



Hubei Kangning Protective Products Co., Ltd

Add: Special No. 1, Xuefu Road, 433000, Xiantao, Hubei, China

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The Specification of Non Woven Face Mask

NON WOVEN FACE MASK

CE certification

Designed for medical use

High performance of BFE, PFE and ΔP

Good performance of anti micro-dust, anti-spray, anti-virus

CONFIGURATION OVERVIEW

This Mask is an air breathing apparatus designed for bacterial filtration. It consists of:

2 polypropylene (PP) layers

1 layer Melt blown (middle layer)

2 Holding Elastics

1 Nose Barrette

TECHNICAL SPECIFICATIONS

NON WOVEN FACE MASK—according to EN14683:2006 standard:

Bacterial Filtration Efficiency(BFE)>99% at $3.0 \pm 0.3 \mu m$.

Raw Material:

Layer 1: Blue, Green, Yellow, lilac, Orange, Fresh Green, Pink or White, PP Layer

Layer 2: White, Purpose-made Melt blown

Layer 3: White, PP Non woven

Holding Elastics: Urethane Elastic Fiber

Nose Barret: Polyethylene with Iron wire

Fiberglass-free and latex-free

Force at Break

Dimensions and Weight:

Dimensions: 17.5cm*9.5cm (± 1 cm)

Ear-loop: (16 ± 1)cm, elongation between 220% and 260%

Packaging

50 pcs in a PE bag, then in a box, 2000 Pcs/Carton

Box: 18cm*10cm*7cm

Carton: 52cm*38cm*30cm

THIS MASK FEATURES AND INSTRUCTIONS

Mask Features:

1. Outer Layer:

Water-repellant, to prevent fluids from entering the mask

2. Middle Layer:

Being high level static filtration non-woven, effectively preventing micro dust and bacteria with Bacteria Filtration Efficiency (BFE) at 99% at $0.1 \pm 0.003 \mu m$, tested by Nelson Lab.

3. Inner Layer:

Soft and comfortable PP non-woven

4. Total Mask:

Be good at anti-spray, blood penetration resistance at 120mm Hg.

Instructions:

1. Take and face the outer-surface of the mask.
2. While facing the outer-surface of the mask away from you, loop the ear loops comfortably around your ears.
3. Adjust the nose band to fit nicely on the bridge of your nose, conforming to the contour of your face.
4. Now holding the nose band in place, pull the bottom end of the mask under your chin to fully cover your mouth, your nose, as well as your chin.
5. To offer a good protection, it's suggested user to change a new one after using the mask for 4 hours

Storage

1. The product will maintain its properties when it is stored in a dry place at temperatures between 10 ° C and 30 ° C.
2. Not exposed to direct sunlight, the relative humidity is no more than 80%.
3. The period of validity is 5 years.



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60131859 0001

Report No.: 15085898 004

Manufacturer: Hubei Kangning Protective
Products Co., Ltd.
Special No.1 Xuefu Road
433000 Xiantao City, Hubei
China

Products: Medical Devices
(see attachment for products and additional site included)

Replaces Approval, Registration No: DD 60104371 0001

Expiry Date: 2023-10-22

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-12-04

Date: 2018-12-04



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60131859 0001
Report No.: 15085898 004

Manufacturer: Hubei Kangning Protective
Products Co., Ltd.
Special No.1 Xuefu Road
433000 Xiantao City, Hubei
China

Aspects of manufacture concerned with securing and
maintaining sterile conditions of Medical Non-woven Masks,
Medical Non-woven Gowns, Medical Coveralls

Site included:

Jiandi Village, Huchang Town, Xiantao City, Hubei, China

Date: 2018-12-04



Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: KN-FM-N01
LOT: FM20170410
Product Name: Disposable medical face mask
Study Number: 960454-S01
Study Received Date: 24 Apr 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

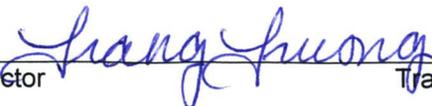
The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 175 \text{ mm} \times \sim 155 \text{ mm}$
Positive Control Average: 2.4×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $3.1 \mu\text{m}$



Study Director



Trang T. Truong, B.S.

Study Completion Date

08 May 2017



960454-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9	5.3	52.5
2	>99.9	5.2	51.3
3	99.9	5.6	54.7

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Hubei Kangning Protective
Products Co., Ltd.**
Special No.1 Xuefu Road
433000 Xiantao City, Hubei
China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-04
Certificate Registration No.: SX 60131860 0001
An audit was performed. Report No.: 15085898 004
This Certificate is valid until: 2021-10-22

Certification Body



Date 2018-12-04



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60131860 0001
Report No.: 15085898 004

Organization: Hubei Kangning Protective
Products Co., Ltd.
Special No.1 Xuefu Road
433000 Xiantao City, Hubei
China

Scope:

Products:

Medical Non-woven Masks, Medical Non-woven Gowns,
Medical Coveralls, Medical Caps, Medical Coats, Surgical
Sheets, Medical Shoe Covers, Medical Sleeve Covers,
Medical Non-woven Gloves

Site included:

Jiandi Village, Huchang Town, Xiantao City, Hubei, China
Manufacture and Distribution of the a.m. products

Certification Body



Date: 2018-12-04

