

3 Masks Norms

Dust Mask

is a flexible pad held over the nose and mouth by elastic or rubber straps to protect against dusts encountered during construction or cleaning activities.

Surgical mask, also known as a **procedure mask**, **medical mask** or simply as a **face mask** is intended to be worn by health professionals during surgery and during nursing to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose. They are not designed to protect the wearer from inhaling airborne bacteria or virus particles and are less effective than respirators, such as N95 or FFP masks, which provide better protection due to their material, shape and tight seal.

The design of the surgical masks depends on the mode, usually the masks are three-ply (three layers). This three-ply material is made up from a melt-blown material placed between non-woven fabric. The melt-blown material acts as the filter that stops microbes from entering or exiting the mask. Most surgical masks feature pleats or folds.

Norms: YY0469-2011, YY/T0969-2013, EN14683-2019+AC-2019, ASTM F2100-2019

- Dust PM10
- Particulate Matter PM2.5 PM0.3
- Viruses Bacteria Gas pollution

EN14683 Medical Facemask	Bacterial Filtration Efficiency (%)	Differential Pressure (Pa/cm ²)	Splash Resistance Pressure (kPa)	Microbial Cleanliness (cfu/g)
Type I	≥ 95	< 29.4	Not required	≤ 30
Type II	≥ 98	< 29.4	Not required	≤ 30
Type IIR	≥ 98	< 49.0	≥ 16	≤ 30

4 Respirators Norms

Respirator is a device designed to protect the wearer from inhaling hazardous atmospheres, including particulate matter such as dusts and airborne microorganisms, as well as hazardous fumes, vapors and gases. United States norms the National Institute for Occupational Safety and Health, NIOSH, defines the following categories of particulate filters as of 2011:

Oil resistance	Rating	Description
Not oil resistant	N95	Filters at least 95% of airborne particles
	N99	Filters at least 99% of airborne particles
	N100	Filters at least 99.97% of airborne particles
Oil resistant	R95	Filters at least 95% of airborne particles
	R99	Filters at least 99% of airborne particles
	R100	Filters at least 99.97% of airborne particles
Oil proof	P95	Filters at least 95% of airborne particles
	P99	Filters at least 99% of airborne particles
	P100	Filters at least 99.97% of airborne particles

European norms EN 149-2000+A1-2009 defines the following classes of "filtering face pieces" (FFP), that is respirators that are entirely or substantially constructed of filtering material:

Physical Properties EN149		FFP1	FFP2	FFP3
Total Inward Leakage		Not more than 22% Average	Not more than 8% Average	Not more than 2% Average
Penetration of filter material, maximum initial penetration of test aerosols	Sodium chloride test 95l/min% max	20	6	1.0
	Paraffin oil test 95l min % max	20	6	1.0
Breathing resistance, maximum permitted resistance (mbar)	Inhalation 30 l/min	0.6	0.7	1.0
	Inhalation 95 l/min	2.1	2.4	3.0
	Exhalation 160 l/min	3	3	3.0

Australia norms AS/NZS 1716:2012 specified two level masks, P1 for 80% filter penetration limit, and P2 for 94%. Chinese norms GB19083-2010 specified KN95 for 95% filter penetration limit.

Poor fit can have a negative impact on the respirator's overall filtering effectiveness by as much as 65%.

5 Qualification



QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No: 03506011228905

This is to certify that the quality management system of **Hubei Maixin Protective Products Co., Ltd.**, No. 188 Gule Street, Yuanzhi Town, Songzi City, Hubei, China. Post Code: 434200

is in conformity with **GB/T 19001-2000 — ISO 9001:2000 Standard**

This certificate is valid to the following product(s)
Process and Service of the Disposable Non-woven Products.

Date of issue: October 25, 2008
Date of expiry at most: October 24, 2009
Representative: *Wang Penglin*

IAF (International Accreditation Forum) and **CNAB** (China National Accreditation Board) logos.

ISO 9001



CERTIFICATE

No. Q2N 87 01 51118 004

Holder of Certificate: **Hubei Maixin Protective Products Co., Ltd.**
No. 188, Gule Street, Yuanzhi Town, Songzi City, Hubei, China. PEOPLE'S REPUBLIC OF CHINA.

Facilities: Hubei Maixin Protective Products Co., Ltd. No. 188, Gule Street, Yuanzhi Town, Songzi City, Hubei, China. PEOPLE'S REPUBLIC OF CHINA.

Certification Mark: **TUV ISO**

Scope of Certificate: **Production and Distribution of Medical Use Non-woven Products for Medical Use including Non-woven Caps, Non-woven Face Masks, Non-woven Gowns, Non-woven Shoe Covers, Plastic Products for Medical Use including PE or CPE Shoe Covers, Surgical Gowns.**

Applied Standard(s): **ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements for regulatory purposes**

The Certificate Mark of TUV ISO Product Service System certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard. See also other related information.

Report No.: 1111800008
Valid until: 2009-09-24

Signature: *R. Kne*

Date: 2007-09-19
Page 1 of 2

TUV ISO Product Service System
Zertifizierungs-Systeme AG, 9000 Nürnberg, Germany

ISO 13485



EC-CERTIFICATE

Production Quality Assurance System

(Article 9 of the Directive 93/42/EEC on Medical Devices)
No. Q2N 04 05 51118 003

Manufacturer: **Hubei Maixin Protective Products Co., Ltd.**
No. 188, Gule Street, Yuanzhi Town, Songzi City, Hubei, China.

EC Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Glockenstr. 4
10245 Berlin, Germany

Product Category(ies): **Surgical Gowns, Sterile Gauze Sponges, Latex Examination Gloves.**

The Certificate Mark of TUV Product Service System certifies that the aforementioned manufacturer has implemented a quality management system for production according to Article 9 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with security and conformity with the conditions of the Directive in products intended for sale and use in the territories of the Directive. It is subject to periodic surveillance and audit conducted by the presence of the Director. It is subject to periodic surveillance and audit conducted by the presence of the Director. It is subject to periodic surveillance and audit conducted by the presence of the Director. It is subject to periodic surveillance and audit conducted by the presence of the Director.

Report No.: 1111800001
Valid until: 2009-09-24

Signature: *R. Kne*

Date: 2007-09-19

TUV PRODUCT SERVICE SYSTEM certifies a Member State (according to Council Directive 93/42/EEC) concerning medical devices and classification in CE.

Page 1 of 2

TUV PRODUCT SERVICE SYSTEM - Zertifizierungsausschuss - Erlangenstrasse 19 - D-9000 Nürnberg
Erzeuge TUV Zertifikatsausdruck

CE



NELSON
THE QUALITY CONNECTION

Hubei Maixin Protective Products Co., LTD. | Beierstrasse 19, Erlangen, Germany
Lab Number: 203548 | Report Page: 4

TABLE 1: Results

SAMPLE NUMBER	SAMPLE IDENTIFICATION	PERCENT BFE
1	2 ply mask 15-20x20 cm, Blue - 1	99.9%
2	3 ply mask 15-20x20 cm, Blue - 2	99.9%
3	3 ply mask 15-20x20 cm, Blue - 3	99.9%
4	3 ply mask 15-20x20 cm, Blue - 4	99.9%
5	3 ply mask 15-20x20 cm, Blue - 5	99.9%
6	3 ply mask 20-25x25 cm, White - 1	99.9%
7	3 ply mask 20-25x25 cm, White - 2	99.9%
8	3 ply mask 20-25x25 cm, White - 3	99.9%
9	3 ply mask 20-25x25 cm, White - 4	99.9%
10	3 ply mask 20-25x25 cm, White - 5	99.9%

CONTROL AVERAGE: 99.92%
MEAN PARTICLE SIZE: 2.7 µm

Nelson Report for BFE > 99.5%



FDA U.S. Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

15800 Registration & Listing | Address Events | E266 | Classification | CDR

CDR 506.20 | Address Comments | Assessor | Events | Guidance | Standards

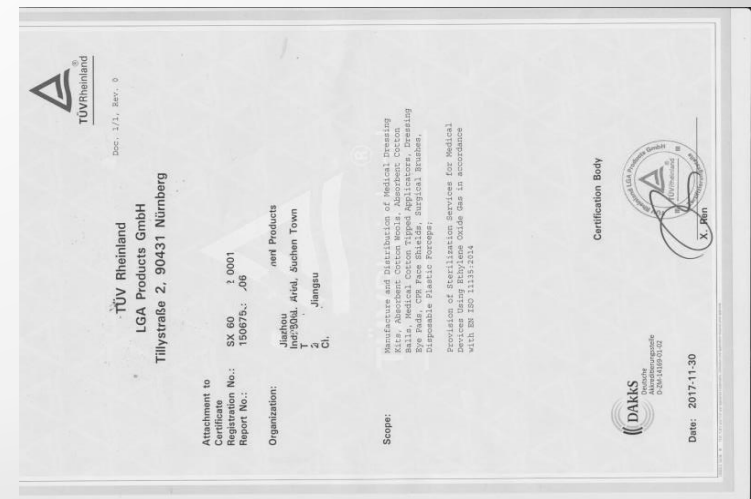
3 registered establishments meeting your search criteria returned. Established Registrations: 300/150769

Name	State/Country	Registration Number	Current Registration Yr
Hubei Maixin Protective Products Co., Ltd	CHINA	3004158259	2008

- REGIONS DISPOSABLE MEDICAL DISPOSABLE FACE SHEET Manufacturer
- DISPOSABLE SHOE COVER CONDUCTIVE NON-WOVEN NON-WOVEN SHOE COVER Manufacturer
- DISPOSABLE SURGICAL DISPOSABLE ISOLATION GOWN Manufacturer
- CPE SURGICAL DISPOSABLE BULKHEAD CAP Manufacturer
- NON-SURGICAL ISOLATION GOWN Manufacturer
- ACCESSORIES SURGICAL ATTIRE Manufacturer
- COVER, WHITNESS MEDICAL PURPOSES Manufacturer
- END USE Manufacturer

Database Updated: 07/08/2008

FDA



TUV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc.: 111, Rev.: 0

SX 60 ? 0001
158073: 26

Organization: **Jiehwei Protective Products GmbH**
Industriepark Aitel, Aichelberg
3, Janguau, 90431 Nürnberg, Germany

Scope: **Registration of Recyclization Service for Medical Devices Using Ethylene Oxide Gas in accordance with ISO 11135:2004**

DARKS
158073: 26

Date: 2017-11-30

ISO 11135

Disposable Medical Facemask

- Filter class: Type II
- Standard: EN 14683-2019+AC-2019
- Nose Clip Material: Steel
- Strap Type: Elastic earloop
- Size: 170×100mm ± 10%
- Construction: Three-ply design and made up from a melt-blown filter placed between soft non-woven fabric.



Benefits: It provides good barrier protection of bacterial and dust, low breathing resistance.

Item No.	Bacterial Filtration Efficiency(%)	Sizes	Color	Packaging	EXW Price
YCRF01	≥ 98%	adult sizes	White/ Blue/ Light Blue	100pcs/Box	Send Mail

N95 Respirator

3M 9502V+

- Filter class: FFP2 NR D
- Standard: EN 149:2001 & A1:2009, NIOSH-42CFR84, GB 2626-2006
- Nose Clip Material: Metal
- Strap Type: Elastic headband
- Construction: Hot and cold breathing valve make the breathing more comfortable and suit for more than 4hrs' wearing.



Benefits: It provides good barrier protection of bacterial and dust, low breathing resistance. The 3D design increases the oral and nasal space to eliminate the general mask respiratory urgency. CE, FDA certified.

Item No.	Bacterial Filtration Efficiency(%)	Sizes	Color	Packaging	EXW Price
YCRF10	≥ 95%	adult sizes	White	25pcs/Box	Send Mail

KN95 with Valve

- Filter class: FFP2 NR D
- Standard: EN 149:2001 & A1:2009, GB 2626-2006
- Nose Clip Material: Metal
- Strap Type: Elastic ear loop
- Construction: Hot and cold breathing valve make the breathing more comfortable and suit for more than 4hrs' wearing.



Benefits: It provides good barrier protection of bacterial and dust, low breathing resistance. The 3D design increases the oral and nasal space to eliminate the general mask respiratory urgency. CE certified.

Item No.	Bacterial Filtration Efficiency(%)	Sizes	Color	Packaging	EXW Price
YCRF11	≥ 95%	adult sizes	White/ Grey	1pc/bag,50pcs/Box, 2000pcs/carton	Send Mail

KN95

- Filter class: FFP2 NR D
- Standard: EN 149:2001 & A1:2009 and GB 2626-2006
- Nose Clip Material: Steel
- Strap Type: Elastic earloop
- Construction: Six-ply design and made up from two 25g melt-blown 90-95 standard filter with a cotton filter in the middle placed between 45g soft non-woven fabric.



Benefits: It provides good barrier protection of bacterial and dust, low breathing resistance. The 3D design increases the oral and nasal space to eliminate the general mask respiratory urgency. CE certified.

Item No.	Bacterial Filtration Efficiency(%)	Sizes	Color	Packaging	EXW Price
YCRF02	≥ 95%	Adult	White	1pc/bag,50pcs/Box, 2000pcs/carton	Send Mail

3D N95 for Children

- Filter class: FFP2 NR D
- Standard: EN 149:2001 & A1:2009 and GB 2626-2006
- Nose Clip Material: Steel
- Strap Type: Elastic earloop
- Construction: Three-ply design and made up from a melt-blown filter placed between soft non-woven fabric.



Benefits: It provides good barrier protection of bacterial and dust, low breathing resistance. The 3D design increases the oral and nasal space to eliminate the general mask respiratory urgency. CE, FDA, NIOSH, SAI certified.

Item No.	Bacterial Filtration Efficiency(%)	Sizes	Color	Packaging	EXW Price
YCRF03	≥ 95%	For 2-7 years age	Blue/White	5pcs/Bag, 2500pcs/Carton	Send Mail
YCRF04	≥ 95%	For 7-12 years age, suitable for adult as well	Blue/White	5pcs/Bag, 2500pcs/Carton	Send Mail