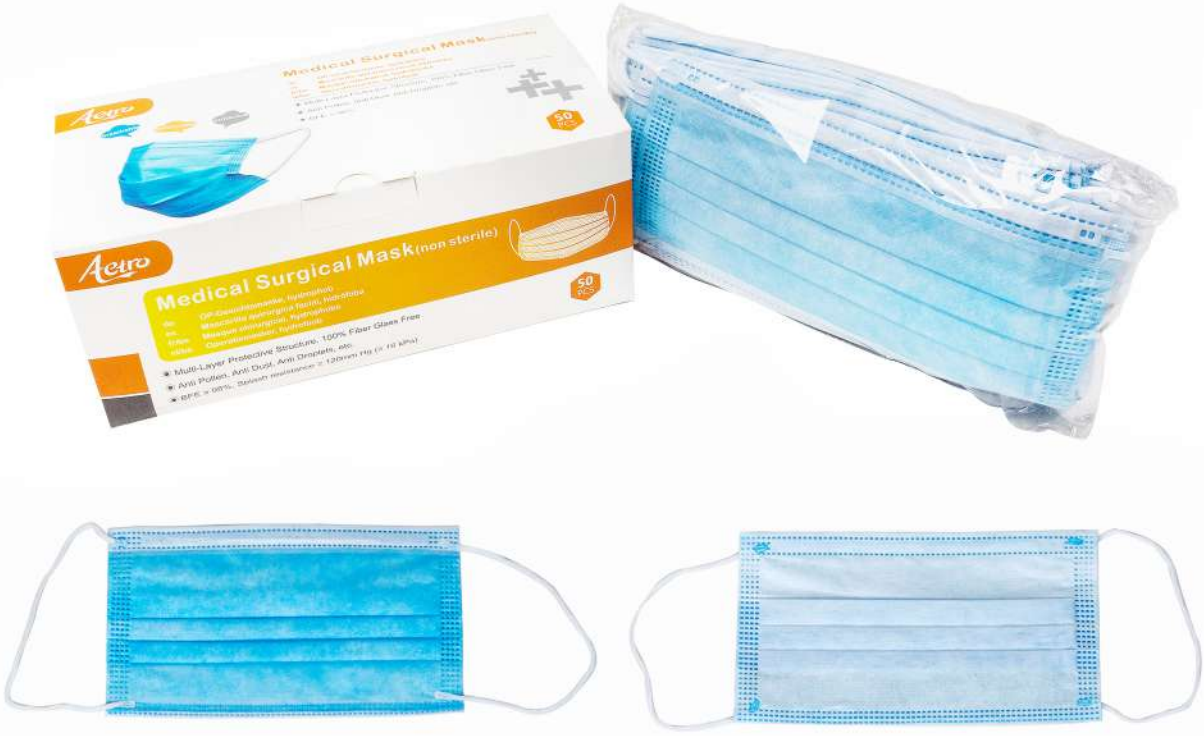
Disposable Surgical Mask

These blue and white 3 ply face masks with an integrated nose clip have different layer materials and thicknesses to correctly reach Type IIR Mask (EN14683) certification. The masks are made of skin-friendly materials and are very comfortable to wear with an exceptionally high bacterial filtration efficiency (BFE) of ≥ 98%.



Size	17.5 x 9.5 cm (± 0.5 cm) *One Size Fits All
Material Specifications 3 Layers	PP Non-Woven 25gsm ± 1gsm | Melt Blown 25gsm ± 1gsm | PP Non-Woven 25gsm ± 1gsm
Packaging	50 pcs / bag packed in unit box | 40-unit boxes / master carton
Carton Measurement	52 x 41.5 x 32 cm / 2000 pieces
G.W.	8.3 KGS
Standard	CE EN14683:2019 TYPE IIR
Bacterial Filtration Efficiency (BFE)	≥ 98%
Splash Resistance Pressure	≥ 16.0 kPa
Microbial Cleanliness	≤ 30 cfu/g
Breathability	< 60 Pa/cm²

DECLARATION OF NOTIFICATION

As the EU Representative, SUNGO Europe B.V., hereby declare that:

[redacted]

has signed the EC Declaration of Conformity in agreement with the Annex VII of the European Directive 93/42/EEC on In Medical Device Directive and has submitted the required technical documentation, for the following MDD products (for professional use only):

Name Device	Reference Numbers
Medical surgical masks (non-sterile)	20201673

The notification to the Netherlands Competent Authorities has been carried out on April 24, 2020 by SUNGO Europe B.V., the appointed Authorized Representative of Anshun xinsiya maternity products co.Ltd

Information on the notification to the competent Authorities of other European countries is available upon request.

SUNGO Europe B.V.
Authorized Representative

CE

EC Declaration of Conformity

[redacted]

Product:
Name:Medical Surgical Masks (non-sterile)
UMDNS-Code: 12447

Type:17.5cmx9.5cm

EU-ERP:
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)

Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(MDD 93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 14683:2019

郑秀邦

Signature

2020.5.1

Date

Zhongren Certification Co., Ltd.

QMS CERTIFICATION OF REGISTRATION

Certification No.：27320QM10517R0S

Awarded to

[redacted]

Unified social credit code: 91520423MA6DKDK52E

Registration address: [redacted]

The Quality Management System of the above organization has been assessed and found to be in accordance with the requirements of the standard:

YY/T0287-2017 idt ISO13485:2016

Certification Scope of the Management System

Production of surgical masks (non-sterile) (within the scope of epidemic emergency registration certificate)

Validity of the certificate, certified organizations subject to supervision and review at least once a year,after the examination and approval, the organization updates the two-dimensional code information, Issuance of certificates of conformity for supervision and audit. The certificate information is available at the Certification and Accreditation Regulatory Commission official website (www.cnca.gov.cn) query, but also through the company's website (www.zrcln.com) query.

First certified date：May.15, 2020　　Date of Issued：May.15, 2020　　Valid date：Nov.14, 2020

Zhongren Certification Co., Ltd.

Issued by：Haibo che

Address：Room 1413, Floor 14, Building 3, No. 1 Shujin Road, Qingyang District, Chengdu

Tel：400-025-9001

Zhongren Certification Co., Ltd.

QMS CERTIFICATION OF REGISTRATION

Certification No.：27320Q20354R0M

Awarded to

[redacted]

Unified social credit code: 91520423MA6DKDK52E

Registration address [redacted]

The Quality Management System of the above organization has been assessed and found to be in accordance with the requirements of the standard:

GB/T19001-2016 idt ISO9001：2015

Certification Scope of the Management System

Disposable civil protective masks for daily use and surgical masks for medical use (non-sterile) (within the scope of epidemic emergency registration certificate)

Validity of the certificate, certified organizations subject to supervision and review at least once a year,after the examination and approval, the organization updates the two-dimensional code information, Issuance of certificates of conformity for supervision and audit. The certificate information is available at the Certification and Accreditation Regulatory Commission official website (www.cnca.gov.cn) query, but also through the company's website (www.zrcln.com) query.

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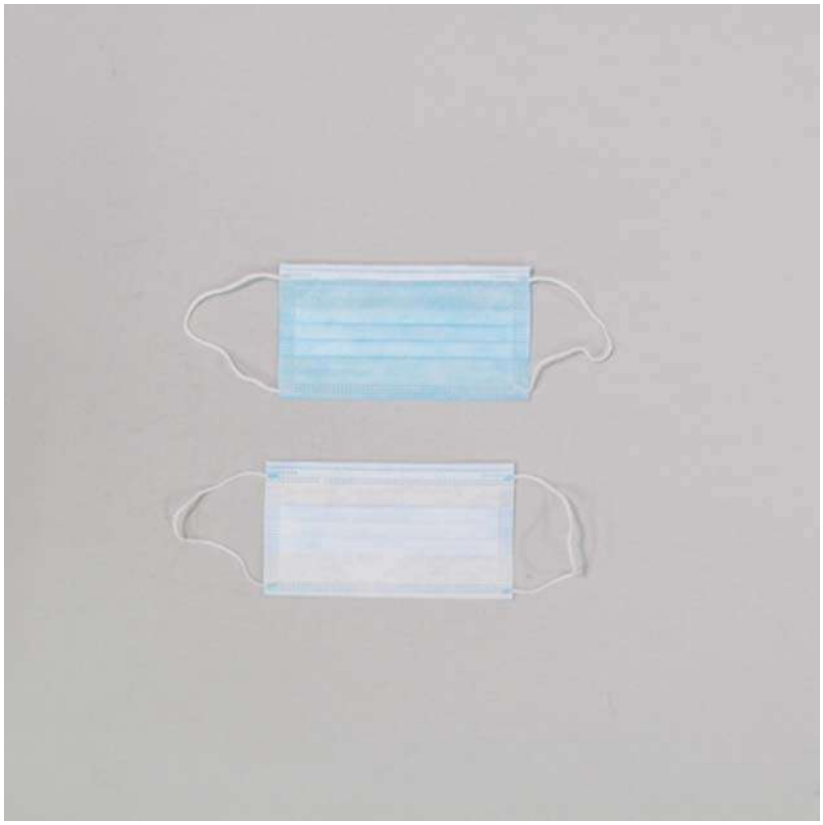
Issued by：Haibo che

Address：Room 1413, Floor 14, Building 3, No. 1 Shujin Road, Qingyang District, Chengdu

Tel：400-025-9001

REPORT NUMBER: SHAT06472056S1



TEST REPORT

Number : SHAT06472056S1

Applicant : [redacted]

Date : May 27, 2020
THIS IS TO SUPERSEDE REPORT NO. SHAT06472056 DATED MAY 07, 2020

Sample Description As Declared :

No. Of Sample	:	Several
Material	:	Non Woven Fabric/Melt Blown Fabric
Sample Name	:	Medical surgical Mask(Non Sterile)
Finishing	:	-
End Uses	:	-
Colour	:	Blue/White
Style No.	:	A-M01A50
Order No./PO No.	:	-
Standard	:	EN 14683:2019+AC:2019
Rating	:	Type IIR
Buyer's Name	:	-
Manufacturer's Name	:	[redacted]
Ref.	:	-

Applicant's Provided Care Instruction/Label : -

Date Sample Received : Apr 16, 2020
Date Testing Started : Apr 18, 2020

Summary of testing:

With reference to following standard:

- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness and Bacterial Filtration Efficiency, Differential Pressure, Splash Resistance Pressure tests.

Prepared And Checked By:
For Intertek Testing Services Ltd.,Shanghai

Jennifer Ren
General Manager

INTERTEK TESTING SERVICES LTD., SHANGHAI 上海天祥质量技术服务有限公司 检验检测专用章

Intertek Testing Services Ltd., Shanghai
2/F, Building No.4, Shanghai Comalong Technology Service Park,
889 Yishan Road, Shanghai 200233, China
上海天祥质量技术服务有限公司
中国上海宜山路 889 号上海齐来科技服务园区 4 号楼 2 楼 邮编:200233
Tel: +86 21 5339 5999 Fax: +86 21 5426 2030 E-mail: textile.shanghai@intertek.com Website:Intertek.com

TEST REPORT

Number : SHAT06472056S1

Tests Conducted (As Requested By The Applicant)

1 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical Face Masks - Requirements And Test Methods Annex D.

Test Item	Result (cfu/g) Test component	Requirement (cfu/g)
	(1)	
Total Plate Count (30℃)	8	-
Total Plate Count (20 to 25℃)	2	-
Microbial cleanliness	10	Type IIR: ≤30

cfu = Colony Forming Unit
≤ = Not More Than

Sample received condition: Sample in closed plastic bag.

Tested Component:
(1) Blue/white Face Mask

Remark: This Test Was Conducted By Intertek Testing Services Guangzhou Ltd.

2 Bacterial Filtration Efficiency (EN 14683:2019+AC:2019, Clause 5.2.2, Testing Refer To Annex B): Flow rate: 28.3L/min, Test area: 77 cm^2, Test bacteria: Staphylococcus aureus ATCC 6538, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.6 X 10^3 CFU, The average plate count results of the negative controls: <1 CFU.

Tested Sample	Result (%)	Performance Requirement for Medical Face Mask Type IIR : ≥ 98%
Specimen (1)	99.3	
Specimen (2)	99.5	
Specimen (3)	99.5	
Specimen (4)	99.6	
Specimen (5)	99.5	

Remark : Test was conducted by external provider

Intertek Testing Services Ltd., Shanghai
2/F, Building No.4, Shanghai Comalong Technology Service Park,
889 Yishan Road, Shanghai 200233, China
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Tel: +86 21 5339 5999 Fax: +86 21 5426 2030 E-mail: textile.shanghai@intertek.com Website:Intertek.com

TEST REPORT

Number : SHAT06472056S1

Tests Conducted (As Requested By The Applicant)

3 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm^2.

Tested Sample	Result (Pa/cm^2)	Performance Requirement for Medical Face Mask Type IIR < 60 Pa/cm^2
Specimen (1)	44.2	
Specimen (2)	46.8	
Specimen (3)	44.0	
Specimen (4)	41.0	
Specimen (5)	44.8	
Average	44.2	

Remark :Test was conducted by external provider

4 Splash Resistance Pressure (ISO 22609:2004):

Synthetic Blood Surface Tension: 0.040 N/m, Distance Between Blow Head Front End And Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

Tested Sample	Result (kPa)	Performance Requirement for Medical Face Mask Type IIR: No penetration at 16.0 kPa
Specimen (1)	None Seen	
Specimen (2)	None Seen	
Specimen (3)	None Seen	
Specimen (4)	None Seen	
Specimen (5)	None Seen	
Specimen (6)	None Seen	
Specimen (7)	None Seen	
Specimen (8)	None Seen	
Specimen (9)	None Seen	
Specimen (10)	None Seen	
Specimen (11)	None Seen	
Specimen (12)	None Seen	
Specimen (13)	None Seen	

Remark : Test was conducted by external provider.

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TEST REPORT

Number : SHAT06472056S1

Tests Conducted (As Requested By The Applicant)

4 Product Size Measurement:

Width	>10 cm

End of Report

Remark: This statement of conformity is only based on the actual measured test result by the laboratory, without taking the influence of uncertainty into accord.

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Tel: +86 21 5339 5999 Fax: +86 21 5426 2030 E-mail: textile.shanghai@intertek.com Website:Intertek.com

To : [redacted]
Attention : ZHU CHEN Date : May 27, 2020

Re : Report Revision Notification

Labtest Report Number SHAT06472056 date MAY 07, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number SHAT06472056S1 , issued on May 27, 2020 .

Thank you for your attention

Prepared And Checked By:
For Intertek Testing Services Ltd.,Shanghai

Jennifer Ren
General Manager

INTERTEK TESTING SERVICES LTD., SHANGHAI 上海天祥质量技术服务有限公司 检验检测专用章

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