

This product is a non medical device

# FACE MASKS

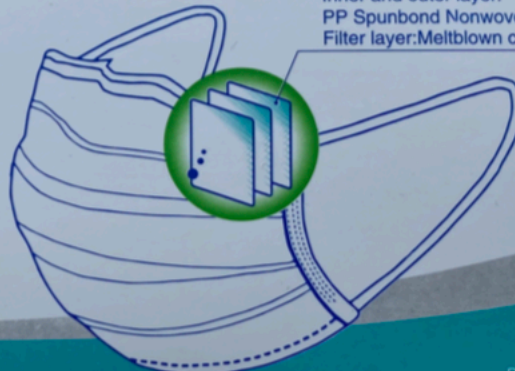
Filter efficiency:95%

Middle layer:Electret-treated meltblown cloth

High efficiency to filter pollendust and droplet

\*Middle layer:Electret-treated meltblown cloth,  
High efficiency to filter pollen dust and droplet

50PCS



Three layers of protection

Inner and outer layer:  
PP Spunbond Nonwoven  
Filter layer:Meltblown cloth



Size About 175x95mm

















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## Establishment Registration & Device Listing

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<b>Proprietary Name:</b>	Disposable Face Mask
<b>Classification Name:</b>	ACCESSORY, SURGICAL APPAREL
<b>Product Code:</b>	<a href="#">LYU</a>
<b>Device Class:</b>	1
<b>Regulation Number:</b>	<a href="#">878.4040</a>
<b>Medical Specialty:</b>	General & Plastic Surgery
<b>Registered Establishment Name:</b>	<a href="#">WEIHAI HAI NA BAI CHUAN PHARMACEUTICAL GROUP</a>
<b>Registered Establishment Number:</b>	3016933465
<b>Owner/Operator:</b>	<a href="#">Weihai HAI NA BAI CHUAN PHARMACEUTICAL GROUP</a>
<b>Owner/Operator Number:</b>	10065384
<b>Establishment Operations:</b>	Manufacturer



Test Report

SL52025269649001TX

Date: June 28, 2020

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WEIHAI HAINABAICHUAN PHARMACEUTICAL GROUP CO. LTD  
NO.25, DUO SHAN ROAD, WENDENG ECONOMIC DEVELOPMENT ZONE, WEIHAI CITY, SHANDONG  
PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Single-use medical face mask

Style No. : Large

Lot No./Batch No. : Not provided

Sample Color : (A) BLUE

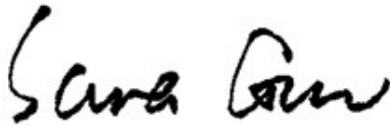
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 04, 2020

Testing Period : Jun 04, 2020 - Jun 28, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



Sara Guo (Account Executive)



Dongjing Liu (Authorized Signatory)



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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods****Clause 5.2 Performance Requirement****Clause 5.2.2 Bacterial filtration efficiency (BFE)\***

(EN 14683:2019 Annex B)

Sample: A

Conditioning Parameters : Minimum of 4 hours at 21.1°C and 85.0% R.H.  
 Dimensions of test specimen : 15 cm x 12.7cm  
 Test Area : 95cm<sup>2</sup>  
 Test Side : Outside  
 Flow Rate : 28.3 L/min  
 Positive Control Average : 2162CFU  
 Negative Monitor Count : 0 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I ≥ 95%, Type II ≥ 98%, Type IIR ≥ 98%

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

**Clause 5.2.3 Breathability**

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : 5 random areas for each specimen (face mask)  
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Test Area : 4.9 cm<sup>2</sup>  
 Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm <sup>2</sup> )	38	38	36	37	37

Remark: Performance Requirement: Type I < 40 Pa/cm<sup>2</sup>, Type II < 40 Pa/cm<sup>2</sup>, Type IIR < 60 Pa/cm<sup>2</sup>

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**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Fail	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass
Number of Pass:			29				
Overall result:			Acceptable				

## Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:  $\geq 16.0\text{kPa}$
- 2) Distance of the medical face mask target area surface to the tip of cannula is  $300 \pm 10\text{mm}$ .
- 3) Condition and Test temperature  $(21 \pm 5)^{\circ}\text{C}$ , relative humidity  $(85 \pm 10)\%$
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

**Clause 5.2.5 Microbial Cleanliness**

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

	1#	2#	3#	4#	5#
CFU/g	<1	<1	1	<1	5

Remark: Performance Requirement: Type I  $\leq 30\text{ CFU/g}$ , Type II  $\leq 30\text{ CFU/g}$ , Type IIR  $\leq 30\text{ CFU/g}$ 

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Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*