.com
Web: www.ctc-086.com

CTC REGISTRATION GROUP SEAL

Validity: Dec.31,2020

Conclusion:
This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CTC assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CTC is not affiliated with the U.S. Food and Drug Administration.

FDA Official Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

CERTIFICATE

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

techray

Certificate No: TECA20200520

Manufacturers Declaration of Conformity

Manufacturer:

Hunan Techray Medical Technology Co., Ltd
1-3 Layer, Unit A1-229 Guyuan Road, Hunan Lu Valley International Medical Equipment Industrial Park, High-Tech District, Changsha City, Hunan Province, China

We, the manufacturer, herewith declare that the products

Medical Surgical Mask(Non-Sterile)
Flat Earloop Mask 17.5cm*9.5cm(L)

Class: Class 1
Standard: EN14683: 2019 Type IIR

Conformity Assessment Procedure: Annex VII

Meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

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

Hunan Techray Medical Technology Co., Ltd
1-3 Layer, Unit A1-229 Guyuan Road, Hunan Lu Valley International Medical Equipment Industrial Park, High-Tech District, Changsha City, Hunan Province, China

Changsha 2020.5.20
Place, Date

techray CE
Legally binding signature, Function

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0599

Test Report **SL52025245710101TX** **Date:April 28,2020**

NINGBO HST INDUSTRIAL CO.,LTD
4F, UNIT B, HUASHANG BUILDING, NO.100 OF XINGHAI SOUTH RD, YINZHOU DISTRICT, NINGBO, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable medical surgical mask: 3 layer,surface 23gsm sss non-woven fabric 1 layer;Middle-layer 25gsm Melt blown cloth 1 layer;Inner layer 23gsm sss non-woven fabric 1 layer in blue/white
Manufacturer	:	HUNAN TECHRAY MEDICAL TECHNOLOGY CO LTD
Country of Destination	:	United States
Country of Origin	:	China
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 23, 2020
Testing Period	:	Apr 24, 2020 - Apr 28, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64953763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64953763 e sgs.china@sgs.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

SGS

Test Result

Personal Protective Equipment - Standard Specification for Performance of Materials Used in Medical Face Masks

ASTM F2100-19

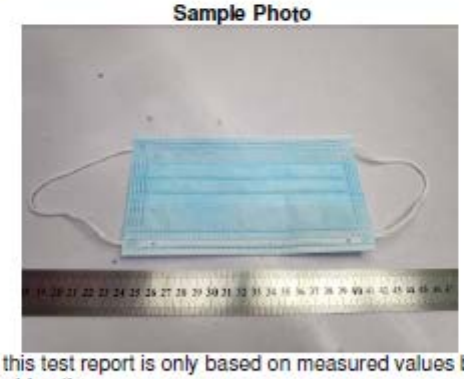
Section 6.1 Resistance to Penetration by Synthetic Blood
(ASTM F1862/F1862M-2017)

Pressure 120mmHg

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:
1) Performance Requirement Level 1 Barrier: 80mmHg, Level 2 Barrier: 120mmHg, Level 3 Barrier: 160mmHg
2) Distance of the medical face mask target area surface to the tip of cannula is 30.5cm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±5)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

3rd Building,No.889,Yishan Road,Xuhui District,Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958783 e sgs.china@sgs.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

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	**Hunan Techray Medical Technology Co., Ltd**
CLIENT ADDRESS	1-3 Layer, Unit A1-229 Guyuan Road, Hunan Lu Valley International Medical Equipment Industrial Park, High-Tech District, Changsha City, Hunan Province, China
TEST PERIOD	17-Apr-2020~08-May-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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

TEST REPORT

Sample Description	:	Medical surgical mask (non sterile type)
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	/
Specification	:	Flat Earloop
Size	:	17.5*9.5cm
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type IIR	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)	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

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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.4% Specimen 2#: 99.3% Specimen 3#: 99.3% Specimen 4#: 99.4% Specimen 5#: 99.2%
2	Differential Pressure Test	31.6 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 2 CFU/g Specimen 2#: 12 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: 2 CFU/g Specimen 5#: 4 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. **Purpose**

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

2. **Sample description was given by client**

   Sample description : Medical surgical mask (non sterile type)
   Specification : Flat Earloop
   Lot Number : /
   Sample Receiving Date : 2020-04-17

3. **Test Method**

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

4. **Apparatus and materials**

   4.1 *Staphylococcus aureus* ATCC 6538.
   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.

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

Surgical Face Mask - Type IIR

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre 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 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: 77cm^2).
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.

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

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	19	45	0	0	0	0	0	0
2	41	78	0	0	0	0	0	0
3	101	131	0	0	0	0	0	0
4	206	256	0	0	1	0	0	0
5	1179	1371	0	11	7	12	13	14
6	739	513	0	2	7	5	1	5
Total (T), CFU	2285	2394	<1	13	15	17	14	19
Average (C), CFU	$2.3x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.4	99.3	99.3	99.4	99.2
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.							

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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

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 surgical mask (non sterile type)
Specification : Flat Earloop
Lot Number : /
Sample Receiving Date : 2020-04-17

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) 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/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	30.3	31.6	< 60	Pass
2#	32.9			
3#	28.4			
4#	31.7			
5#	34.6			

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

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 surgical mask (non sterile type)
Specification	:	Flat Earloop
Lot Number	:	/
Sample Receiving Date	:	2020-04-17

3.Test Method

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 13 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

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).

Surgical Face Mask - Type IIR

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:
(ρ is the density of the test fluid.) $t = 0.5 + (2\times \rho$ - g at 0.5 s) / (g at 1.5 s - g 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 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.

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	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
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

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 surgical mask (non sterile type)
Specification	:	Flat Earloop
Lot Number	:	/
Sample Receiving Date	:	2020-04-17

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)℃ 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.

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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Test Report No.: 721654524-6
Report Date: 15 May 2020

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	1	1	2	EN 14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	10	2	12		
3#	0	0	<1		
4#	1	1	2		
5#	3	1	4		

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-

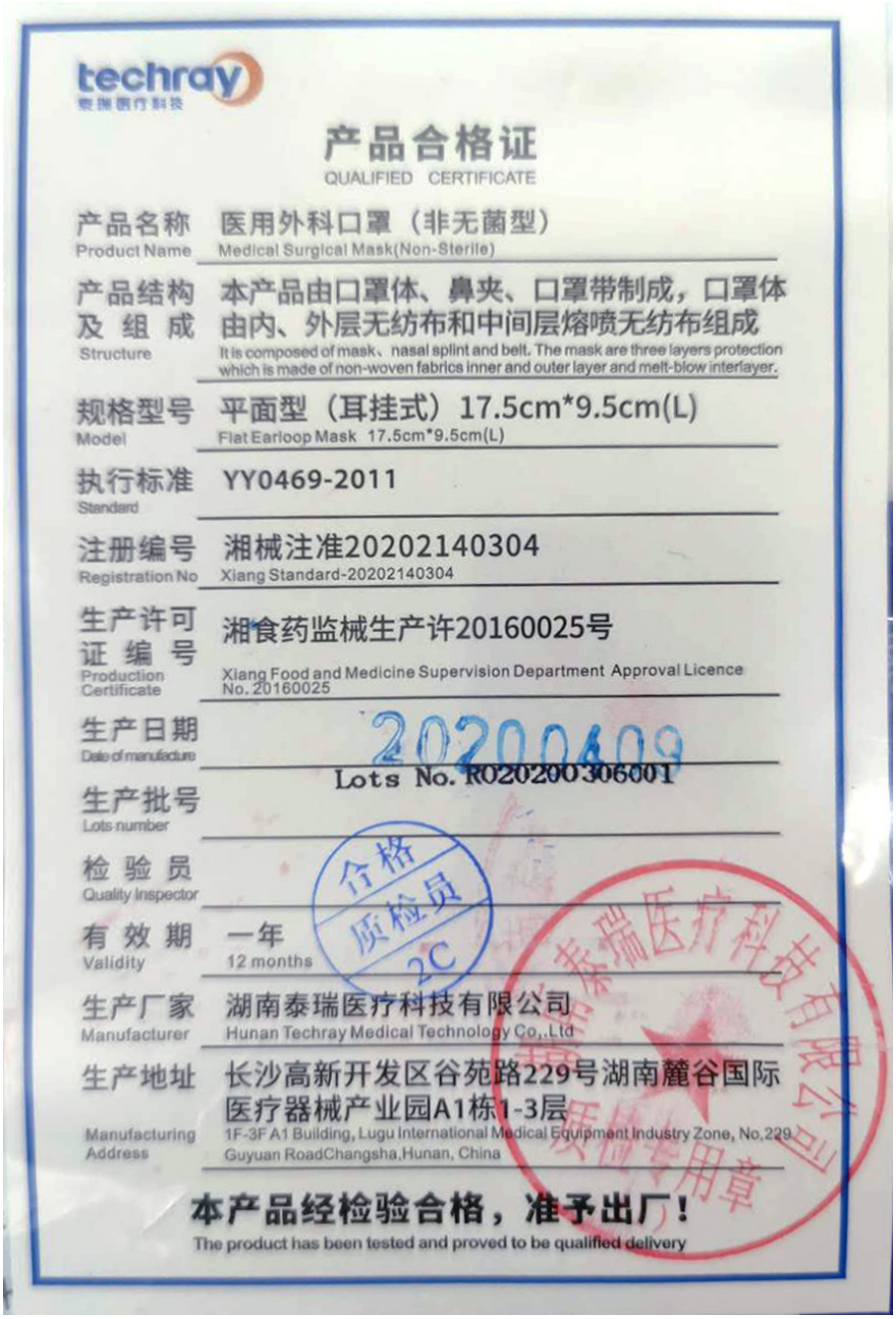
Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

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

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR



techray

产品合格证
QUALIFIED CERTIFICATE

产品名称 Product Name	医用外科口罩（非无菌型） Medical Surgical Mask(Non-Sterile)
产品结构及组成 Structure	本产品由口罩体、鼻夹、口罩带制成，口罩体由内、外层无纺布和中间层熔喷无纺布组成 It is composed of mask、nasal splint and belt. The mask are three layers protection which is made of non-woven fabrics inner and outer layer and melt-blow interlayer.
规格型号 Model	平面型（耳挂式）17.5cm*9.5cm(L) Flat Earloop Mask 17.5cm*9.5cm(L)
执行标准 Standard	YY0469-2011
注册编号 Registration No	湘械注准20202140304 Xiang Standard-20202140304
生产许可证编号 Production Certificate	湘食药监械生产许20160025号 Xiang Food and Medicine Supervision Department Approval Licence No. 20160025
生产日期 Date of manufacture	20200609
生产批号 Lots number	Lots No. R020200306001
检验员 Quality Inspector	合格 质检员 2C
有效期 Validity	一年 12 months
生产厂家 Manufacturer	湖南泰瑞医疗科技有限公司 Hunan Techray Medical Technology Co.,Ltd
生产地址 Manufacturing Address	长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层 1F-3F A1 Building, Lugu International Medical Equipment Industry Zone, No.229 Guyuan RoadChangsha,Hunan, China

本产品经检验合格，准予出厂！
The product has been tested and proved to be qualified delivery

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

techray 泰瑞医疗科技

FDA CE

医用外科口罩（非无菌型）说明书
USER MANUAL DISPOSABLE MEDICAL SURGICAL MASK

【产品名称】医用外科口罩（非无菌型）
【产品结构及组成】本产品由口罩体、鼻夹、口罩带制成，口罩体由内、外层无纺布和中间层熔喷无纺布组成，产品为非无菌供应
【性能指标】产品符合YY 0469-2011的要求
【产品适用范围】 适用于医务人员或相关人员的基本防护，以及在有创操作过程中阻止体液和喷溅物传播的防护
【规格型号】平面型耳挂式 17.5cm×9.5 cm(L)（允差±5%）
【禁忌症】对非织造布过敏者慎用
【使用说明】使用前应检查包装是否破损，以及产品是否在有效期内。取出口罩后，将白色一面朝里，蓝色一面朝外，有鼻夹的一面向上，两侧的橡筋挂于双耳。轻按鼻夹贴合鼻梁。整理口罩，使其完全覆盖鼻梁至下颌处
【贮藏】 本产品应贮存在相对湿度不超过80%，无腐蚀性气体，通风良好的室内，避免高温
Product Name: Disposable Medical Surgical Mask
Structure: It is composed of mask、nasal splint and belt. The mask are three layers protection which is made of non-woven fabrics inner and outer layer and melt-blow interlayer.. It is none-aseptic.
Standard:YY0469-2011; Type ⅡR under CE mark
Application: It is used for the protection of medical personnel or related person for protecting the wound on the operation to prevent the spread of the bodyfluid and spatter.
Model: Flat Earloop Mask 17.5cm*9.5cm(L)(±5 error allowed)
Contraindication: It is forbidden for persons who is allergic to none-weave fabric.
Instructions: Please check if the product are in period of validity. Then you need check if there' s damage in the package. Take out the mask. And make the nasal splint up. Closed to the face. Stretch the mask to cover your nose mouth and chin completely.
Storage: The mask should store in the place with Good ventilation to avoid the high temperature. And there' s no corrosive gas. The humidity should less than 80%

【符号说明 Notice】


不得二次使用
Disposable use


包装破损请勿使用
Do not use it if the package is damaged

【生产日期】见包装
【有效期】1年
【产品注册号/产品技术要求编号】湘械注准20202140304
【生产许可证编号】湘食药监械生产许20160025号
【生产企业】 湖南泰瑞医疗科技有限公司
【公司地址】长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层
【生产地址】长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1层
【注意事项】1.一次性使用
2.包装破损禁止使用
3.请在有效期内使用
4.使用前应认真阅读使用说明书
【联系方式】电话：400-625-7090 网址：http://www.techray.cn
Production date: Showed on pack
Validity: 12 months
Registration No: Xiang Standard-20202140304
Production Certificate: Xiang Food and Medicine Supervision Department Approval Licence No. 20160025
Manufacturer: Hunan Techray Medical Technology Co,.Ltd
Registered Address: 1F-3F A1 Building, Lugu International Medical Equipment Industry Zone, No,229, Guyuan Road Changsha, Hunan, China
Manufacturing Address: 1F A1 Building, Lugu International Medical Equipment Industry Zone, No,229, Guyuan Road Changsha,Hunan, China
Notes:
1. Disposable Use
2. Do not use if the package is damaged
3. Please use it within the validity period.
4. Please read the user manual carefully before use

Tel: +86 136 6738 5786 Web: www.techray.cn www.techraychina.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

对外贸易经营者备案登记表

统一社会信用代码：91430100796886272X

备案登记表编号：03600808　　进出口企业代码：

经营者中文名称	湖南泰瑞医疗科技有限公司		
经营者英文名称	Hunan Techray Medical Technology Co., Ltd		
组织机构代码		经营者类型（由备案登记机关填写）	有限责任公司
住　所	长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层		
经营场所（中文）	长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层		
经营场所（英文）	1F-3F A1 building, Lugu International Medical Equipment Industry Zone, No. 229, Guyuan Road,Changsha,Hunan, China		
联系电话	15116462913	联系传真	0731-83092294
邮政编码	410205	电子邮箱	1875509433@qq.com
工商登记注册日期	2007-1-29	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	叶钊晖	有效证件号	440225197509300017
注册资金	叁仟叁佰叁拾叁点叁叁叁叁万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产		（折美元）	

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2018 年 06 月 15 日

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

2018 年 6 月 25 日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

统一社会信用代码
91430100796886272X

营业执照

（副 本） 副本编号：6 - 1

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　湖南泰瑞医疗科技有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　叶钊晖

经营范围　医疗器械技术开发；辐射防护器材销售、安装、维护、研发；Ⅱ类：医用制氧设备的安装、研发、制造、销售；Ⅱ类：医用供氧吸引系统的制造、销售、安装、研发；二类医疗器械、电子产品、水处理设备的研发；医疗设备的维护；自营和代理各类商品及技术的进出口，但国家限定公司经营或禁止进出口的商品和技术除外；机电设备安装工程专业承包；环保工程专业承包；水处理设备的安装；计算机械助设备、计算机外围设备、污水处理设备、水处理剂、电子产品、计算机软件、水处理设备的销售；医疗设备维修；电子产品、二类医疗器械的生产；建筑装饰；洁净净化工程设计；洁净净化工程施工；电子自动化工程安装服务；智能化安装工程服务；医疗设备租赁服务；软件技术服务；计算机技术开发、技术服务；智能化技术服务；医疗器械技术咨询、交流服务；一类医疗器械、二类医疗器械、三类医疗器械的批发；医疗信息、技术咨询服务；医疗设备的技术咨询，管道工程施工服务，计算机技术咨询；二次供水设施清洗消毒；污水处理设备的制造；投资咨询（不含金融、证券、期货）（不得从事吸收存款、集资收款、受托贷款、发放贷款等国家金融监管及财政信用业务）。（依法须经批准的项目，经相关部门批准后方可开展经营活动。未经批准不得从事P2P网贷、股权众筹、互联网保险、资管及跨界从事金融、第三方支付、虚拟货币交易、ICO、非法外汇等互联网金融业务）

注册资本　叁仟叁佰叁拾叁万叁仟叁佰叁拾叁元整

成立日期　2007年01月29日

营业期限　2007年01月29日 至 2057年01月28日

住　　所　长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层

登记机关

2020 年1 月3 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

医疗器械生产许可证

许可证编号：湘食药监械生产许20160025号

企业名称：湖南泰瑞医疗科技有限公司

生产地址：长沙高新开发区谷苑路 229 号湖南麓谷国际医疗器械产业园 A1 栋 1-3 层、长沙市岳麓区长沙高新开发区麓谷大道679号通发高新厂房、宁乡市高新区金水西路66号大科园 D 区 9 栋 4 楼

法定代表人：叶钊晖

生产范围：Ⅱ类：14-14 医护人员防护用品；14-13 手术室感染控制用品；14-06 与非血管内导管配套用体外器械；08-07 医用供气排气相关设备；08-04 医用制氧设备； Ⅲ类：- 旧版Ⅱ类：医用制气设备-6854-8；供氧系统-6856-1； 旧版Ⅲ类：-

企业负责人：叶钊晖

住　　所：长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层

发证部门：湖南省药品监督管理局

有效期限：至 2021 年 06 月 12 日

发证日期：2020 年 03月 10 日

国家药品监督管理局制

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

医疗器械经营许可证

许可证编号：湘长食药监械经营许20170092号

企业名称：湖南泰瑞医疗科技有限公司

法定代表人：叶钊晖

经营方式：批发

企业负责人：叶钊晖

住　　所：长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋1-3层

经营范围：III类医疗器械：6821 医用电子仪器设备（不含植入式心脏起搏器），6822 医用光学器具、仪器及内窥镜设备 ，6823医用超声仪器及有关设备，6824医用激光仪器设备，6825医用高频仪器设备，6826物理治疗及康复设备，6828医用磁共振设备，6830医用X射线设备，6840临床检验分析仪器及诊断试剂（诊断试剂除外），6845体外循环及血液处理设备，6854手术室、急救室、诊疗室设备及器具，6877介入器材。

经营场所：长沙高新开发区谷苑路229号湖南麓谷国际医疗器械产业园A1栋3层

库房地址：长沙高新开发区麓松路489号湖南惠同公司生产厂房101-1

发证部门：长沙市食品药品监督管理局

有效期限：至　二〇二二　年　四　月　二十六日

发证日期：二〇一七　年　四　月　二十七日

国家食品药品监督管理总局制

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Certificate of Registration

nqa.

This is to certify that the Quality Management System of

Hunan Techray Medical Technology Co., Ltd.

Unified Social Credit Code： 91430100796886272X

Operation Address : 1-3 Layer, Unit A1-229 Guyuan Road, Hunan Lu Valley International Medical Equipment Industrial Park, High-Tech District, Changsha City, Hunan Province, China; North Chamber of Hunan Huitong Company's Production Plant, No.489, Lusong Road, Changsha High-tech Development Zone, Changsha City, Hunan Province, China

Registered Address : 1-3 Layer, Unit A1-229 Guyuan Road, Hunan Lu Valley International Medical Equipment Industrial Park, High-Tech District, Changsha City, Hunan Province, China

applicable to

Design, production, sale, installation and after-sales service of medical central oxygen generator system, medical central oxygen supply and suction system(within the scope of license)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number	**40154**
Date:	10 September 2014
Reissue Date:	25 March 2019
Valid Until:	25 March 2022
EAC Code:	19

UKAS MANAGEMENT SYSTEMS
015

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

To: Whom it may concern

Letter of Authorization

Whereas, Hunan Techray Medical Technology Co., Ltd located at 1F-3F A1 building, Lugu International Medical Equipment Industry Zone, No. 229, Guyuan Road,Changsha,Hunan, China
an established and reputable manufacturer of: **MEDICAL SURGICAL MASKS.**

We do hereby authorize our Regional General Agent:

CHINA 2 WEST SERVICES LTD.
and its subsidiary SHIELD WORKS

to be sales representative in **the territories of USA, UK and EU** to offer and supply our products.

We assure to supply, good quality products guaranteed as per the manufacturer's standard. Thank you for considering our products as your preferred choice.

Please do not hesitate to contact us if further clarification is required. Your Sincerely,

VALIDITY: May 1,2020 - Dec.30,2020

Signature of authorized representative of the manufacturer:

Manufacturer Stamp:

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Document Number: SWPPE-CE-3PLY-003 Version: 001

EC DECLARATION OF CONFORMITY

Manufacturer

Name: **HUNAN TECHRAY MEDICAL TECHNOLOGY CO., LTD.**

Address: **1F-3F A1 BUILDING, LUGU INTERNATIONAL MEDICAL EQUIPMENT INDUSTRY ZONE, NO. 229, GUYUAN ROAD CHANGSHA, HUNAN, CHINA**

Authorized Representative

Name: **China 2 West Services Limited**

Address: **Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong**

Declares that the MDD described hereafter

Product name and model:

Medical Surgical Mask (non-sterile)

The product is certified to meet the Essential requirements and relevant provisions of EC Directive: Medical Devices Directive 93/42/EEC

Standard(s)/Directive(s):

EN 14683:2019+AC:2019

as shown in the test reports:

721654524-6

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

The above-mentioned declaration of conformity is exclusively under the responsibility of

Company: China 2 West Services Limited
Address Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong

Zhuhai China, 2020-05-20
Place, date

Expiry date: 2021-05-20

CHINA 2 WEST SERVICES LIMITED

Mark Clayton, Group CFO
Legally binding signature

shieldworksppe.com

Get in touch

For serious inquiries, contact us for more information and an accurate quote.

shieldworksppe.com

info@shieldworksppe.com
China Headquarters: +86 (0)756 3828390
US Head Office: (+1) 650 666 0050

Part of the C2W Group - Supply Chain Management Experts in China since 2005.

www.china2west.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT