



bacterium



dust



droplet



pollen

99%

Medical

Face Mask



50  
PCS

175\*95mm  
ADULT USE



Hubei Mingerkang Health & Safety Appliances Co., Ltd

2  
Single Use



bacterium



dust



droplet



pollen

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Medical

Face Mask



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PCS

175\*95mm  
ADULT USE





bacterium



dust



droplet



pollen

BFE  
99%

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175\*95mm  
ADULT USE

# Medical Face Mask



Hubei Mingerkang Health & Safety Appliances Co., Ltd

2

Single Use

### 【Product Structure】

The main structures are ear-loop, nose clip and non-woven fabric, which is made of medical non-woven or mixture material with filter film.

### 【Scope of Application】

Mainly used for general medical environment without risk of liquid spraying.

### 【Announcements】

1. Please use the product within the validity period. It is valid for two years. 2. Please destroy it after single use. 3. If found package damage or broken, please do not use it. 4. Please find box side marks for production date.

### 【Storage condition】

Recommended for storage in dry, ventilated, non-corrosive gases and well.

## YOUR HEALTH WE CARE

### 【Use method】



1  
Choosing the colored mask  
be outside, wear ear hang belt



2  
Closely paste to the face, stretching  
to completely cover the nose, mouth  
and chin



3  
Adjust the nose bridge and  
pressing, let the mask and  
the nose, cheeks tightly



4  
If damaged, odor and moisture  
should be replaced immediately

**HUBEI MINGERKANG HEALTH & SAFETY APPLIANCES CO., LTD.**

**ADD.: NO. 1, DUTAI INDUSTRIAL PARK,  
XIANTAO-433000, HUBEI PROVINCE, CHINA**

**TEL: 0086-728-3245848**

**FAX: 0086-728-3238189**

**website: [www.hbmek.com](http://www.hbmek.com)**

**E-mail: [hbmek@mingerkang.com](mailto:hbmek@mingerkang.com)**



Descriptions:	Disposable medical face mask
Art. No.:	M001-B
Color:	white <input type="checkbox"/> light blue <input type="checkbox"/>
Style:	17.5x 9.5cm-M-C, EAR-LOOP



ISO 13485



Medical  
**Face Mask**



99%



50

Small text at the bottom of the box, likely containing manufacturing details.



Descriptions:	Disposable medical face mask		
Art. No.:	M001-B		
Color:	white <input type="checkbox"/>	light blue <input type="checkbox"/>	
Style:	17.5x 9.5cm-M-C, EAR-LOOP		
			
ISO 13485			





**Surgical Face Mask**

**DISPOSABLE SURGICAL FACE MASK**

**HUBEI MINGERKANG HEALTH & SAFETY APPLIANCES CO., LTD.**

Add: No.1, Dufai Industrial Park, Xiantao City, Hubei Province, China 433000

Carton Size: 52X42X36CM

Quantity: 2000pcs

Lote No.:

MFG Date:

Validity:



Wechat

Tel: 0086 (0) 728-3257514

Fax: 0086 (0) 728-3238189

Email: hbmek@mingerkang.com

Web: <https://www.hbmek.com>

<https://mingerkang.en.alibaba.com>

**MADE IN CHINA**

**Blue**

**MILKON**

**DISPOSABLE SURGICAL FACE MASK**



6 970478 126011



## Compliance Report

**Applicant:** Hubei Mingerkang Health & Safety Appliances Co., Ltd.  
**Address:** No.1, Dutai Industrial Park, Xiantao City Hubei Province, China.

**Product:** Working Clothes, Isolation Gown, Surgical gown, Lab Coat, Face Mask, Caps, Sleeve Cover, Shoe Cover, Boot Cover, Beard Cover, Bed Cover (Bed Sheet), Bath Loofah, Pillow Case, Pants/Bikini, Slipper, Apron, Coverall, Shopping Bag, Glove, Brassiere

**Type:** See annex for details

**Product Classification:** Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

**No. 02366**

**Initial Issue Date: 07 Jul 2015**

*Tony Chen*

General Manager (Signature)



## Annex to Report (No. 02366 )

**Hubei Mingerkang Health & Safety Appliances Co., Ltd.**

Product Name	Type
Working Clothes	S/M/L/XL/XXL/XXXL
Isolation Gown	S/M/L/XL/XXL/XXXL
Surgical gown	S/M/L/XL/XXL/XXXL
Lab Coat	S/M/L/XL/XXL/XXXL
Face Mask	17.5*9.5cm/14.5*9.5cm,14*13*5cm; 1ply/2ply/3ply/4ply/5ply;
Caps	18"/19"/21"/24"/28"; 12*64cm
Sleeve Cover	1,PP non-woven sleeve cover; 2,PE plastic sleeve cover; 3,PP with PE coated sleeve cover Regular size : 40*20cm
Shoe Cover	15*36cm,15*39cm,15*40cm,16*41cm,16*42cm
Boot Cover	40*30*10cm,38.5*48cm
Beard Cover	18",19",21",24"
Bed Cover (Bed Sheet)	210CM*120CM
Bath Loofah	S/M/L/XL/XXL/XXXL
Pillow Case	40*60cm, (80+5)*55cm
Pants/Bikini	S/M/L/XL/XXL
Slipper	27*10cm, 31*11cm or other size
Apron	70CM*115CM; 70CM*140CM
Coverall	S/M/L/XL/XXL/XXXL
Shopping Bag	2.5*50cm or other size
Glove	S/M/L/XL
Brassiere	S/M/L/XL/XXL/XXXL

This annex is only valid if attached to the report mentioned above.



This is to certify that the Quality Management System of

## Hubei Mingerkang Health & Safety Appliances Co., Ltd.

Organization Code : 55974804-4

Operation Address : No.1, Duta Industrial Park, Longhuashan Office, Xiantao City, Hubei Province, China

Registered Address : No.1, Duta Industrial Park, Longhuashan Office, Xiantao City, Hubei Province, China

applicable to

The Production and Sales of Disposable Non-steriled Non-woven Products(Gowns, Caps, Masks, Shoe Cover, Bed Cover) and The Sales of Plastic Products(Shoe Cover, Oversleeve)(Export to Europe and America)

has been assessed and registered by NQA against the provisions of

### ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



015

Certificate Number

45535

Date:

09 November 2018

Valid Until:

09 November 2021

EAC Code:

04/14





## Verification of Conformity

**Applicant:** HUBEI MINGERKANG HEALTH AND SAFETY APPLIANCES CO., LTD.  
**Address:** NO.1, DUTAI INDUSTRIAL PRAK, XIANTAO CITY, HUBEI PROVINCE. P.R. CHINA.  
**Product(s):** Non-woven product: PP and SMS Visitor Gowns, Isolation Gowns, PE coated Isolation Gowns, Surgical Gowns, Patient Gown, Lab Jacket, Lab Coats, Coveralls, Scrub Suit, Visitor Coat, Caps, Hairnets, Face Mask, Dust Mask, Shoe cover, boot cover, sleeve cover, Apron, Pants/Shorts, Beard cover, Pillow case, Bed cover/Bed sheet. Plastic Products: CPE Isolation Gown, CPE/PE Sleeves, CPE/PE shoe cover, PE boot cover, PE Apron, PE visitor coat, PE gloves, PE Cap, PE/CPE Bed cover.  
**Type(s):** See Annex  
**Product Classification:** Category I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Personal Protective Equipment( 2016/425/EU).**

*Standard(s) used for showing compliance with the essential requirements in the specified directive(s):*

**Standard(s):** EN ISO 13688:2013; EN 420:2003+A1:2009;  
EN ISO 10993-1:2009; EN ISO 10993-5:2010;  
EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

**SUNGO Certification Company Limited**



SUNGO CHINA OFFICE Tel: 021-68828052 Email: info@sungoglobal.com Website: www.sungoglobal.com  
Add: 13<sup>th</sup> Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China



扫描全能王 创建

## Annex to Cert. No.: EU141518

Product Name	Model
PP and SMS Visitor Gowns	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Isolation Gowns	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
PE Coated Isolation Gowns	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Surgical Gowns	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Patient Gown	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Lab Jacket	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Lab Coats	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Coveralls	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Scrub Suit	S 74*54cm, 108*51cm, M 76*57,110*53CM, L 78*60cm,113*55cm or as your required
Visitor Coat	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
Caps	18",19",21",24", etc.
Hairnets	17inches, 18inches, 19inches, 20inches, 21inches, 22inches, 23inches, 24inches, etc
Face Mask	17.5CM*9.5CM,14.5CM*9CM, 12.5CM*8.5CM,etc
Dust Mask	14*13*5cm, or Customized according to customer requirements
Shoe Cover	150*360mm, 150*390mm, 150*410mm
Boot Cover	31*35cm or Customized
Sleeve Cover	20CM*40CM or as your required
Apron	100*75cm or Customized
Pants/ Shorts	S, M, L, XL, XXL, XXXL
Beard Cover	14inches, 16inches, 18inches or Customized
Pillow Case	80cm*50cm+15cm or Customized
Bed Cover/Bed Sheet	195*90*20cm,195*180*20cm, 88*210cm, 106*220cm,125*245cm,etc.
CPE Isolation Gown	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
CPE/PE Sleeves	20CM*40CM or as your required
CPE/PE Shoe Cover	150*360mm, 150*390mm or as your required
PE boot cover	S, M, L, XL, XXL, XXXL
PE Apron	65*107cm,69*107cm,72*122cm,76*122cm,80*125cm,80*140cm, etc.
PE Visitor Coat	S:110*130cm,M:115*137cm ,L:120*140cm,XL:125*145cm ,XXL:130*150cm,XXXL:135*160cm or as your required
PE Gloves	L 250-290mm, etc.
PE cap	16inches, 17inches, 18inches, 19inches, 20inches, 21inches, 22inches, 23inches, 24inches, etc
PE/CPE Bed cover	S, M, L, XL, XXL, XXXL

END OF THE ANNEX





Sponsor:  
Peng Aiming  
Hubei Mingerkang Health & Safety Appliances Co., Ltd  
No 1, Dutai Industrial Park  
Xiantao City, Hubei Province, CN433000  
CHINA

## Medical Masks Final Report

Test Article: Face Mask 20200320001  
Study Number: 1235897-S01  
Study Received Date: 20 Mar 2020

Test Procedure(s): Standard Test Protocol (STP) Number: STP0036 Rev 15  
Customer Specification Sheet (CSS) Number: 20200320001 Rev 01  
Deviation(s): None

**Summary:** The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

湖北明尔康  
HUBEI MINGERKANG

### Results:

Test	EN 14683
	Type IIR
Bacterial filtration efficiency	≥98
Differential pressure, Pa/cm <sup>2</sup>	<49.0
Splash resistance pressure(kPa)	≥16,0
Microbial cleanliness(cfu/g)	≤30

Note: The results are reported as colony forming units (CFU) per mask.

< = No Organisms Detected

UTD = Unable to Determine

<sup>a</sup> UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Hu Shengguo electronically approved

Study Director

湖北明尔康卫生防护用品有限公司  
HUBEI MINGERKANG HEALTH & SAFETY APPLIANCES CO., LTD

20 Mar 2020 19:29 (+00:00)

Study Completion Date and Time



**Milkon**

1. Company information

1.1 Name: Hubei Mingerkang Health & Safety Appliances Co., Ltd

1.2 Address :  
No 1, Dutai Industrial Park  
Xiantao City, Hubei Province, China

Tel: +86-728-3245848 Fax: +86-728-3238189  
e-mail: [hbmek@mingerkang.com](mailto:hbmek@mingerkang.com)  
Site internet: [mingerkang.en.alibaba.com](http://mingerkang.en.alibaba.com)

1.3 Corresponding person:  
Allen King

[Hbmek03@mingerkang.com](mailto:Hbmek03@mingerkang.com)  
Phone: +86-18986920304

2. Product information:

Product name: Medical face mask with earloops, TYPE IIR

2.1



2.2 Applied standards: CE ISO13485  
SGS

卫生防护  
HEALTH & SAFETY

Device description:

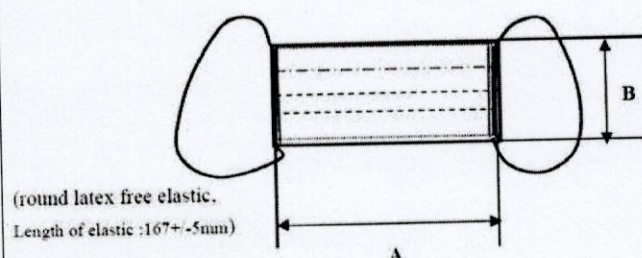
Non sterile disposable face mask with earloop, Type IIR

Composition

Composition	Color	weight	Raw material
Outer layer	Blue	$25\text{g/m}^2 \pm 1\text{g/m}^2$	polypropylene
Filter layer melt blown	white	$25\text{g/m}^2 \pm 1\text{g/m}^2$	polypropylene
Inner layer	white	$25\text{g/m}^2 \pm 1\text{g/m}^2$	polypropylene
Elastic loops	white	N/A	Polyamide + polyurethane
Nose bar	white	N/A	plastic

Latex Free

Mask form :



Dimensions :

A : 17.5 cm +/- 0.5 cm

B : 9 cm +/- 0.5 cm

用品有限  
ETY APPLIANCES

2.4	<p><u>Packaging</u> :</p> <p>50 pcs/inner box, 40 boxes/carton</p> <p>Size of carton: 52cm*42cm*36cm</p>														
2.5	<p><u>Device and accessories composition</u> :</p> <table border="1"> <thead> <tr> <th>Characteristics</th><th>Results</th></tr> </thead> <tbody> <tr> <td>Dimensional mask</td><td> Length : 175 mm <math>\pm</math> 5 mm  width: 90mm <math>\pm</math> 5 mm  Length of latex free elastic: 167 <math>\pm</math> 5 mm  Nose bar length : 135mm<math>\pm</math> 5 mm </td></tr> <tr> <td>Biocompatibility</td><td>Non cytotoxic, non irritant and non sensitive</td></tr> <tr> <td>Bacterial filtration efficiency BFE</td><td><math>\geq</math> 98.8 %</td></tr> <tr> <td>Mean particle size (MPS)</td><td>3.0 <math>\mu</math>m</td></tr> <tr> <td>respiratory strength</td><td>Delta P &lt; 31.1 Pa/cm<sup>2</sup></td></tr> <tr> <td>Microbial cleanliness</td><td><math>\leq</math> 30 cfu/g</td></tr> </tbody> </table>	Characteristics	Results	Dimensional mask	Length : 175 mm $\pm$ 5 mm width: 90mm $\pm$ 5 mm Length of latex free elastic: 167 $\pm$ 5 mm Nose bar length : 135mm $\pm$ 5 mm	Biocompatibility	Non cytotoxic, non irritant and non sensitive	Bacterial filtration efficiency BFE	$\geq$ 98.8 %	Mean particle size (MPS)	3.0 $\mu$ m	respiratory strength	Delta P < 31.1 Pa/cm <sup>2</sup>	Microbial cleanliness	$\leq$ 30 cfu/g
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# 医疗器械生产许可证



许可证编号：鄂食药监械生产许20200874号

企业名称：湖北明尔康卫生防护用品有限公司

生产地址：仙桃市龙华山办事处杜台工业园1号

法定代表人：彭爱明

生产范围：二类：6864医用卫生材料及敷料。\*\*\*

企业负责人：彭爱明

住所：仙桃市龙华山办事处杜台工业园1号

发证部门：湖北省药品监督管理局



有效期限：至 2025 年 1 月 24 日

发证日期：2020 年 1 月 25 日