

# 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  $\geq 98\%$ .



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)	$\geq 98\%$
Splash Resistance Pressure	$\geq 16.0$ kPa
Microbial Cleanliness	$\leq 30$ cfu/g
Breathability	$< 60$ Pa/cm <sup>2</sup>



## DECLARATION OF NOTIFICATION

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

Anshun xinsiya maternity products co.Ltd  
Industrial park of zhenning autonomous county, anshun city, guizhou province

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.





## EC Declaration of Conformity

**Manufacturer's Company Name:** Anshun Xinsiya Maternity Products Co., Ltd  
**Address:** Light Industry Industrial Park, Zhenning Buyi and Miao Autonomous County, Anshun City, Guizhou Province.

**Product:**

Name: Medical Surgical Masks (non-sterile)  
UMDNS-Code: 12447  
ART.NO: A-M01A50  
Type: 17.5cmx9.5cm

**European authorized representative (EC REP):**

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 that our product meets 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 Type IIR



Signature

2020-07-01

Date





Zhongren Certification Co., Ltd.

# QMS CERTIFICATION OF REGISTRATION

Certification No. : 27320QM10517R0S

**Awarded to**

**Anshun Xinsiya maternity products Co.,Ltd**

Unified social credit code: 91520423MA6DKDK52E

Registration address: Light Industry Industrial Park ,Zhenning Buyi and Miao Autonomous County, Anshun City, Guizhou Province

Audit address: Light Industry Industrial Park ,Zhenning Buyi and Miao Autonomous County, Anshun City, Guizhou Province

Post Code: 561200

**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](http://www.cnca.gov.cn)) query, but also through the company's website ([www.zrcn.com](http://www.zrcn.com)) query.

First certified date : May.15, 2020

Date of Issued : May.15, 2020

Valid date : Nov.14, 2020



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**

**Anshun Xinsiya maternity products Co.,Ltd**

Unified social credit code: 91520423MA6DKDK52E

Registration address: Light Industry Industrial Park ,Zhenning Buyi and Miao Autonomous County, Anshun City, Guizhou Province

Audit address: Light Industry Industrial Park ,Zhenning Buyi and Miao Autonomous County, Anshun City, Guizhou Province

Post Code: 561200

**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](http://www.cnca.gov.cn)) query, but also through the company's website ([www.zrcn.com](http://www.zrcn.com)) query.



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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 : ANSHUN XINSIYA MATERNITY PRODUCTS  
LIGHT INDUSTRY INDUSTRIAL PARK,  
ZHENNING BUYI AND MIAO AUTONOMOUS  
COUNTY, ANSHUN CITY, GUIZHOU PROVINCE.  
Attn : ZHU CHEN

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 : Anshun Xinsiya Maternity Products Co., Ltd  
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**

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889 Yishan Road, Shanghai 200233, China  
上海天祥质量技术服务有限公司

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Tel: +86 21 5339 5999 Fax: +86 21 5426 2030 E-mail: textile.shanghai@intertek.com Website: Intertek.com  
Attention is drawn to the terms and conditions printed overleaf

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.

<u>Test Item</u>	<u>Result ( cfu/g )</u>	<u>Requirement ( cfu/g )</u>
	<u>Test component</u>	
	(1)	
Total Plate Count (30°C)	8	-
Total Plate Count (20 to 25°C)	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<sup>2</sup>, 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<sup>3</sup> CFU, The average plate count results of the negative controls: <1 CFU.

<u>Tested Sample</u>	<u>Result (%)</u>	<u>Performance Requirement for Medical Face Mask</u> 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



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<sup>2</sup>.

<u>Tested Sample</u>	<u>Result (Pa/cm<sup>2</sup>)</u>	<u>Performance Requirement for Medical Face Mask</u> Type IIR < 60 Pa/cm <sup>2</sup>
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.

<u>Tested Sample</u>	<u>Result (kPa)</u>	<u>Performance Requirement for Medical Face Mask</u> 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.

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 account.*

*This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct.*

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To : ANSHUN XINSIYA MATERNITY PRODUCTS  
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**

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Attention is drawn to the terms and conditions printed overleaf