

*drive*



**International**

**Basic Face mask overview**

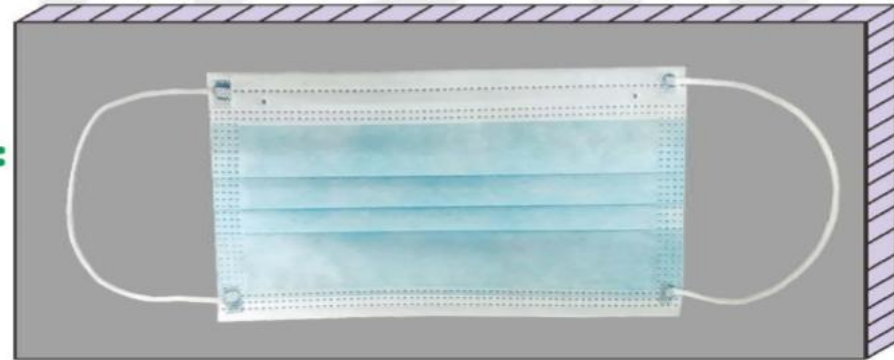
# Summary details

Fluid resistance	120mmHg
Filtration efficiency BFE	98.5 to 99%
Filtration efficiency PFE	98.5 to 99%
Breathability	49 pa/cm <sup>2</sup> (0.499 mmH <sub>2</sub> O/cm <sup>2</sup> )
Flame retardancy	Class 1
Standard compliance	EN14683
Mask type	Type II
TUV certificate	Available, within presentation
CE marked	Yes

# Mask Style

## *Disposable Face Mask Key Features:*

- Skin Friendly High Quality PP Material, 3-Ply*
- Low Breathing Resistance*
- High Bacterial Filtration Efficiency*
- Ear Loop, Elastic Band, Latex Free*
- Anatomic Adjustable Integrated nose bridge*
- Size:17.5\*9.5cm*



# Carton Label

**NONWOVEN  
FACE MASK**

**DISPOSABLE SURGICAL**

**50 Pcs/Box 40Boxes/Ctn**  
17.5x9.5cm **3ply**

**QJMDM**

**REF** JHFM002

**EC REP**  
Shanghai International Holding  
Corp. GmbH (Europe)Eiffestrasse  
80, 20537 Hamburg, Germany

**LOT**

**CE ISO13485**

**CE EN14683**    

 HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO.,LTD  
YUAN GUANG ROAD,QIANJIANG,HUBEI 433100,CHINA  
TEL:+86 728 6480411,FAX:+86 728 6480939,INFO@QJMDMGAUZE.COM  
Made in China

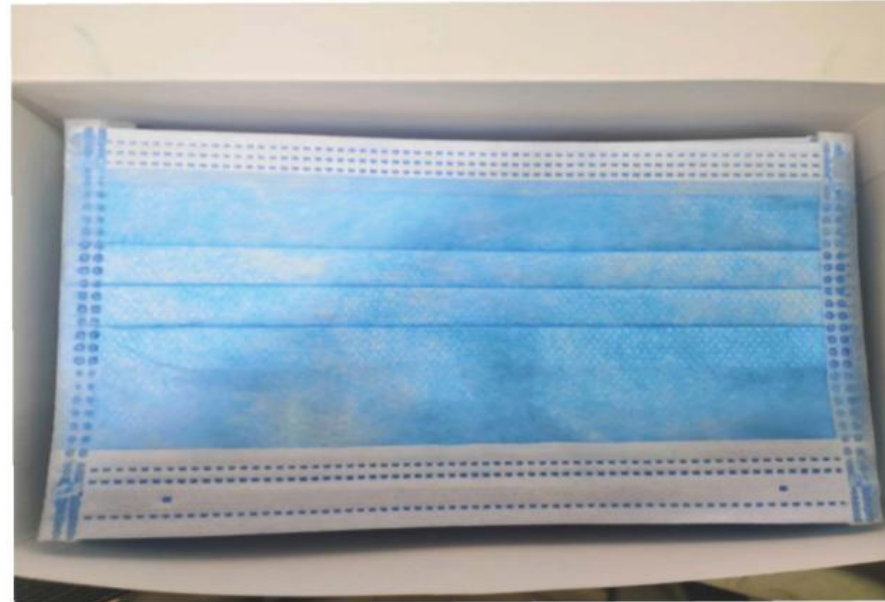
# Box layout



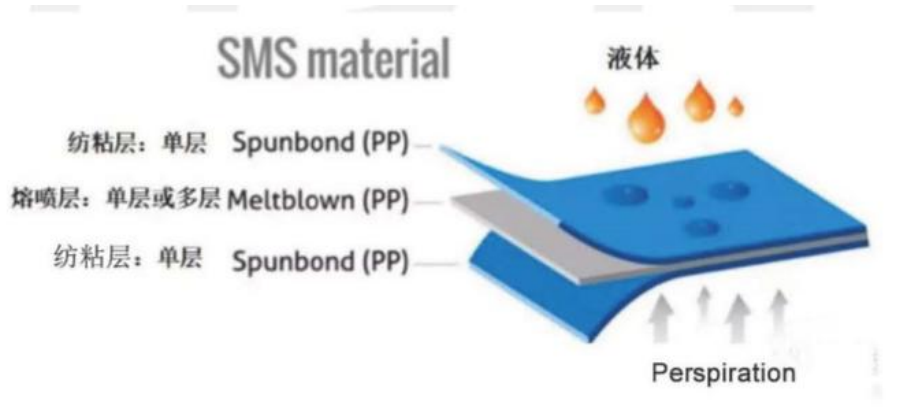
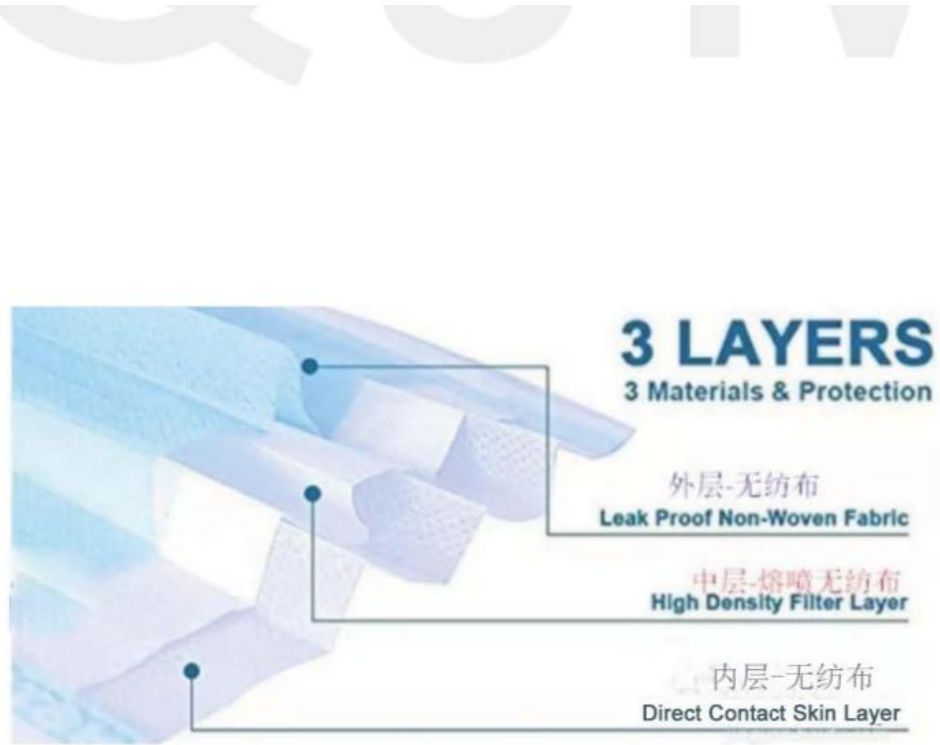
# Box and carton



50pcs/box, 40box/carton  
Carton size: 52x38x30cm



# Construction



# China National Medical Products Administration (NMPA) registration

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info@protranslate.net

## 中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20142641370

注册人名称	湖北省潜江市赫医用材料有限公司
注册人住所	潜江市园林办事处袁光路
生产地址	潜江市园林办事处袁光路
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	无纺布型 规格：10~20cm×9~12cm-(2-5)层； 脱脂纱布型 规格：10~20cm×9~14cm-(12-20)层。
结构及组成	A) 无纺布型：无纺布和过滤布经折叠、热合压片、裁切、点焊松紧带整理而成，包含挂耳式和绑带式。 B) 脱脂纱布型：脱脂纱布和口罩带缝制整理而成。
适用范围	主要供医疗卫生单位和家庭卫生护理使用。
附件	产品技术要求。
其他内容	无
备注	无

审批部门：湖北省食品药品监督管理局

批准日期：2018年04月25日

有效期至：2023年04月24日



Original  
Certificate

Certified  
Translation

## Registration Certificate For Medical Device Of The People's Republic Of China

Registration Certificate Number: Hubei Mechanical Note 20142641370

Registrant Name	Hubei Qianjiang Kingphar Medical Material Co., Ltd
Registrant Residence	Yuanguang Road, Qianjiang Garden Office
Production Address	Yuanguang Road, Qianjiang Garden Office
Agent Name	Not Applicable
Agent Residence	Not Applicable
Product Name	Disposable Medical Mask
Model, Specification	Non-woven Type Specification: 10-20 cm X 9-12cm - (2-5) layer Absorbent Gauze Type Specification: 10-20 cm X 9 - 14cm - (12-20) layer
Structure and Composition	A: Non-woven and filter cloth are finished by folding, hot-pressing, cutting and spot welding elastic bands, including ear-hanging and strap-binding types. B: Absorbent Gauze Type: It is sewn and finished by the absorbent gauze and mask band
Scope of Application	Mainly used for medical and health units and family health care.
Annex	Product technical requirements.
Other Content	No
Remarks	No

Licensing authority: Hubei Food and Drug Administration

Approval Date: 25 April 2018

Valid Until: 24 April 2023

(Seal of the licensing authority)

Hubei Food and Drug Administration

Stamp For Registration Certificate For Medical Device

Kerem KALKANCI  
Noter Terimli Tercüman  
Notary Certified Translator

# Declaration of Conformity



湖北省潜江市江赫医用材料有限公司  
HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO., LTD

## Declaration of Conformity

**Manufacturer:**

Hubel Qianjiang Kingphar Medical Material Co., Ltd.  
Yuanguang Road, 433100, Qianjiang, P. R. China

**European Representative:**

Shanghai International Trading Corp. GmbH (Hamburg)  
Eiffestrasse 80, 20537 Hamburg, Germany

**Product Name:** face mask

**Model Number:** see CE-labeled products list Q/JH.CE-001

**UMDNS Code:** 12447

**Classification (MDD, Annex IX):** I, Annex IX Rule 1

**Conformity Assessment Route:** Annex VII of MDD

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is responsible for the DOC. we are responsible for the declaration of conformity.

## DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Signature: 

Name: Wang Zhongxiao

Position: President

# UK Test & Conformity Certificate

Original  
Certificate



Certified  
Translation

## Medical Face Mask

Qualified Certificate (Seal)

Specification: 17.5 cm * 9.5 cm
Quantity: 50 PCS
Batch No: 20200404
Valid Until: 20250403
Quality Inspector No: 03

Hubei Qianjiang Kingphar Medical Material Co., Ltd

This product meets the requirements of the specified quality standards according to the delivery inspection.

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info@protranslate.net

Kerem KALKANCI  
Noter / Eminli Tercüman  
Notary Certified Translator

# ISO 13485 Certification

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認證證書

 Deutsche  
Akkreditierungsstelle  
D-ZM-13321-01-00



 Product Service

## Certificate

No. Q6 045790 0024 Rev. 01

**Holder of Certificate:** Hubei Qianjiang Kingphar  
Medical Material Co., Ltd.  
Yuanguang Road  
433100 Qianjiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 

**Scope of Certificate:** Production and Distribution of  
Sterile and Non-sterile Gauze Swabs  
with X-Ray and without X-Ray Detectable,  
Sterile and Non-sterile Lap Sponges  
with X-Ray and without X-Ray Detectable,  
Sterile and Non-sterile Gauze Balls  
with X-Ray and without X-Ray Detectable,  
Sterile and Non-sterile Cotton Filled Sponges,  
Sterile and Non-sterile Non-woven Sponges  
with X-Ray and without X-Ray Detectable,  
Sterile and Non-sterile Bandages,  
Sterile and Non-sterile Absorbent Gauze (Cutting,  
Folded or Rolled) with X-Ray and without X-Ray  
Detectable, Adhesive Wound Dressing,  
Abdominal Dressing Pad,  
Disposable Non-woven Wearing,  
Sterile and Non-sterile Absorbent Cotton,  
Dressing Kit

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1901223


**Valid from:** 2019-08-16  
**Valid until:** 2020-06-15


**Date,** 2019-08-16   
Stefan Preiß  
Head of Certification/Notified Body

Page 1 of 2  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認證證書

 Deutsche  
Akkreditierungsstelle  
D-ZM-13321-01-00

 Product Service


## Certificate

No. Q6 045790 0024 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Hubei Qianjiang Kingphar Medical Material Co., Ltd.  
No. 272 Hongjun Road, 433100 Qianjiang, PEOPLE'S REPUBLIC  
OF CHINA  
  
Hubei Qianjiang Kingphar Medical Material Co., Ltd.  
Yuanguang Road, 433100 Qianjiang, PEOPLE'S REPUBLIC OF  
CHINA

Page 2 of 2  
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不得转发

不得转发

# Certification to the Medical Device Directive

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-BS-244.10.08



Product Service

## EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)  
**No. G2S 045790 0026 Rev. 01**

**Manufacturer**      **Hubei Qianjiang Kingphar  
Medical Material Co., Ltd.**  
Yuanguang Road  
433100 Qianjiang  
PEOPLE'S REPUBLIC OF CHINA

**Product  
Category(ies):**      **Sterile Gauze Swab without X-ray Detectable,  
Sterile Gauze Ball without X-ray Detectable,  
Sterile Bandage,  
Sterile Non-woven Swab,  
Sterile Gauze Roll,  
Absorbent Cotton,  
Disposable Non-woven Wearing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:**                      SH1901223  
**Valid from:**                      2019-08-16  
**Valid until:**                      2024-04-13  
**Date,**                              2019-08-16

*S. Preiß*  
Stefan Preiß  
Head of Certification/Notified Body

Page 1 of 2  
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TUV®  
AM 1/07/17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-BS-244.10.08



Product Service

## EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)  
**No. G2S 045790 0026 Rev. 01**

**Facility(ies):**                      Hubei Qianjiang Kingphar Medical Material Co., Ltd.  
Yuanguang Road, 433100 Qianjiang, PEOPLE'S REPUBLIC OF  
CHINA  
  
Hubei Qianjiang Kingphar Medical Material Co., Ltd.  
No. 272 Hongjun Road, 433100 Qianjiang, PEOPLE'S REPUBLIC  
OF CHINA

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# USA FDA Certification

The screenshot displays the FDA's 'Establishment Registration & Device Listing' page. At the top, the U.S. Department of Health & Human Services logo is visible, along with the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION'. A search bar is located in the top right corner. Below the navigation menu, the page title 'Establishment Registration & Device Listing' is prominently displayed. A search results box is centered on the page, containing the following information:

New Search		Back To Search Results
Proprietary Name:	face mask	
Classification Name:	MASK, SCAVENGING	
Product Code:	KHA	
Device Class:	1	
Regulation Number:	868.5590	
Medical Specialty:	Anesthesiology	
Registered Establishment Name:	HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO., LTD	
Registered Establishment Number:	9616872	
Owner/Operator:	HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO., LTD	
Owner/Operator Number:	9041777	
Establishment Operations:	Repackager/Relabeler	

Below the search results, there is a 'Page Last Updated' notice and a 'Language Assistance Available' section listing various languages including Spanish, Chinese, Vietnamese, Korean, Tagalog, Greek, Arabic, Hebrew, French, Polish, Portuguese, Italian, German, Japanese, and English. The footer of the page contains the FDA logo, a list of links (Accessibility, Contact FDA, Careers, FDA Basics, FOIA, No FEAR Act, Nondiscrimination, Website Policies), the U.S. Food and Drug Administration address and contact information, a list of additional services (Combination Products, Advisory Committees, Science & Research, Regulatory Information, Safety, Emergency Preparedness, International Programs, News & Events), and the U.S. Department of Health & Human Services logo.

# Cytotoxicity Test



中国认可  
国际互认  
检测  
TESTING  
CNAS L2954

**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH-M201900219-1(E)

In Vitro Cytotoxicity Test of  
Disposable Non-woven wearing  
using ISO 10993-5: 2009 Test Method  
MTT Method  
MEM with 10%FBS extract

**Sponsor**

HuBei Qianjiang Kingphar Medical Material CO.,LTD  
Yuan Guang Road, Qianjiang, City, Hubei Province.

**Manufacturer**

HuBei Qianjiang Kingphar Medical Material CO.,LTD

Sanitation & Environment Technology Institute, Soochow University  
No.199 Ren'ai Road, Suzhou Industrial Park, China, PC 215123, <http://www.sudatest.com>  
Direct: +86 512 65880038, Free: 4001078828, Email: med@sudatest.com

SDWH -M201900219-1(E)

**STUDY VERIFICATION AND SIGNATURE**

Test Article												
	<table border="1"> <tr> <td>Test Article Receipt</td> <td>2019-01-16</td> </tr> <tr> <td>Protocol No</td> <td>SDWH-PROTOCOL-M201900219-1</td> </tr> <tr> <td>Protocol Effective Date</td> <td>2019-01-18</td> </tr> <tr> <td>Technical Initiation Date</td> <td>2019-01-18</td> </tr> <tr> <td>Technical Completion Date</td> <td>2019-01-23</td> </tr> <tr> <td>Final Report Completion Date</td> <td>2019-03-07</td> </tr> </table>	Test Article Receipt	2019-01-16	Protocol No	SDWH-PROTOCOL-M201900219-1	Protocol Effective Date	2019-01-18	Technical Initiation Date	2019-01-18	Technical Completion Date	2019-01-23	Final Report Completion Date
Test Article Receipt	2019-01-16											
Protocol No	SDWH-PROTOCOL-M201900219-1											
Protocol Effective Date	2019-01-18											
Technical Initiation Date	2019-01-18											
Technical Completion Date	2019-01-23											
Final Report Completion Date	2019-03-07											

Edited by: Wang Dehong

2019.03.07  
Date

Checked by: Zhang Liang  
Study Director

2019.3.7  
Date

Approved by: Wang Jie  
Authorized signatory



Sanitation & Environment Technology Institute, Soochow University

# Skin Sensitisation Test - 1



中国认可  
国际互认  
检测  
TESTING  
CNAS L2954

**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH- M201900219-2(E)

Skin Sensitization Test of  
Disposable Non-woven wearing  
Using ISO 10993-10:2010 Test Methods  
Guinea Pig Maximization Test  
0.9% Sodium Chloride Injection Extract

**Sponsor**

HuBei Qianjiang Kingphar Medical Material CO.,LTD  
Yuan Guang Road, Qianjiang, City, Hubei Province.

**Manufacturer**

HuBei Qianjiang Kingphar Medical Material CO.,LTD

Sanitation & Environment Technology Institute, Soochow University  
No.199 Ren'ai Road, Suzhou Industrial Park, China, PC 215123, <http://www.sudatest.com>  
Direct: +86 512 65880038, Free: 4001078828, Email: [med@sudatest.com](mailto:med@sudatest.com)

SDWH-M201900219-2(E)

**STUDY VERIFICATION AND SIGNATURE**

Test Article	
Test Article Receipt:	2019-01-16
Protocol No:	SDWH-PROTOCOL-M201900219-2
Protocol Effective Date:	2019-01-18
Technical Initiation Date:	2019-01-18
Technical Completion Date:	2019-02-14
Final Report Completion Date:	2019-02-28

Edited by: Jiang Yanan

2019-02-28  
Date

Checked by: Zhong Yan  
Study Director

Approved by: Wang Yuzi  
Authorized signatory

2019-02-28  
Date

Sanitation & Environment Technology Institute, Soochow University

# Skin Sensitisation Test - 2



中国认可  
国际互认  
检测  
TESTING  
CNAS L2954

**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH-M201900219-6(E)

Skin Sensitization Test of  
Disposable Non-woven wearing  
Using ISO 10993-10:2010 Test Methods  
Guinea Pig Maximization Test  
Sesame oil Extract

**Sponsor**

HuBei Qianjiang Kingphar Medical Material CO.,LTD  
Yuan Guang Road, Qianjiang, City, Hubei Province.

**Manufacturer**

HuBei Qianjiang Kingphar Medical Material CO.,LTD

Sanitation & Environment Technology Institute, Soochow University  
No.199 Ren'ai Road, Suzhou Industrial Park, China, PC 215123, <http://www.sudatest.com>  
Direct: +86 512 65880038, Free: 4001078828, Email: [med@sudatest.com](mailto:med@sudatest.com)

SDWH-M201900219-6(E)

**STUDY VERIFICATION AND SIGNATURE**

Test Article												
	<table border="1"> <tr> <td>Test Article Receipt:</td> <td>2019-01-16</td> </tr> <tr> <td>Protocol No:</td> <td>SDWH- PROTOCOL- M201900219-6</td> </tr> <tr> <td>Protocol Effective Date:</td> <td>2019-03-22</td> </tr> <tr> <td>Technical Initiation Date:</td> <td>2019-03-26</td> </tr> <tr> <td>Technical Completion Date:</td> <td>2019-04-25</td> </tr> <tr> <td>Final Report Completion Date:</td> <td>2019-04-29</td> </tr> </table>	Test Article Receipt:	2019-01-16	Protocol No:	SDWH- PROTOCOL- M201900219-6	Protocol Effective Date:	2019-03-22	Technical Initiation Date:	2019-03-26	Technical Completion Date:	2019-04-25	Final Report Completion Date:
Test Article Receipt:	2019-01-16											
Protocol No:	SDWH- PROTOCOL- M201900219-6											
Protocol Effective Date:	2019-03-22											
Technical Initiation Date:	2019-03-26											
Technical Completion Date:	2019-04-25											
Final Report Completion Date:	2019-04-29											



Edited by: Wang Dekang

Checked by: Zhang Yan  
Study Director

Approved by: Peng Singsi  
Authorized signatory



2019-04-29  
Date

2019-05-09  
Date

Sanitation & Environment Technology Institute, Soochow University

# Skin Irritation test - 1



中国认可  
国际互认  
检测  
TESTING  
CNAS L2954

**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH- M201900219-3(E)

Skin Irritation Test of  
Disposable Non-woven wearing  
Using ISO 10993-10:2010 Test Method  
0.9% Sodium Chloride Injection Extract

Sponsor

HuBei Qianjiang Kingphar Medical Material CO.,LTD  
Yuan Guang Road, Qianjiang, City, Hubei Province.

Manufacturer

HuBei Qianjiang Kingphar Medical Material CO.,LTD

Sanitation & Environment Technology Institute, Soochow University  
No.199 Ren'ai Road, Suzhou Industrial Park, China, PC 215123, <http://www.sudatest.com>  
Direct: +86 512 65880038, Free: 4001078828, Email: [med@sudatest.com](mailto:med@sudatest.com)

SDWH -M201900219-3(E)

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-01-16
Protocol No:	SDWH-PROTOCOL-M201900219-3
Protocol Effective Date:	2019-01-18
Technical Initiation Date:	2019-01-18
Technical Completion Date:	2019-01-25
Final Report Completion Date:	2019-02-28

Edited by: Jiang Yanjun

Checked by: Dan Mengkui  
Study Director

Approved by: [Signature]  
Authorized signatory



2019-02-28  
Date

Sanitation & Environment Technology Institute, Soochow University

# Skin Irritation test - 2



**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH- M201900219-7(E)

Skin Irritation Test of  
Disposable Non-woven wearing  
using ISO 10993-10:2010 Test Method  
Sesame Oil Extract

Sponsor  
HuBei Qianjiang Kingphar Medical Material CO.,LTD  
Yuan Guang Road, Qianjiang, City, Hubei Province.  
Manufacturer  
HuBei Qianjiang Kingphar Medical Material CO.,LTD

Sanitation & Environment Technology Institute, Soochow University  
No.199 Ren'ai Road, Suzhou Industrial Park, China, PC 215123, <http://www.sudatest.com>  
Direct: +86 512 65880038, Free: 4001078828, Email: med@sudatest.com

SDWH-M201900219-7(E)

## STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-01-16
Protocol No:	SDWH- PROTOCOL- M201900219-7
Protocol Effective Date:	2019-03-22
Technical Initiation Date:	2019-03-26
Technical Completion Date:	2019-04-05
Final Report Completion Date:	2019-04-11

Edited by: Chen zengrong      2019-04-11  
Date

Checked by: Jiao Mengwei      2019-04-11  
Study Director      Date

Approved by: Pangfeng      2019-04-11  
Authorized signatory      Date

Sanitation & Environment Technology Institute, Soochow University

# Test report and Type 1 Standard test data



## 检验检测报告 Test Report

(2020) WSZ FHL 第 1018 号

产品名称 一次性使用医用口罩  
Product Name Disposable Medical Face Mask

委托单位 湖北省潜江市江赫医用材料有限公司  
Applicant Hubei Qianjiang Kingphar Medical Material Co., Ltd

生产单位 湖北省潜江市江赫医用材料有限公司  
Manufacturer Hubei Qianjiang Kingphar Medical Material Co., Ltd

检验检测类别 委托检验  
Test Type Entrusted Inspection

江苏国健检测技术有限公司  
Jiangsu Guojian Testing Technology Co., Ltd

## 检验检测报告

Test Report

[2020] WSZ FHL 第 1018 号

共 2 页 第 1 页

产品名称 Product name	一次性使用医用口罩 disposable medical face mask	规格型号 Specification	无纺布型 17.5cm×9cm Non-woven 17.5cm×9cm
委托单位/地址/联系电话 Applicant/Addr/Tel	湖北省潜江市江赫医用材料有限公司/湖北省潜江市园林办事处袁光路/18565868631 Hubei Qianjiang Kingphar Medical Material Co., Ltd/Yuanguang Road, Qianjiang, Hubei, China		
生产单位/地址/联系电话 Manufacturer/Addr/Tel	湖北省潜江市江赫医用材料有限公司/湖北省潜江市园林办事处袁光路/18565868631 Hubei Qianjiang Kingphar Medical Material Co., Ltd/Yuanguang Road, Qianjiang, Hubei, China		
样品等级 Sample grade	—	样品编号 Sample number	GW 1018-2020
样品数量 Sample quantity	10 袋 10bags	样品接收日期 Receiving date of sample	2020 年 02 月 25 日 2020-02-25
检验检测类别 Test type	委托检验 Entrusted Inspection	货号/批号/款号 Article number/Batch number/Style number	20200213
检验检测日期 Test date	2020/02/27~2020/02/29	检验检测地点 Test site	本公司检验室 Guojian Laboratory
样品状态 Sample state	符合检验检测要求 Meet the tests requirements		
检验检测依据 Test standard(s)	YY 0469-2011《医用外科口罩》 YY 0460-2011 Surgical Face Mask 鄂械注准 20142641370：一次性使用医用口罩 鄂械注准 20142641370：Disposable Medical Face Mask		
检验检测项目 Test items	通气阻力、细菌过滤效率 airflow resistance\ BFE		
检验检测结论 Test conclusion	样品经检验，所检项目符合鄂械注准 20142641370：一次性使用医用口罩产品技术要求，具体检验结果详见第 2 页。 The samples meet the standard 鄂械注准 20142641370：Disposable Medical Face Mask The test result detail is in attached page 2. 签发日期 2020 年 2 月 23 日		
备注 Note	Entrusting party requires to test according to the technology of 鄂械注准 20142641370：Disposable Medical Face Mask 委托方要求所检项目按照鄂械注准 20142641370：一次性使用医用口罩产品技术要求进行判定。 样品信息由委托方提供，本报告只对来样负责 The sample information is provided by entrusting party, the report is only responsible for the tested samples		

批准: 审核: 主检:   
approved by reviewed by tested by

## 检验检测报告

Test Report

[2020] WSZ FHL 第 1018 号

共 2 页 第 2 页

序号 Number	检验检测项目 Test item	单位 UNIT	技术要求 Technical requirement	检验检测结果 Test result	单项评价 Single item decision
1	通气阻力* airflow resistance	Pa/cm <sup>2</sup>	口罩两侧面进行气体交换的通气阻力应不大于 49。	21.2	合格
				21.7	
				20.9	
2	细菌过滤效率 BFE	—	≥95%	98.2%	合格

备注 \*项目参照鄂械注准 20142641370：一次性使用医用口罩，该技术要求不在本公司 CMA 资质认定范围内。  
Note The items is referenced to 鄂械注准 20142641370：Disposable Medical Face Mask  
the technology requirement isn't within the scope of Guojian CMA qualification.

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# Quality Assurance Certificate of Analysis

Hubel Qianjiang Kingphar Medical Material Co., Ltd

湖北省潜江市江赫医用材料有限公司

无纺布口罩检验报告

QC REPORT - Face Mask

品名 PRODUCT	口罩 Face Mask	规格型号 SIZE	17.5*9.5cm, 3ply blue	
生产日期 Mfg Date	2020-3-05	批号 LOT	70200305	
检验日期 INS DATE	2020-3-13	报告日期 REP DATE	2020-3-15	
序号 NO.	检验项目 Testing	标准要求 Standard	检验结果 results	结论
1	外观要求 Appearance	颜色 The color must be as spec.	Blue	PASS
		表面不允许有污点, 褶皱, 破损 No stain, wrinkle or damage on the surface.	ok	PASS
		鼻夹不允许有断裂 No breaking of nose clip	ok	PASS
2	平方克重 Gram	每层每平方米重量不少于 20 克。 Not less than 20g/m <sup>2</sup> each layer.	20-25G	PASS
3	基本尺寸 Size	长度 17.5cm±5%, 宽度 9.5cm±5% The length 17.5cm±5%, The width 9.5cm±5%	Length:17.4cm Width: 9.5cm	PASS
		口罩耳环长度范围为 16cm±1cm The length is 16cm±1cm for ear loop.	length:16cm	PASS
		鼻夹长度不小于 8.0cm The length of nose clip is not less than 8.0cm	length:10.5cm	PASS
		折叠宽度均与一致 The width of fold is even	ok	PASS
4	耳带断裂强力 Strength of earloop	不小于 10N Not less than 10N	12N	PASS
5	合成血液渗透 Blood penetration	Synthetic Blood penetration resistance Test by 16.0KPa(120mmHg)	None penetration	PASS
6	阻燃性能 Flame Retardancy	离开火焰燃烧不大于 5s Not more than 5s	0	PASS
7	通气阻力 (Pa/cm <sup>2</sup> )	不大于 49 Not more than 49 Pa/cm <sup>2</sup>	20.9 - 21.7	PASS
8	微生物含量 Bioburden	不超过 30cfu/g Not more than 30cfu/g	25	PASS
9	过滤效率 Filtration Efficiency	细菌过滤效率应不小于 98% BFE shall not be less than 98% 颗粒过滤效率应不小于 30% PFE shall not be less than 30%	98.5-99%	PASS
结论 Results		经质量部确认, 产品质量符合 EN14683 要求。 The above results compiled with standard EN14683.		



检验人/Test: Liu Yan

复核人/Check: Liu Guijiao