



产品合格证

产品名称:	一次性使用医用口罩
产品规格:	YY 0469-2011 2号 (卫生防护为普通级)
型号:	WYMA2012
医疗器械生产许可证号:	豫械注准20180629号
医疗器械注册证号:	豫械注准20182142554
医疗器械执行标准号:	20131287-6
医疗器械技术要求编号:	豫械注准20182142554
注册地址:	河南省信阳市平桥区西店街
生产单位:	湖北万星防护用品有限公司
生产地址:	湖北省仙桃市西店街
生产型号:	2020030846
生产日期:	2020/03/08
检验员:	003
售后服务:	0728-3227299
销售期限:	自生产日期起至保质期六个月



FACE MASK
DISPOSABLE 3-PLY



Size:17.5x9.5cm

Style: with ear-loop

2020-03

2023-03



FACE MASK
DISPOSABLE 3-PLY
blue

50 pieces

FDA CE EN 14683 TYPE II & TYPE IIR



FACE MASK
DISPOSABLE 3-PLY



Size:17.5x9.5cm

Style: with ear-loop

2020-03

2023-03

Application: ideal for daily use or in normal medical environment without the high risk of fluid and spray made in china



FACE MASK
DISPOSABLE 3-PLY
blue

50 pieces

FDA CE EN 14683 TYPE II & TYPE IIR



FACE MASK
DISPOSABLE 3-PLY
50 pieces

52x38x34cm



CE FDA EN 14683

FACE MASK

Disposable 3-ply

Blue

2000 pieces

3-PLY FACE MASK

G.W.: 6.5 KGS

N.W.: 5.5 KGS

MEAS: 52x38x34cm

MADE IN CHINA

Production Date: March 2020

Expiration date: March,2023



CE FDA EN 14683

FACE MASK

Disposable 3-ply

Blue

2000 pieces

3-PLY FACE MASK

G.W.: 6.5 KGS

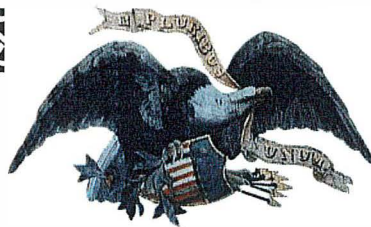
N.W.: 5.5 KGS

MEAS: 52x38x34cm

MADE IN CHINA

Production Date: March 2020

Expiration date: March,2023



Certificate of Registration

This certifies that:

HUBEI WANLI PROTECTIVE PRODUCTS CO.,LTD

Yuanshi, Ganhe,

Xiantao, CHINA 433000

Is registered with the U.S. Food and Drug Administration pursuant to Title 21, Part 820 of the United States Code of Federal Regulations.

U.S. FDA Registration Number: 3008770063

Listing Number	Proprietary Names	FDA Code	Device (s) Names
D114392	Cover, Shoe, Operating Room	FXP	Disposable Shoe Cover
D130471	Sheet, Burn	FPY	Burn Sheet
D114390	Bedding, Disposable, medical	KME	Disposable bed sheet, non woven sheet, SMS Sheets, PP +PE sheet, CPE sheets
D114391	Accessory, Surgical Apparel	LYU	Disposable Coverall, Non-Woven Coverall, SMS coverall, micro porous coverall, PP+PE coverall
D114389	Cap, Surgical	FYF	Disposable cap, non-woven cap, bouffant cap, clip cap, nylon cap, PE cap
D114388	Mask, Scavenging	KHA	Disposable face mask, dust masks, paper mask
D114387	Non-Surgical Isolation Gown Disposable Pants	OEA	Disposable Non-surgical Gown, Lab Coat, Sauna Clothes, Disposable Pants
D218020	Strap, Head, Gas Mask	BTK	Ear Loop Mask
D244766	Sling, Arm	ILI	Triangular Bandage

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant Title 21, Part 820 of the United States Code of Federal Regulations and that such registration has been verified as effective. This certificate does not make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. 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.



Certificate Valid from
January 1, 2020 to December 31, 2020



Verification of Conformity

Applicant:	Hubei Wanli Protective Products Co.Ltd
Address:	Yuanshi,Ganhe,Xiantao,Hubei,China
Product(s):	Short Pants, CPE Gown, Bed Sheet, Surgical Gown, Lab Coat, Coverall, Isolation Gown, Cap, Face Mask, Shoe/Boot Cover, Oversleeve, Apron, Beard Cover, Visitor Gown
Type(s):	see ANNEX
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 Medical Device Directive (93/42/EEC).

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

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016;
EN ISO 10993-1:2010; EN ISO 10993-5:2009;
EN ISO 10993-10:2010

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 Cert GmbH



Bacterial Filtration Efficiency (BFE) Final Report


Test Article: WLM2002
Purchase Order: WL201906-1121T
Study Number: 1253866-S01
Study Received Date: 26 Dec 2019
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s): None


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 $1.7 - 3.0 \times 10^3$ 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 F2101-19 and EN 14683:2019, Annex B.

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)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 174 \text{ mm} \times \sim 154 \text{ mm}$
Positive Control Average: 1.8×10^3 CFU
Negative Monitor Count: <1 CFU
MPS: $3.1 \mu\text{m}$




Study Director


Janelle R. Bentz, M.S.

07 Jan 2020
Study Completion Date



Results:

Test Article Number	Percent BFE (%)
1	>99.9 ^a
2	>99.9 ^a
3	>99.9 ^a
4	>99.9 ^a
5	>99.9 ^a

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

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

Synthetic Blood Penetration Resistance Final Report

Test Article: WLM2002
Purchase Order: WL201906-0920
Study Number: 1225963-S01
Study Received Date: 26 Sep 2019
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s): None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of $21 \pm 5^{\circ}\text{C}$ and a relative humidity of $85 \pm 10\%$. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 30
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 20.6°C and 23% RH (Units 1-16)
 22.1°C and 21% RH (Units 17-32)


Study Director

For
Janelle R. Bentz, M.S.

11 Nov 2019
Study Completion Date



1225963-S01

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)
Test Date: 03 Oct 2019

Test Article Number	Synthetic Blood Penetration
1-3, 5-16	None Seen
4	Yes

Test Pressure: 120 mmHg (16.0 kPa)
Test Date: 07 Nov 2019

Test Article Number	Synthetic Blood Penetration	Test Article Number	Synthetic Blood Penetration
17-27, 29-32	None Seen		
28	Yes		

Differential Pressure (Delta P) Final Report

Test Article: SAMPLE ID: WLM2002
Purchase Order: WL201906-0920
Study Number: 1225964-S01
Study Received Date: 26 Sep 2019
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 17
Deviation(s): None


Summary: 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

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
Delta P Flow Rate: 8 Liters per minute (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: ~176 mm x ~159 mm

Results:

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	3.0	29.2
2	3.0	29.8
3	3.0	29.8
4	3.0	29.0
5	3.0	29.2


Study Director


Janelle R. Bentz, M.S.


Study Completion Date



1225964-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

hcb

FRT0004-0001 Rev 21

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