COVID-19
PPE & Medical Equipment

Certified. Reliable. Trusted.

Surgical Face Mask - TypeIIR

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-3PLY-TYPEIIR

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

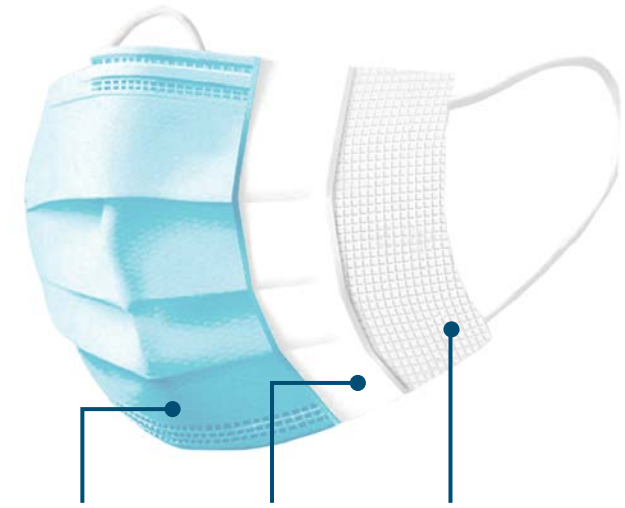
CE FDA






SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR



Certifications

AC

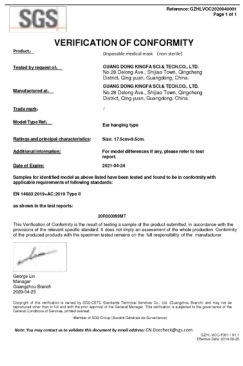

GTTC

Test Report

CE


SGS

DECLARATION OF COMPLIANCE


SGS

VERIFICATION OF CONFORMITY

FDA


FDA CERTIFICATION OF REGISTRATION
2020

Packaging

10 pieces per PP bag

50 pieces per box

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

FDA CERTIFICATION OF REGISTRATION 2020

This certifies that:
GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
has complected the FDA Establishment Registration and Device Listing with the US Food & Drug Administration.

Owner/Operator Number: 10065634

Proprietary Name	Product Codes	Premarket Submission Number/Type	Listing Number	Establishment Operations
Disposable Protective Mask	QKR	Enforcement Discretion	D384830	Manufacturer
Protective Mask				

Search Database : https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Issued: Mar.31.2020

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

VERIFICATION OF CONFORMITY

Product:	Disposable medical mask (non-sterile)
Tested by request of:	**GUANG DONG KINGFA SCI.& TECH.CO., LTD.** No.28 Delong Ave., Shijiao Town, Qingcheng District, Qing yuan, Guangdong, China.
Manufactured at:	**GUANG DONG KINGFA SCI.& TECH.CO., LTD.** No.28 Delong Ave., Shijiao Town, Qingcheng District, Qing yuan, Guangdong, China.
Trade mark:	/
Model/Type Ref:	**Ear hanging type**
Ratings and principal characteristics:	**Size: 17.5cm×9.5cm.**
Additional information:	**For model differences if any, please refer to test report.**
Date of Expire:	**2021-04-24**

Samples for identified model as above listed have been tested and found to be in conformity with applicable requirements of following standards:

EN 14683:2019+AC:2019 Type II

as shown in the test reports:

20R000099MT

This Verification of Conformity is the result of testing a sample of the product submitted, in accordance with the provisions of the relevant specific standard. It does not imply an assessment of the whole production. Conformity of the produced products with the specimen tested remains on the full responsibility of the manufacturer.

George Lin
Manager
Guangzhou Branch
2020-04-25

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

KINGFA

DECLARATION OF CONFORMITY

Manufacturer:	Guangdong KINGFA SCI.&TECH. Co., Ltd.
Address of manufacturer:	NO,28. Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product:	Disposable Medical Mask
Model Ref.:	KF-B P01(R)
Class characteristics:	Class Ⅰ (not sterile or measuring via Annex Ⅸ Rule Ⅹ)
UMDNS-Code:	12458

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(Type IIR)
	EN ISO 10993-1: 2009/AC:2010
	EN ISO 10993-5: 2009
	EN ISO 10993-10: 2010
	EN ISO 14971: 2012
	EN ISO 15223-1: 2016
	EN 1041: 2008
Conformity assessment procedure:	EC Declaration of Conformity (Annex II) + Technical Files)
EC representative:	Share Info Consultant Service LLC Repräsentanzbüro
Address:	Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 27 Apr., 2020.
Authorized by:

CE

Signature
General manager
Place: Qingyuan, China
Date: Apr. 27, 2020

广东金发科技有限公司

GUANGDONG KINGFA SCI. & TECH. CO., LTD

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report (Electronic version)

Verification Website: www.gttc.net.cn
Verification Code: UOMX-3359-44

No:20R000099MT Issue Date: 2020-04-23

Applicant: GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address: NO.28 DELONG AVE.,SHIJIAO TOWN,QINGCHENG DISTRICT,QING YUAN,GUANGDONG,CHINA

Information confirmed by applicant:
Disposable medical mask(non-sterile)
Quantity: sixty pieces
Lot number: 20031601
Size: 17.5cm×9.5cm
Model: ear hanging type
Classification: Type ⅡR

Standard Adopted:
EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-03-21

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M
Materials and construction	M
Design	M
General	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
Modified content: increased CMA affirmation and CNAS accreditation marks.
This report replaces test report 20R000099MO which has become invalid automatically.
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Nan Ma
Nan Ma Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China. Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report (Electronic version)

No: 20R000099MT

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 50.5%
Culture medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^5 CFU /ml
Positive control average (C): 1.9×10^3 CFU
Negative monitor count: ＜1 CFU
Test area: 40 cm^2
Dimensions of the test specimens:12cm×12cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

170000113982

Test Report

(Electronic version)

No: 20R000099MT

Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	5	99.74	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	8	99.58			
3	10	99.47			
4	12	99.37			
5	12	99.37			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

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

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Inspection & Testing Services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm 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 Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 50.5%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Results:

Microbial	Measured value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	4	5	≤30 EN 14683:2019+AC:2019	Type ⅡR	Pass
Fungi	1				

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Differential pressure
Test method: EN 14683:2019+AC:2019 Annex C

Test principle:
This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:
GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:
Air flow: 8 l/min
Test area: 4.9cm^2
Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
General location of the areas of the mask the differential measurements: specimen center

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Results:

Sample	Measured value (Pa)	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	149	28.2	<60 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	123				
3	136				
4	144				
5	140				
Average	138				

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

Surgical Face Mask - Type IIR

Test Report

(Electronic version)

No: 20R000099MT

Splash resistance pressure
Test method: ISO 22609:2004

Test principle:
A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:
Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:
Pretreatment: Condition each specimen for 24 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
Pressure: 16.0 kPa
Velocity: 550 cm/s

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Results:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type ⅡR	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			
Final result	pass			

Remarks:

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.

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

Materials and construction
Test Method: EN 14683:2019+AC:2019 5.1.1

Results:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	**Pass**
The medical face mask shall not disintegrate, split or tear during intended use.	**Pass**
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	**Pass**

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

170000113982

Test Report

(Electronic version)

No: 20R000099MT

Design

Test Method: EN 14683:2019+AC:2019 5.1.2

Results:

Requirement	Conclusion
The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	**Pass**
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	**Pass**

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

Test Report

(Electronic version)

No: 20R000099MT

General

Test Method: EN 14683:2019+AC:2019 5.2.1

Results:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	**Pass**

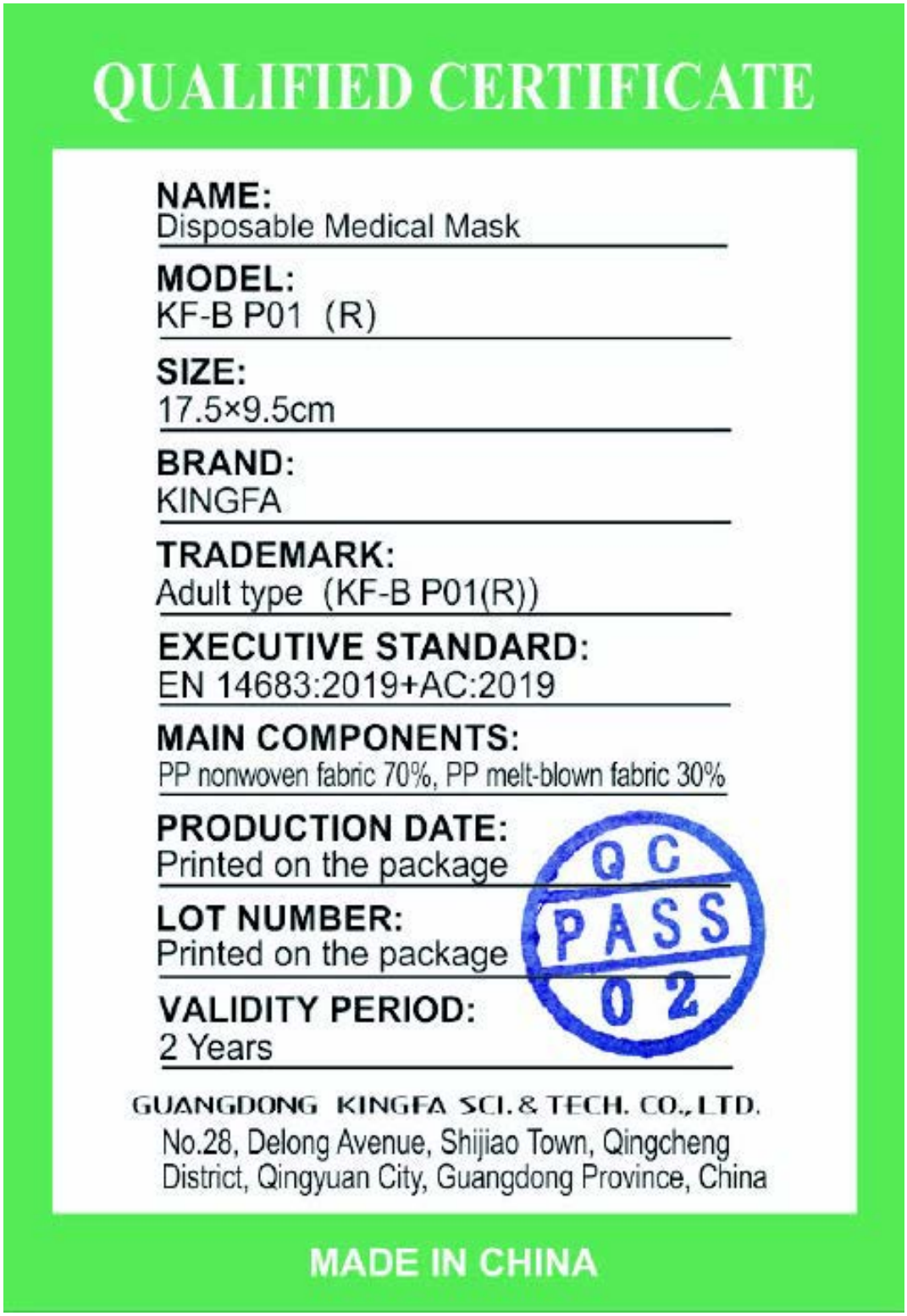
Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

———End of Report———

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR



QUALIFIED CERTIFICATE

NAME:
Disposable Medical Mask

MODEL:
KF-B P01 (R)

SIZE:
17.5×9.5cm

BRAND:
KINGFA

TRADEMARK:
Adult type (KF-B P01(R))

EXECUTIVE STANDARD:
EN 14683:2019+AC:2019

MAIN COMPONENTS:
PP nonwoven fabric 70%, PP melt-blown fabric 30%

PRODUCTION DATE:
Printed on the package

QC PASS 02

LOT NUMBER:
Printed on the package

VALIDITY PERIOD:
2 Years

GUANGDONG KINGFA SCI.& TECH. CO.,LTD.
No.28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China

MADE IN CHINA

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

INSTRUCTION MANUAL

[GRAPHS AND SYMBOLS DESCRIPTION]

1	CE	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
2	NON STERILE	Non-sterilized
3		Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.
4	EC REP	Indicates the authorized representative in the European Community.
5		Refer to instruction manual before use
6		Date of manufacture. This symbol shall be accompanied by a date to indicate the date of manufacture
7		Do not use if the package is damaged
8		Do not re-use
9		Do not dispose of this product together with domestic household wastes
10		Keep dry
11		This side up
12		Fragile, handle with care
13		Keep away from sunlight
14		Use-by date
15	LOT	Lot number
16	5	Maximum number of stack levels

GUANGDONG KINGFA SCI.& TECH. CO.,LTD.
No. 28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Tel: (+86-763) 3516888 Email: sales@kingfa.com.cn
Fax: (+86-763) 3516888 Web: http://www.kingfa.com.cn
EC REP Share Info Consultant Service LLC Repräsentanzbüro
Heerdter Lohweg 83, 40549 Düsseldorf

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

INSTRUCTION MANUAL

[Model] KF-B P01 (R)
[Trademark] Adult type (KF-B P01(R))
[Executive standard] EN 14683:2019+AC:2019
[Level] Type IIR
[Specification] Flat type 17.5cm×9.5cm
[Structure and composition] This product consists of PP nonwoven fabric , PP melt-blown fabric, nose clip and ear loops.
[Intended use]
The disposable medical mask is intended use for clinical medical personnel to wear it during invasive environment, covering the user's mouth, nose and jaw, providing a physical barrier to prevent the direct penetration of pathogens, microorganisms, body fluid, particles, etc.
[Product performance]
1.Bacterial filtration efficiency (BFE): ≥98%
2.Differential pressure (Delta-P): <60 Pa/cm^2
3.Splash resistance pressure :≥16 kPa (120mmHg)
4.Microbial cleanliness: ≤30cfu/g
[Instructions for use]
1.Open the sealed package and take out the mask.
2.Attach the mask to the face and nose horizontally, with the nose clip pointing upwards.
3.Place the fingertips of both hands on the nose clip, from the middle position, with the fingers to press inward, and gradually move to the sides to make the nose clip of the mask fit the shape of the nose.
4.Pull the ear loops while wearing the mask on the ear.
5.Spread the pleated creases and extend the mask.
[Precautions]
1.This product is a non-sterile type mask.
2.This product's validity period is 2 years. Please use within validity period.
3.The product is disposable and cannot be reused or recycled. After use, it shall be immediately destroyed or thrown into a special treatment box.
4.Please check the integrity of the package before use. Do not use the product if the package is damaged.
5.Do not use the product if you are allergic to it.
6.Incorrect wearing of this product may cause breathing difficulties.
7.Used masks are considered highly contaminated, it is essential that:
a)The body of the mask is not touched by the fingers/hands of the wearer;
b)Hands are disinfected (full hand disinfection) after mask removal;
c)A mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer;
d)A used mask should be disposed of when no longer needed or between two procedures; when there is further need for protection, a new mask should be put on.
[Validity period] 2 years
[Storage and transportation conditions] The packaged medical mask shall be stored in a room with normal temperature and relative humidity of no more than 80%, no corrosive gas, good ventilation, and fire, rat and insect prevention facilities.
During transportation, keep away from moisture, light and heat.
[Package] 50pcs/bag.
[Production date] See package
[Lot number] See package

GUANGDONG KINGFA SCI.& TECH. CO.,LTD.
No. 28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Tel: (+86-763) 3516888 Email: sales@kingfa.com.cn
Fax: (+86-763) 3516888 Web: http://www.kingfa.com.cn
EC REP Share Info Consultant Service LLC Repräsentanzbüro
Heerdter Lohweg 83, 40549 Düsseldorf

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

中国商品条码系统成员证书
GS1 China Membership License

物编注字第 Certificate No 850352 号

成员名称：广东金发科技有限公司
Prefix Licensee's Name

注册地址：广东省清远市清城区石角镇德龙大道28号
Registration Address

QR码　汉信码

厂商识别代码：697316340
GS1 Company Prefix（GCP）

厂商识别代码可用于生成下述标识代码：
GS1 Company Prefix is used to create the following GS1 Identification Keys:

全球贸易项目代码（GTIN）　全球位置码（GLN）　系列货运包装箱代码（SSCC）　全球型号代码（GMN）
全球可回收资产代码（GRAI）　全球单个资产代码（GIAI）　全球服务关系代码（GSRN）　全球文件类型代码（GDTI）
全球货物托运标识代码（GINC）　全球货物装运标识代码（GSIN）

持有本证书的成员对厂商识别代码及上述标识代码享有专用权。
The GS1 Company Prefix and other ID keys shown above are licensed for the sole use of the member named on this certificate.

机构全球位置码：6973163400014
Legal Entity Global Location Number (GLN)

有效期：2020年03月21日 至 2022年03月21日
This License shall become effective as of 21/03/2020 (d/m/y) and remain valid until 21/03/2022 (d/m/y).

NO. 0172917

GS1 China 中國物品編碼中心

中国物品编码中心 1100000003735

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

医疗器械生产许可证

许可证编号：粤食药监械生产许 20203598 号

企业名称：广东金发科技有限公司

生产地址：清远市清城区石角镇德龙大道 28 号中试车间 2-3 楼

法定代表人：宁红涛

生产范围：见医疗器械生产产品登记表

企业负责人：宁红涛

住　　所：清远市清城区石角镇德龙大道 28 号

发证部门：广东省药品监督管理局

有效期限：至 2025 年 04 月 20 日

发证日期：2020 年 04 月 21 日

国家食品药品监督管理总局制

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

统一社会信用代码
91441802077867032A

营业执照

(副 本) (副本号:1-1)

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　广东金发科技有限公司

类　　型　其他有限责任公司

法定代表人　宁红涛

经营范围　塑料、化工产品（不含危险化学品、易制毒化学品、监控化学品）、日用机械、金属制品新材料及产品的开发、研究、加工、制造、技术服务、技术转让；废旧塑料回收及利用；建筑用木料及木材组件加工；木门窗、楼梯制造；地板制造；软木制品及其他木制品制造；室内装饰、设计；模具制造；非织造布的制造及销售；卫生材料及卫生用品制造及销售；医疗器械制造及进出口业务；医用口罩、日用口罩（非医用）制造及销售；劳动防护用品制造及销售；房地产投资；物业管理；利用自有资金投资；国内商品贸易（属国家专营、专控、专卖、限制类、禁止类的商品除外）；自营进出口业务（国家限定公司经营或禁止进出口的商品和技术除外）。（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。）〓

注册资本　人民币叁亿伍仟伍佰零陆万元

成立日期　2013年09月03日

营业期限　长期

住　　所　清远市清城区石角镇德龙大道28号

登记机关　清远市清城区市场监督管理局

2020 年 3 月 19 日

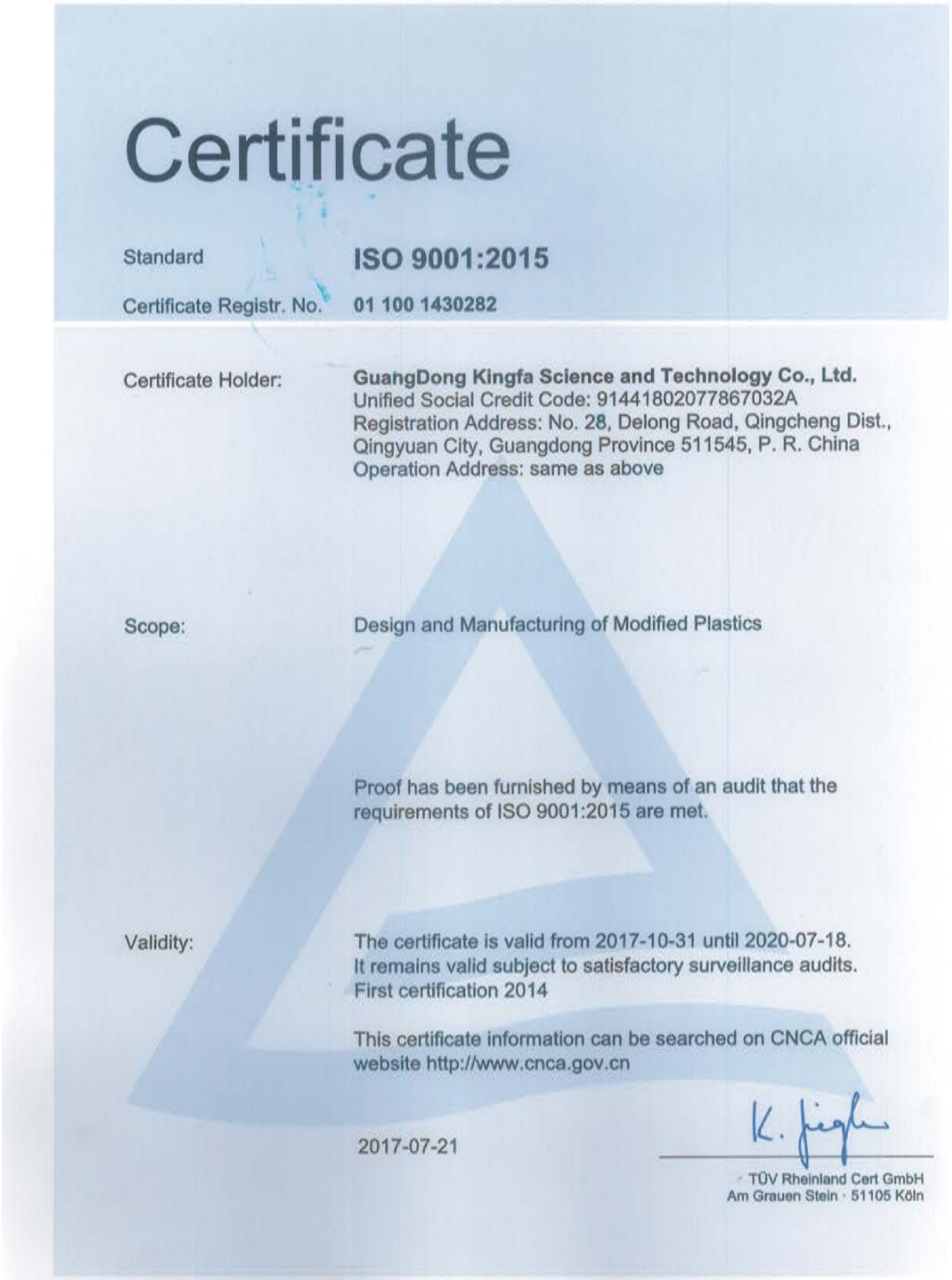
国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

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



Certificate

Standard: **ISO 9001:2015**

Certificate Registr. No.: **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist., Qingyuan City, Guangdong Province 511545, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-10-31 until 2020-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2017-07-21

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Surgical Face Mask - Type IIR

Framework Cooperation Agreement

Party A: Guangdong Kingfa Sci. & Tech. Co. Ltd.

Party B: CHINA 2 WEST SERVICES LTD. and its subsidiary SHIELD WORKS

In view of the fact that Party A has the qualification and continuous supply capacity to produce and sell mask products (in accordance with the standards stipulated by the China Drug Administration) and Party B has a wide and good global sales network in the world, especially the United States, the United Kingdom and the European Union, Party B purchases mask products and promotes overseas markets to reach a framework cooperation agreement as follows between both parties:

1. Cooperation Content

The two parties have established a long-term communication mechanism around the overseas sales of mask products. Party B collects and analyzes market data, demand, regulatory policies and other information through its sales network to visit and communicate with key customers, and Party A provides timely information and suggestions on the design, production, circulation and sales of mask products. Party A feeds back to Party B timely information on the factors affecting the supply price of mask products and real-time production capacity, and cooperates with Party B and / or target customers in the process of joint customer development and review to provide corresponding product information.

2. Cooperation Mode

If there is no other written agreement, both parties are in the relationship of sales and purchase. Party B regularly issues procurement forecasts to Party A based on market and customer development (no binding on both parties), and after Party B locks its customer's ordering requirements, it will formally issue procurement contracts / orders to Party A and follow the contracts / orders signed by both parties carried out. Party A understands that Party B will resell the mask products purchased from Party A according to its customer' s ordering. Party A recognizes that the target customers of Party B could make contact with Party A directly for whatever reasons like due diligence and factory inspections or any others. Party A recognizes that such customers are customers

Surgical Face Mask - Type IIR

of Party B and that sales to these target customers are performed by Party B.

3. Confidentiality

In the process of performing this agreement, the confidential information disclosed by one party to the other party shall not be disclosed to any third party or used for purposes other than the cooperation projects under this agreement without the written consent of the disclosing party.

4. Other

1. If both parties want to modify this agreement, they must sign a supplementary agreement in writing.

2. This agreement is effective from the date signed by the authorized representatives of both parties and affixed with the company's official seal, and is valid for one year. During the aforementioned validity period, if one party intends to terminate this agreement, it must notify the other party in writing 3 months in advance, and negotiate with the other party about the termination of the agreement.

3. Dispute resolution method: For disputes arising from the execution of this agreement, the two parties shall negotiate in a friendly way as amicable partners; if the negotiation fails, it will be submitted to the people's court in the place where the contract was signed to settle the case.

4. This agreement is made in duplicate, and each party holds one copy, which has the same legal effect.

Party A: Guangdong Kingfa Sci. & Tech. Co. Ltd.

Signature of authorized representative:

Date: May 19. 2020

Party B: *Mark Clayton, Group CFO*

Signature of authorized representative:

Date:

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Document Number: SWPPE-CE-TYPEIIR-001 Version: 001

EC DECLARATION OF CONFORMITY

Manufacturer

Name: **GUANG DONG KINGFA SCI.& TECH.CO., LTD.**

Address: **No.28 Delong Ave., Shijiao Town, Qingcheng District, Qing yuan, Guangdong, 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:

Disposable medical mask (non-sterile) KF-B P01(R)

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 Type IIR
EN ISO 10993-1: 2009/AC:2010 EN ISO 10993-5: 2009
EN ISO 10993-10: 2010
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2008

as shown in the test reports:

20R000099MT

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, 2020-04-29
Place, date

Expiry date: 2021-04-29

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