

# DOKUMENTATION

## Mund-Nasen-Schutz / OP Maske EN14683 Typ IIR

Medizinischer Standard

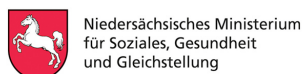
Hersteller ist auf der White List Medical für medizinische Produkte



50 Stück im Polybag in Spender-Box

## Mund-Nasen-Schutz OP Maske medizinisch EN14683 Typ IIR

Lieferant für:



# DOKUMENTATION

## Mund-Nasen-Schutz / OP Maske EN14683



**Speranza**

CE  
EN 14683:2014

### SOFT • Medical Mask

• Procédure Earloop Face Masks • Masques de procédure avec boucles auriculaires  
• Mascarrillas de procedimiento con cintas elasticas  
• Gesichtsmaken mit Ohrenschlaufen

BFE>95%  
Blue • Bleu • Azul • Blau

**50** Masks  
Masques

MADE IN CHINA

STERILE EO    STERILE    

**RONGJUN**  
Rongjun Medical  
荣军医疗



**RONGJUN**  
Rongjun Medical  
荣军医疗

# Speranza



**Speranza**

**[Model & specification]** Ear hook method (mm) 178X89  
**[Color]** Blue  
**[For more details, please refer to the user manual]**

• Complied with ASTM F2100 Level I Standards for Face Masks  
• Soft, Odorless • Non Irritating • Comfortable Fit • Latex Free



**Speranza**

XINXIANG CITY RONGJUN MEDICAL DEVICES CO., LTD.

[ Name of the production enterprise ]  
Xinxiang City Rongjun Medical Devices Co., Ltd.  
[ Address ] East to 308 Provincial Highway,  
South to Changtan Laoan Cross Road  
[ Tel of the production enterprise ] 0373-8909218  
[ Tel of Hangzhou Branch ] 0571-82675507  
[ Enterprise website of the company ] <http://www.xrongjun.com>  
[ Enterprise email of the company ] [rongjunmedical@gmail.com](mailto:rongjunmedical@gmail.com)

**ISO** 

Xinxiang Rongjun Medical Devices Co. Ltd.

## EU Declaration of Conformity

**Manufacturer:** Xinxiang Rongjun Medical Devices Co. Ltd.  
On the eastern side Highway 308, Laoan Shizo South  
Road, Changyuan Country, Xinxiang City,  
Henan Province, China

**Product Name:** Medical Mask W20200593  
NMPA No. 20172640642

**Relevant EC Directive:** This product is a class I medical device according to  
Annex VII of Regulation (EU) 93/42/EEC, which is used  
in the patient environment to protect the patient.

**Standard:** The product complies with the following harmonized  
standard: EN 14683:2019

We herewith declare that above mentioned product complies with the requirements  
of regulation (EU) 93/42/EEC. All supporting documentations are retained under the  
premises off the manufacturer.

Signature: \_\_\_\_\_

Xinxiang Rongjun Medical Devices Co. Ltd.



# CERTIFICATE

With EU Directive  
Medical devices Directive (MDD 93/42/EEC)

Certificate No.: NB0316XRM011677

Holder: Xixiang City Rongjun Medical apparatus Co., Ltd.  
On the eastern side Highway 308, Laoan Shizi South Road ,  
Changyuan County, Xixiang City, Henan Province, China

Product: Medical mask

Model(s): Type— I Type—II

Standards: EN 14683:2014

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.

of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.



Certification Body  
For and on behalf of  
NIMU (UK) CERTIFICATION SERVICES GROUP LIMITED  
*Spencer*  
Authorized Signatory  
NIMU (UK) certification

The CE marking may be used if all relevant and effective EC directives are complied with.

NIMU (UK) Certification Services Group Limited  
Chase Business Centre 39/41 Chase Side, Southgate, London, England

**Test Report**                      **SL52025257797101TX**                      **Date: June 06, 2020**                      **Page 1 of 3**  
**XINXIANG CITY RONGJUN MEDICAL APPARATUS CO., LTD.**  
**ON THE EASTERN SIDE HIGHWAY 308, LAOAN SHIZI SOUTH ROAD, CHANGYUAN COUNTY, XINXIANG**  
**CITY, HENAN PROVINCE, CHINA**

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

Sample Description                      :    **Medical face mask**

Sample Color                                :    **Blue**

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

Sample Receiving Date                 :    **May 18, 2020**

Testing Period                             :    **May 18, 2020 - Jun 06, 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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3<sup>rd</sup> Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233    t (86-21) 61402666    f (86-21) 64958763    www.sgsgroup.com.cn  
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Test Result

**Medical Face Masks-Requirements and Test Methods**  
(EN 14683:2019)

**Clause 5.2.2 Bacterial filtration efficiency (BFE)\***  
(EN 14683 :2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	99.1	98.9	99.0	98.7	98.9

Remark: Performance Requirement: Type I  $\geq 95\%$ , Type II  $\geq 98\%$ , **Type IIR  $\geq 98\%$**

\* 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 (Differential Pressure)**  
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure $\Delta P$ (Pa/cm <sup>2</sup> )	50	53	51	54	50

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>**

**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	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			31				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, **Type IIR:  $\geq 16.0$  kPa**
- 2) Distance of the medical face mask target area surface to the tip of cannula is  $300 \pm 10$  mm.
- 3) Condition and Test temperature  $(21 \pm 5)^\circ$  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



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SGS-CSI Technical Services (Shanghai) Co., Ltd.  
Testing Center

3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666  
f (86-21) 61402666

f (86-21) 64958763  
f (86-21) 64958763

[www.sgs.com](http://www.sgs.com)  
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**Clause 5.2.5 Microbial Cleanliness**  
(EN ISO 11737-1:2018)

	1#	2#	3#	4#	5#
CFU/g	28	19	22	28	27

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

**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\*\*\*



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SGS-CS1000 SGS Technical Services (Shanghai) Co., Ltd.  
Testing Center: 3rd Floor, No. 889, Yeshan Road, Xuhui District, Shanghai, China 200233

中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666

f (86-21) 64958763

www.sgs.com.cn  
e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)