

KF-B P01(R)

# DISPOSABLE MEDICAL MASK

TYPE IIR





### **STAY PROTECTED!**

Our face masks go through rigorous testing and strictly follow EN14683+AC:2019 guidelines. Provide you with the best protection available.

KINGFA has 400 functional flat mask production lines, with a total daily production capacity of 40 million units.





#### **ABOUT KINGFA**

KINGFA Group was founded in 1993 and listed on the Shanghai Stock Exchange in 2004 (stock code: 600143.SH), which is the world's leading high-tech manufacturing company committed to R&D, production and marketing of advanced polymer materials, PPE & Medical supplies.

With corporate headquarters located in Guangzhou, China, and 18 manufacturing bases around the globe, KINGFA has approximately 10,000 employees worldwide. Nine global R&D centers and an industry leading investment of 4% of annual revenue into research and development further demonstrates KINGFA's commitment to innovation and advancing technology in a global market.



Founded 1993



Employees **10000+** 



Manufacturing Bases



Invention Patents **4000+** 



Countries served **130+** 



Revenue of 2020 **5,400,000,000 USD** 

KINGFA MEDICAL adheres to the development mission of "Protecting People, Building a Healthier and Better Life." and strive to become a globally trusted medical and healthcare brand. Effectively providing high quality, Chinese-made PPE & Medical supplies to people all over the world.







- 3 National Science and Technology Awards
- 15 China Patent Awards
- 93 Drafting and revision of national and industrial standards

- ISO/IEC 17025 State Accredited Laboratory
- ISO 9001 Quality Management System Certification
- ISO 13485 Medical Device Quality Management System
- QSR820 FDA Quality System Regulation
- ISO 14001 Environmental Management System
- 5 State Council Special Allowance Experts
- 15 R&D Leading Academicians
- 108 Senior Experts
- 112 Senior Professional Titles
- 125 Doctors
- 651 Masters
- UL-CTDP Accredited Laboratory
- State Key Laboratory
- National Enterprise Technology Center
- Post-doctoral Research Center
- Academician Workstation

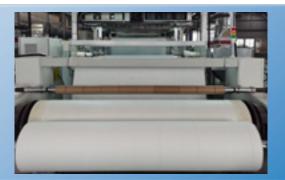


# KINGFA controls the entire industrial chain to maintain excellence within every stage of mask production.

#### **Upstream**

Polypropylene Polymerization





Midstream

Melt Blown Fabric

Downstream

Masks



KINGFA has made full use of its accumulated technology in the modified plastic industry over 27 years. With experiences and advantages in polymer processing control, testing and certification acquisition, we have successfully developed melt-blown fabric with high filtration efficiency, providing essential quality reassurance for our mask products.



#### **HOW IS A MEDICAL SURGICAL MASK MADE?**

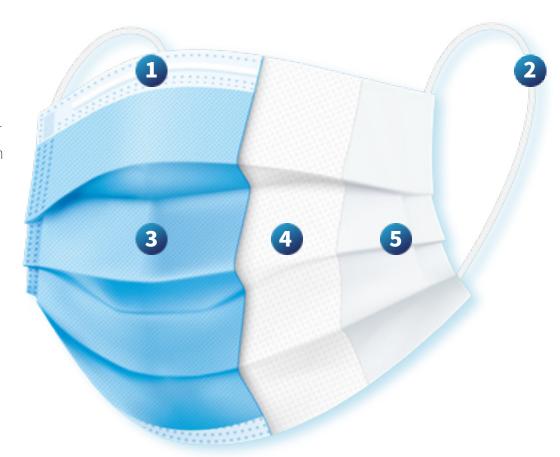
Medical surgical mask has a multilayer design. It is crafted from non-woven filtering materials, embedded with electrostatic charged microfibers.

1 NOSE CLIP

Forms strong seal for maximum protection and comfort

2 HANDY EARLOOPS

Provide a secure fit



3 EXTERIOR PROTECTIVE LAYER: PP non-woven

The colored exterior is designed to inform consumers of the proper utilization method. It is essential that one wears the mask with the colored layer facing outwards.

4 FILTRATION
LAYER:
Melt-blown

Bacteria filtration efficiency at ≥ 98%

5 INTERIOR COMFORT LAYER: PP non-woven

Enables users to wear the masks comfortably for an extended period

Medical surgical masks work as a protection barrier minimizing direct transmission of infected fluids or particles among healthcare professionals and patients.



#### **Type IIR Disposable Medical Mask**

#### Ref. No.: KF-B P01(R) Blue



#### **Application**

Medical surgical masks providing barrier to minimize the direct transmission of infective agent between staff and patients are principally intended for use by healthcare professionals in an operating room and other medical settings with similar requirements.

Technical Data Sheet			
Standard	EN14683:2019+AC: 2019		
<b>Product Classification</b>	Class I Medical Device(Annex VIII of the MDR)		
Product Dimension	Length: 175mm Width: 95mm Ear Loops Length: 175±10mm Nose Wire Length: ≥ 80mm		
Material	Inner Layer&Out Layer: PP non-woven fabric,25g/ ㎡ Filter Media: Melt-blown,25g/ ㎡		
Free of	Glass fibre, Latex, Additives		
Sterilization	Non-sterile		
Shelf Life	2 years		
Performance	Bacterial filtration efficiency (BFE)	≥ 98%	
	Differential pressure (Pa/cm²)	< 60	
	Splash resistance (kPa)	≥ 16,0	
	Microbiological Cleanliness (cfu/g)	≤ 30	





#### **Package Designs**

#### **Exterior Design**

- Size:190\*100\*80mm
- Gross weight: 207 ± 10g





#### **Carton Design**

- 50 boxes/carton
- Size:525\*395\*420mm
- Gross weight:  $11,520 \pm 500g$





#### **Container Loading**

(For Reference Only/Without Pallets)

20GP	280 cartons (700,000 units)	
40GP	600 cartons (1,500,000 units)	
40HQ	750 cartons (1,875,000 units)	_

#### **Storage And Disposal**

















#### **QUALITY CONTROL SYSTEM CERTIFICATION**

ISO 9001 Certification

# 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, Oinocheng Dis-

Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China

Operation Address: same as above

Scope:

Design and Manufacturing of Modified Plastics;

Design and Manufacturing of Masks and Non-Powered Air-

Purifying Particle Respirator

Proof has been furnished by means of an audit that the

requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2020-07-19 until 2023-07-18. 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

2020-06-08

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln











#### **QUALITY CONTROL SYSTEM CERTIFICATION**

#### ISO 13485 Certification

#### Certificate

TÜVRheinland

Quality Management System EN ISO 13485:2016

Registration No.: SX 2136111-1

Organization: GuangDong Kingfa Science and Technology

Co., Ltd.

No. 28, Delong Road, Qingcheng Dist.,

Shijiao Town, Qingyuan City,

511545 Guangdong

P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable

Medical Face Masks (non-sterile), Disposable Medical Gloves (non-sterile)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918575-100
Effective date: 2021-06-04
Expiry date: 2023-07-12
Issue date: 2021-06-04

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Akkreditierungsstelle
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TÜV Riteinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

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Contact your KINGFA representative for more information

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