

Executive Summary

Product - IIR STERILE Medical Masks

- **28,600,000** – IIR Sterile EO masks
 - Packed in pouches of 10 (pictured)
 - Bags of 200 (10x20)
 - Cartons of 2,000 masks (10x20x10)
 - 16 Containers = 1 container = 1,300,000 masks
- **Certification**
 - TUV Test Report EN14683
 - CE marking by TUV
 - ISO 13485 & 11135
 - SGS Factory Audit (11th May 2020)
 - SGS FRI checks on all batches
 - SGS Loading supervision & container sealing on all batches
 - Manufacturer declaration of conformance
- **Manufacturer**
 - NMPA White-Listed
 - UK Government Technical Advisory sign off
 - Licensed medical device manufacturer
 - Trading over 30 years
 - 500+ staff



Mask: Type IIR Sterile [EO]

Characteristics of Type IIR face masks include:

- Pleat style with ear loops or ties
- Protective three-layer construction
- Splash resistant layer against bodily fluids.

The masks we are offering are the highest-grade mask, IIR and offer 98%+ bacterial filtration efficiency (BFE).

Sterilisation by ethylene oxide [EO]. There are a very limited number of factories ISO certified to sterile masks to EC standards.

The masks are produced to EC standard EN14683, and are CE marked by an EU approved body, TÜV.

TEST AREA	EU TYPE IIR REQUIREMENTS
BACTERIAL FILTRATION (3.0µm)	≥ 98%
SPLASH RESISTANCE PRESSURE / kPa	≥ 16kPa
DIFFERENTIAL PRESSURE / Pa/cm ²	< 60.0
MICROBIAL CLEANLINESS / CFU/g	< 30

Mask Specification



Product Pictures



Packing specification

- 10 masks per pouch
- 20 pouches per bag
- 10 bags per carton
- 2,000 pcs total.



3 barcodes (EAN-13)

- 1 on pouch
- 1 on bag
- 1 on carton

(For simple inventory management.)





Certification

2. TÜV Test Report (EN14683)

TEST REPORT

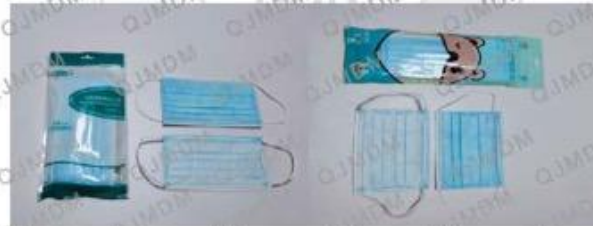
Sample Description : Non-woven surgical mask
Sample Quantity : 50 pieces
Lot Number/Batch Code : 20200228
Specification : /
Size : 17.5x9.5cm-3ply
Type of Mask : Type IIR
Brand Name : /
Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN-14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
= No comment;
N.D. = Not detected.

Photo of Samples



44 / 05.17

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Certification

3. TÜV ISO 13485

Certificate

No. Q6 045790 0024 Rev. 02

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.: SH2001202
Valid from: 2020-06-16
Valid until: 2020-12-31

Date, 2020-06-05
Christoph Dicks
Head of Certification/Notified Body



Full document available

CERTIFICATE

No. Q8 18 01 45790 025



Product Service

Certification
4. TÜV ISO 11135

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

**Certification Mark:**

Scope of Certificate: ETO Sterilization Service for Medical Devices
 Steam Sterilization Service for Medical Devices

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

Report No.: SH1801222

Valid from: 2018-06-13
Valid until: 2020-06-15



Date, 2018-06-13

S. Preiß
 Stefan Preiß

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TUV®

Section 1: Company Profile

Certification

5. SGS Factory Audit (11th May 2020)

1.1 Basic Information			
Name of Supplier	HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO., LTD. 湖北省潜江市江赫医用材料有限公司		
Address in License	Yuan'guang Road, Qianjiang City, Hubei Province, China		
Audited Address	Yuan'guang Road, Qianjiang City, Hubei Province, China		
Main Product	Disposable Medical Mask, 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		
Industry experience	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: 19 years; Disposable Medical Mask: 16 years		
License Number	914290051836675600	Corporate Representative	Mr. Zhongxiao Wang
Registration Date	10 Oct., 2001	Expiry Date	Long Valid
Registered Capital	RMB 25,000,000	Paid-in Capital	RMB 6,770,000
Area of Office	2,000 square meters (Observation)	Area of Workshop	23,000 square meters (Observation)
1.2 Contact Way			
Company Representative	Mr. Pascal Liang/ Sales		
Tel. number	86-13667254953	86-13667254953	86-13667254953
E-mail	pascal@kingphar.cn		
1.3 Nature of Enterprise			
Type of Ownership	<input checked="" type="checkbox"/> Privately Owned <input type="checkbox"/> Public Company <input type="checkbox"/> Joint Venture <input type="checkbox"/> Stated Owned <input type="checkbox"/> Others		
Type of Company	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Foreign trader <input checked="" type="checkbox"/> Both		
Subsidiary Factory	NO		
Relationship with Subsidiary Factory	<input checked="" type="checkbox"/> No subsidiary factory <input type="checkbox"/> Shareholder <input type="checkbox"/> Wholly owned <input type="checkbox"/> Belong to one group		
Overview			

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Attention: To ensure the accuracy of testing/inspection report & certificate, please contact us at telephone: (86-755)81671443, or email: CN.Descheck@sgs.com



Certification

6. Manufacturer Declaration of Conformance

Declaration of Conformity

Manufacturer:
Hubei Qianjiang Kingphar Medical Material Co., Ltd.
Yuanguang Road, 433100, Qianjiang, P. R. China

European Representative:
Shanghai International Holding Corp. GmbH (Europe)
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

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

Certification

7. SGS Final Inspection Report

4.4 Function or assembly test: **Conform**
 If factory equipment used, calibration record: No. _____ period: N/A _____

Check points	Qty	Test Result	Specification/Tolerance
Smell check	500	Acceptable	/
Mask inside check	3	3-ply	/
Wearing check	3	Acceptable	/
Carton drop test	1	Acceptable	From 76cm height, 13lines, 6 sider

5. Packing

5.1 Individual packing conformity: **Conform**
 - Each piece in flat packed.

5.2 Inner packing conformity: **Conform**
 - ___10___ pieces solid color & size per bag (heat sealed).
 - ___20___ bags (i.e. ___200___ pieces) per big poly bag sealed by metal string.
 - ___10___ big poly bags (i.e. ___2000___ pieces) per export carton

5.3 Export packing conformity: **Subject to client's eval**
 - ___2___ ply corrugated cardboard carton
 - Sealed by gummed tapes

5.4 Packing assortment checked on ___50___ cartons **Conform**

Carton No.	Size/ style	Color	Deviation (+/- samp)

6. Marking / Label:

6.1 Bar code: **Conform**
 Readable & correct

6.2 Export Carton Marking: **Conform**
 A. Shipping mark conformity: **Conform**
 Stuck on one long side of export carton.
 B. Side mark conformity: **Not Applicable**

6.3 Label/Hangtag conformity:

Inspector: Sddier Zhou Factory Representative: Mr. Liang

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9. Attachment



Inspector: Sddier Zhou Factory Representative: Mr. Liang
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Container NO



Container NO



Empty container



Carton storage



Empty container



Sealed air hole

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Instruction



Production certificate



Packing



Poly bag print



Production view



Container view

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Carton opening



Sealed poly bag



Poly bag printing

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1/2 container



3/4 container



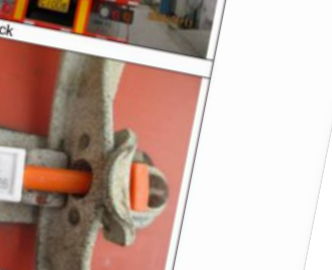
Full container



Sealed with lock



Shipping lock



SGS lock

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