

# CERTIFICATE



中国医药保健品进出口商会  
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## 取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

湖南三瑞

检索

企业名称 (中文)

企业名称 (英文)

产品类别

统一社会信用代码

国外注册认证情况

湖南三瑞生物科技有限公司

Hunan SanRui Biotechnology Co., Ltd

医用口罩

91430122066350820B

欧盟CE

湖南三瑞生物科技有限公司

Hunan SanRui Biotechnology Co., Ltd

非医用口罩

91430122066350820B

欧盟CE

### 友情链接

政府部门

行业组织

国际机构

行业门户



中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

Test Report SL52035260052701TX Date: July 02, 2020 Page 1 of 10

HUNAN SANRUI BIOTECHNOLOGY CO., LTD  
2/F, BUILDING C4, WANGCHENG DISTRICT ECONOMIC DEVELOPMENT ZONE, HUNAN, CHINA

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

Sample Description : (A) Particle Filtering half mask  
Claimed : FFP2

SGS Internal Ref No. : GZHL2006031000CE  
Style No. : SRNS-PM-III-B  
Sample Color : (A) White

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

Sample Receiving Date : Jun 09, 2020  
Testing Period : Jun 09, 2020 - Jul 02, 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).

### Conclusion:

| Sample No. | Recommendation Level |
|------------|----------------------|
| (A)        | FFP2 NR              |

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

Sara Guo (Account Executive)



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Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8367 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)  
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## Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200414-063-01-9A

Certificate holder: Hunan Sanrui Biotechnology Limited Liability Company  
2/F, Building C 4, Golden Enterprise Park, Wangcheng District  
Economic Development Zone, Hunan Province, China

Product: Particle Filtering Half Mask  
Folding filtering half mask without valve fitted with ear loops  
Classification: FFP1 NR

Model reference: SRNS-PM-III-A

Standard(s): EN 149:2001+A1:2009

Test report No.: 2020(D) - 0017

Issue date: 2020-05-01

Expiry date: 2020-07-31

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425 and meeting the needs of WHO document dcp-ncov.pdf and EU Commission Recommendation (EU) 2020/403.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.



Approved by Ireland  
Government  
as a Notified Body  
for CE Marking No.2834



### CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15,  
D15 AKK1, Ireland  
Tel: +00 353 1 588 6920 Website: [www.ccqs.co.uk](http://www.ccqs.co.uk) E-mail: [info@ccqs.ie](mailto:info@ccqs.ie)  
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

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TMHN20031322406

### Technical Construction File

EN 14683:2019

#### Medical face masks - Requirements and test methods

|                           |                                                                                                  |
|---------------------------|--------------------------------------------------------------------------------------------------|
| Report reference No.      | TMHN20031322406-1                                                                                |
| Compiled by (+ signature) | Stephen Zhang / Test Engineer                                                                    |
| Approved by (+ signature) | Kosco Vent / Project Manager                                                                     |
| Date of issue             | March 10, 2020                                                                                   |
| Reviewing laboratory      | Shanghai Global Testing Services Co., Ltd.                                                       |
| Reviewing location        | Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.                |
| Applicant                 | Hunan Sanrui Biotechnology Limited Liability Company                                             |
| Address                   | 2 / F, building C 4, Golden Enterprise Park, Wangcheng District Economic Development Zone, Hunan |
| Manufacturer              | Hunan Sanrui Biotechnology Limited Liability Company                                             |
| Address                   | 2 / F, building C 4, Golden Enterprise Park, Wangcheng District Economic Development Zone, Hunan |
| Factory                   | The same as Manufacturer                                                                         |
| Address                   | The same as Manufacturer                                                                         |
| Standard                  | EN 14683:2019                                                                                    |
| Review Report Form No.    | 14683                                                                                            |
| TRF originator            | GTS                                                                                              |
| Master TRF                | Reference No. EN 14683:2019                                                                      |
| Review procedure          | GTS                                                                                              |
| Type of Review object     | Single-use medical face mask                                                                     |
| Trademark                 | -                                                                                                |
| Model/type reference      | SRNS-SM-A                                                                                        |
| Rating                    | I                                                                                                |



Reference: GZHLVOC2020040017  
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### VERIFICATION OF CONFORMITY

|                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Products                                                                                                                                                                                                                                                                                                                                      | Disposable medical mask(non-sterile)                                                                                                                             |
| Tested by request of:                                                                                                                                                                                                                                                                                                                         | Hunan Sennui Biotechnology Limited Liability Company.<br>2 / F, Building C4, Golden Enterprise Park, Wangcheng District Economic Development Zone, Hunan, China. |
| Manufactured at:                                                                                                                                                                                                                                                                                                                              | Hunan Sennui Biotechnology Limited Liability Company.<br>2 / F, Building C4, Golden Enterprise Park, Wangcheng District Economic Development Zone, Hunan, China. |
| Trade mark                                                                                                                                                                                                                                                                                                                                    | /                                                                                                                                                                |
| Model Type Ref.                                                                                                                                                                                                                                                                                                                               | SRNS-SM-A                                                                                                                                                        |
| Rating and principal characteristics                                                                                                                                                                                                                                                                                                          | Size: 18 x 10cm.                                                                                                                                                 |
| Additional information                                                                                                                                                                                                                                                                                                                        | For model differences if any, please refer to test report.                                                                                                       |
| Date of Expiry                                                                                                                                                                                                                                                                                                                                | 2021-04-27                                                                                                                                                       |
| Samples for identified model as above listed have been tested and found to be in conformity with applicable requirements of following standards:                                                                                                                                                                                              |                                                                                                                                                                  |
| EN 14683:2019+AC:2019 Type IIR                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                  |
| as shown in the test reports:                                                                                                                                                                                                                                                                                                                 | 20R060121MO                                                                                                                                                      |
| This Verification of Conformity is the result of testing a sample of the product submitted in accordance with the provisions of the relevant specific standard. It does not imply an assessment of the whole production. Conformity of the produced products with the specimen tested remains on the full responsibility of the manufacturer. |                                                                                                                                                                  |

George Lin  
Manager  
Guangzhou Branch  
2020-04-28

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Note: You may contact us to validate this document by email address: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)  
GZHLVOC-F01 / V1.1  
Effective Date: 2019-02-25



### Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200414-063-FPC-A

Certificate holder: Hunan Sanrui Biotechnology Limited Liability Company  
2/F, Building C 4, Golden Enterprise Park, Wangcheng District  
Economic Development Zone, Hunan Province, China

The scope of the certification for: Respiratory Protective Equipment  
Products covered by the certificate are described below.

Model: Particle Filtering Half Mask  
SRNS-PM-III-A

Standard: EN 149:2001+A1:2009

Validity from: 2020-05-01

To: 2020-07-31

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation. The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE as identified on this certificate whilst this certificate remains valid. This certificate is the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland  
Government  
as a Notified Body  
for CE Marking No.2834



### CCQS Certification Services Limited

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If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

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