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## Disposable 3-ply Medical masks

Class I, Examp

### ITEM CODES

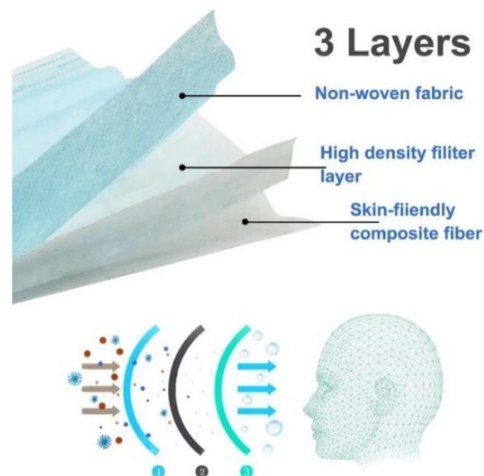
**MAS3B-Y**

**Medical Grade Equal**

**3 ply Non-woven disposable  
medical face mask**



<b>Size:</b>	17.5*9.5 cm
<b>Color:</b>	Blue/White
<b>Material:</b>	Non-woven fabrics+soft cotton, KN 95 melt blown fabric
<b>Weight:</b>	0.04 g
<b>Certificate:</b>	FDA/CE
<b>Quantity per carton:</b>	2000 pcs
<b>G.W. per carton:</b>	8.6 kg
<b>Carton size:</b>	52*38*35



# KN95/N95 MASKS

Class I, Examp



## ITEM CODES

MAN95-A

Size:	12.5*10.5 cm
Color:	White
Material:	Non-woven+soft cotton+melt blown filter
Weight:	5.5 g
Certificate:	FDA/CE
Quantity per carton:	1000 pcs
G.W. per carton:	8.4 kg
Carton size:	62*43*33

## Test Report Digest:

Classification	EN 149:2001+ A1:2009 Clause 5	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3.	Pass. FFP3.														
Penetration of filter material	EN 149:2001+ A1:2009 Clause 7.9.2	<p>The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol. Testing of penetration, exposure and storage shall be done in accordance with EN 13274-7.</p> <p>The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.</p> <table><caption>Table 1 — Penetration of filter material</caption><tr><th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol (%)</th></tr><tr><th>Sodium chloride test 95 l/min % max.</th><th>Paraffin oil test 95 l/min % max.</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>	Classification	Maximum penetration of test aerosol (%)		Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Pass The penetration of paraffin oil test is 4%. The penetration of sodium chloride test is 3.3%.
Classification	Maximum penetration of test aerosol (%)																
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.															
FFP1	20	20															
FFP2	6	6															
FFP3	1	1															
Breathing resistance	EN 149:2001+ A1:2009 Clause 7.16& Clause 8.9	<p>Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continuous flow 160 l/min. Use a suitable pressure transducer.</p> <p>Measure the exhalation resistance with the dummy head successively placed in 5 defined positions:</p> <ul style="list-style-type: none"><li>- facing directly ahead</li></ul>	Pass. Inhalation resistance at 30 l/min:<0.7mbar. Inhalation resistance at 95 l/min:<2.4mbar. Exhalation resistance at 160 l/min:<3.0mbar.														

过滤效率	%	≥95	未预处理	98.0	合格
				97.9	
				98.3	
				98.4	
				98.5	
				98.6	
				98.7	
				98.9	
				99.0	
				98.4	
			预处理	98.8	
				98.7	
				99.2	
				99.2	
				98.6	

**Owner/Operator Number: 10063890**  
**Device Listing#: See annex**  
**Expiration Date: December. 31, 2020**

2020 F&W will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. F&W makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. F&W assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, F&W is not affiliated with the U.S. Food and Drug Administration.



for and on behalf of  
**F&W (Shanghai) Certification Co., Ltd.**

**executive director**

**Dated:** March 22, 2020

**NITRILE GLOVE, Class I, Examp**

**ITEM CODES**

**MNGLOVE-A**

**100% Butyronitrile**  
**No Powder**  
**Blue or White**





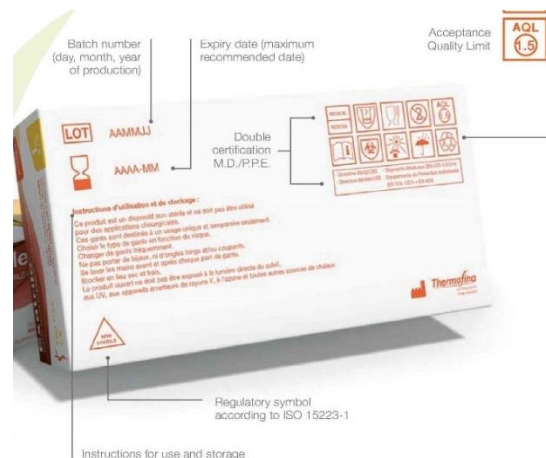


Grove Size	Lange length in mm	Breite width in mm	Artikelbeschreibung Article description	Grove Size	Farbe Color	Box-Inhalt Content
	min		Nitrilhandschuhe / Nitrile gloves	XS	weir / white	100 St. pcs
XS	240	70 + 10	Nitrilhandschuhe / Nitrile gloves	S	weir / white	100 St. / pcs
S	240	80 + 10	Nitrilhandschuhe / Nitrile gloves	M	weir / white	100 St. / pcs
M	240	95 + 10	Nitrilhandschuhe / Nitrile gloves	L	weir / white	100 St. / pcs
L	240	110 + 10	Nitrilhandschuhe / Nitrile gloves	XL	weir / white	100 St. / pcs
XL	240	110	Nitrilhandschuhe / Nitrile gloves			

## ASTM Report

Nitril / Test Report	
<b>1.1) Biocompatibility Tested</b>	
<b>Reference:</b> ISO 10993-10 (Test for Skin Irritation and Skin Sensitization)	
<b>Purpose:</b> Biological evaluation for medical devices for irritation and delayed type hypersensitivity	
<b>Property</b>	<b>Test Results</b>
Primary Skin Irritation	Passes
Skin Sensitization	Not a primary skin irritant under condition of the study
<b>1.2) Viral Penetration Tested</b>	
<b>Reference:</b> ASTM F1671 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood - Borne Pathogens Using Phi-X 174 Bacteriophage Penetration as a Test System	
<b>Purpose:</b> To test the barrier protection of the gloves from the passages of the viruses	
<b>Viral Penetration</b>	<b>Test Results</b>
	Passes
<b>Remarks:</b> Applicable to selected products. Please liaise with our representative for further details.	
<b>1.3) Heavy Metal Tested</b>	
<b>Purpose:</b> To ensure gloves are free from heavy metals substances	
<b>Chemical Test (s)</b>	<b>Test Results (mg/kg)</b>
Cadmium (Cd)	Not Detected
Lead (Pb)	Not Detected
Mercury (Hg)	Not Detected
Arsenic (As)	Not Detected
Antimony (Sb)	Not Detected
Tin (Sn)	Not Detected
<b>Remarks:</b> Applicable to selected products. Please liaise with our representative for further details.	

<b>1.4) Chemical Residue Tested</b>	
<b>Purpose:</b> To ensure gloves are free from any chemical substances	
<b>Chemical Test (s)</b>	<b>Test Results (µg/g)</b>
Butylated Hydroxyanisole (BHA)	Not Detected
Butylated Hydroxytoluene (BHT)	Not Detected
Diphenyl Thiourea (DPT)	Not Detected
Mercaptothiothiazole (MTT)	Not Detected
Tetramethylethylene Disulphide (TMED)	Not Detected
Zinc Dibutylthiocarbamate (ZDBC)	Not Detected
Zinc Diethylthiocarbamate (ZDEC)	Not Detected
Zinc Dimethylthiocarbamate (ZDMC)	Not Detected
Zinc Mercaptothiothiazole (ZMTT)	Not Detected
Zinc Mercaptothiothiazole (ZMTT)	Not Detected
Zinc Pentamethylenedithiocarbamate (ZPMC)	Not Detected
<b>Remarks:</b> Applicable to selected products. Please liaise with our representative for further details.	



## Qualitat / Quality

Qualitätsmanagementsystem nach DIN EN ISO 13485

Quality Management System according to DIN EN ISO 13485

CE-Kennzeichnung: Medizinprodukt Klasse 1 nach 93/42/EWG

CE marking: Medical Device Class 1 according to MDD 93/42/EEC

Personliche Schutzausrüstung nach Verordnung (EU) 2016/425 (Kat. III)

Personal Protective Equipment according to Regulation (EU) 2016/425 (Cat. III)

Lebensmittelkonformität nach Verordnung (EU) 1935/2004

Food Contact Conformity according to Regulation 1935/2004

Normkonformität / Standard conformity

EN 455 1-4, ISO 11193 — 1, EN 420, EN ISO 374, EN 16523



## MEDICAL CAP, Class I, Examp



### ITEM CODES

MCAP-A

Size:	Free size
Color:	Blue
Material:	65% PP+35% PE non-woven fabrics
Weight:	20 g
Certificate:	FDA
Quantity per carton:	250 pcs
G.W. per carton:	6 kg
Carton size:	50*30*35 cm

## MEDICAL CAP, Class I Examp



### ITEM CODES

MCAP-H

25 g, 21", Non-Woven fabric

100 ps per Bag, 10 Bags per carton

## FACE SHIELD, Class I Examp



### ITEM CODES

MFSHIELD-A





Size:	32*22 cm
Color:	Blue
Material:	PET+elastic belt+sponge
Weight:	40 g
Certificate:	FDA
Quantity per carton:	200 pcs
G.W. per carton:	9 kg
Carton size:	50*35*40 cm



**DISPOSABLE Non sterile Gown**  
PE CPE Class I Examp

**ITEM CODES**

**MDDMIG-(PE/CPE)-R**  
AAMI Level 2

Item	material	size	Picture just for your reference	Description	Packing	packing bag
Disposable gowns	CPE	adult		25gsm fabric, one pcs the weight is 50g around . size 120*190CM	10 pcs / bag , 300pcs / ctn , the ctn size : 49*29*60CM GW/NW:18/16kgs	
Disposable gowns	PE	adult		0.02MM thickness, one pcs the weight is 45g around . size 120*190CM	10 pcs / bag , 300pcs / ctn , the ctn size : 46*29*35CM GW/NW:16/15kgs	





**DISPOSABLE Non sterile Gown**

**ITEM CODES**

**MDDMIG-PPEK-S**

**PP+PE 40 GSM**

**Knitted Cuff**




**CE SGS FDA Intertek Level 2**

**MDDMIG-PPEE-S**

**PP+PE 40 GSM**

**Elastic Cuff**







Total Quality. Assured.

TEST REPORT

Tests Conducted (As Requested By The Applicant)

检测

TESTING

CNAS L0220

Number:

GZHT90968229

10. Resistance To Penetration By Liquids (EN 13034:2005+A1:2009(E), 4.1 & EN 14325:2004, 4.13 & BS EN ISO 6530:2005(C1))

Sample	Chemical	Concentration Weight (%)	Specimen	Penetration Index (%)	Requirement	Pass/Fail
-	H <sub>2</sub> SO <sub>4</sub>	30	1	0	-	-
			2	0		
			3	0		
			4	0		
			5	0		
			6	0		
Performance Level (*)			3	0	≥ Level 2 (< 5%)	Pass

Sample	Chemical	Concentration Weight (%)	Specimen	Penetration Index (%)	Requirement	Pass/Fail
-	NaOH	10	1	0	-	-
			2	0		
			3	0		
			4	0		
			5	0		
			6	0		
Performance Level (+)			3	0	≥ Level 2 (< 5%)	Pass

**SMS Class I Examp**

**45 GSM**

**ITEM CODES**

**MDDMIG-SMS-S**

**Knitted Cuff**



## Sterile Surgical Gown

FDA EC TUV Level 3

Material: SMS 35 gram

Item Code: MDMIG-SSM3-S/M/L/XL/XXL/XXXL







- Ultrasonic seal in arm and sleeve
- Sleeve with cuff
- Four belt with belt card
- Comfortable collar using soft white spunlace

Size	A(cm)	B(cm)
S	110	140
M	115	145
L	127	150
XL	135	150
XXL	140	155
XXXL	145	160



## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator XXXXXXXXXX

Listing No.	Code	Device Name	Proprietary Names	Activities
D373299	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	FEMALE SS 3.5MM PELLET INSERTION TRAY	Manufacturer Contract Manufacturer Contract Sterilizer Repackager/Relabeler Remanufacturer Foreign Exporter
D373300	KDD	Kit, surgical instrument, disposable	Surgical Set	
D373303	FYE	DRESS, SURGICAL	Surgical Gown	
D373304	KME	BEDDING, DISPOSABLE, MEDICAL	Surgical Drape	
D373305	FMW	COVER, MATTRESS (MEDICAL PURPOSES)	Tube Cover	
D373306	KET	FILTERS, CELL COLLECTION, TISSUE PROCESSING	Liquid Collection Pouch	
D373307	FXZ	HELMET, SURGICAL	Warm Blanket and Surgical Hood	



## Certificate

No. Q8 083528 0011 Rev. 00

**Holder of Certificate:**

**Products Stock Co., Ltd.**  
Xinxing Road  
The South of Industry District  
LuShan County  
467300 PingDingShan, Henan Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Xinxing Road, The South of Industry District, LuShan County,  
467300 PingDingShan, Henan Province, PEOPLE'S REPUBLIC  
OF CHINA

**Certification Mark:**



**Scope of Certificate:** ETO Sterilization for Medical Device

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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.: SH1978307

Valid from:	2019-04-01
Valid until:	2022-03-31



## Supplement to Quality System Certificate

No. SUP 083528 0012 Rev. 00

**This supplement is only valid in conjunction with the main certificate:**

**Certificate Holder:**

**Products Stock Co., Ltd.**  
Xinxing Road  
The South of Industry District  
LuShan County  
467300 PingDingShan, Henan Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

XinXing Road, The South of Industry District, LuShan County,  
467300 PingDingShan, Henan Province, PEOPLE'S  
REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfils the applicable requirements of

EN ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

Audit Report: SH1978307

Date: 2019-02-20

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

Valid from: 2019-04-01

L. Pennell



## Level 4 sterile surgical gown

**FDA EC TUV Level 4**

**Item Code: MDMIG-SSM4-S/M/L/XL/XXL**

**SMS 45 gram**



Product Service

### **EC Certificate**

#### **Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 17 11 53056 020**

#### **Manufacturer:**

**Product Co., Ltd.**

895 Xinle Rd., Dianshanhu Town

215345 Kunshan

PEOPLE'S REPUBLIC OF CHINA



#### **EC-Representative:**

**Shanghai International Holding  
Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

#### **Product Category(ies):**

**Surgical Gowns, Surgical Drapes,  
Sterile Instrumental Cover,  
Sterile Protective Cover**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:**

SH17031EXT01

**Valid from:**

2018-01-10

**Valid until:**

2023-01-09



**Date,** 2018-01-05

*S. Preiß*  
Stefan Preiß

CERTIFICATE ◆ 證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE

**ISOLATION GOWN**

**ITEM CODES**

**MAMIG-A**



Size:	M、 L
Color:	Blue
Material:	65% PP+35% PE non-woven fabrics
Weight:	250 g
Certificate:	FDA
Quantity per carton:	50 pcs
G.W. per carton:	14 kg
Carton size:	55*37*52 cm

**ISOLATION GOWN**

**ITEM CODES**

**MBMIG-A**



Size:	M、 L
Color:	White
Material:	60% PP+40% PE non-woven fabrics
Weight:	250 g
Certificate:	FDA
Quantity per carton:	50 pcs
G.W. per carton:	14 kg
Carton size:	55*37*52 cm



## ISOLATION GOWN

### ITEM CODES

### MCMIG-A



Size:	M、 L
Color:	Blue
Material:	65%PP+35%PE non-woven fabrics
Weight:	250 g
Certificate:	FDA
Quantity per carton:	50 pcs
G.W. per carton:	14 kg
Carton size:	55*37*52 cm

## Non-Surgical Gown

### ITEM CODES

### MDMIG-A



Size:	M、 L
Color:	Blue
Material:	Non-woven fabrics+composite materials
Weight:	120 g
Certificate:	FDA
Quantity per carton:	200 pcs
G.W. per carton:	27 kg
Carton size:	58*62*43 cm

**LOW COST Non Surgical Gown**

PP gowns

25 g, 115 X 137 cm

Knitted cuff



**ITEM CODES**

PP + PE gowns

30 g, 136 X 137 cm

Knitted cuff



**MDDMIG-(PP/PPE)-H**

Class I, Examp



**SHOE COVER**

Class I, Examp



**ITEM CODES**

Non-woven fabfric

Non skid

35 g

16 X 43 cm

**MSHUC-H**



## SHOE COVER

Class II



## ITEM CODES

MSHUC-A

Size:	Free size
Color:	Blue/White
Material:	65% PP+35% PE non-woven fabrics
Weight:	60 g
Certificate:	FDA
Quantity per carton:	100 pairs
G.W. per carton:	7 kg
Carton size:	52*33*29 cm



**IR Thermometer Scan Gun**

**FDA CE Rohs**

**ITEM CODE:**

**MTGUN-DK-H**

**Brand: Dikang**


# Infrared Thermometer



- 1-Infrared detector
- 2 - LCD
- 3 - Mode switch button
- 4 - Down button
- 5 - Up button
- 6 - Set light
- 7 - Measuring switch
- 8 - Battery compartment cover



Display icon description

Icon definition	Icon	status description
centigrade	°C	Measured by centigrade
Fahrenheit	°F	Measured by Fahrenheit
Battery status		Flashing indicates low power, it should replace battery
Calibration key	MODE	Perform calibration
Record	Log	Memory during measurement
Temperature	Body temp	Body temperature display

Infrared probe

LCD Display

measuring  
switch

Battery cover

Down button

Up button

Mode button



## Three-color backlight fever tips

