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

| | | |
|---|---|---|
| Sample Description | : | Face Mask |
| Style No. | : | Medical face mask (non-sterile) |
| Composition | : | non-woven fabric, melt-blown fabric |
| Sample Color | : | blue |
| Manufacturer | : | |
| Test Performed | : | Selected test(s) as requested by applicant |
| Sample Receiving Date | : | May 19, 2020 |
| Testing Period | : | May 20, 2020 - Jun 11, 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

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)





3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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 e sgs.china@sgs.com

Test Result

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

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

| | 1# | 2# | 3# | 4# | 5# |
|---|---|---|---|---|---|
| (BFE), % | 99.9 | 99.8 | 99.8 | 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, Flow rate 8 l/min)

| | 1# | 2# | 3# | 4# | 5# |
|---|---|---|---|---|---|
| Differential pressure △P ($Pa/cm^2$) | 36 | 26 | 28 | 27 | 26 |

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

**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 | 23 | 25 | 25 | 19 | 24 |

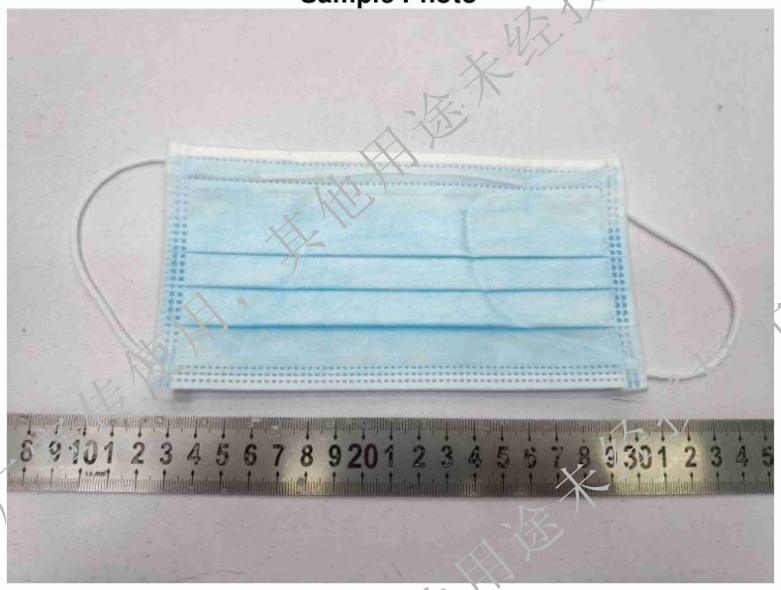
Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g






3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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 e sgs.china@sgs.com

**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***





3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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 e sgs.china@sgs.com

# EC Declaration of Conformity

## Regarding Medical Device Directive(93/42/EEC)

## including Directive 2007/47/EC

**Manufacturer:**

**Name:**

**Address:**

**EC Representative**

**Name:**

**Address:**

**Product**

**Name:** Disposable Medical Face Mask

**Model:** CJ-01

**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(93/42/EEC) and the following harmonized standards.

EN 14683:2019 EN ISO 14971:2012 EN ISO 15223-1:2016 EN 1041:2013
EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013

The CE Mark:

CE

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company:**

**Address:**

April 22nd,2020
*Date*

General Manager,
*Legally binding signature, Function*