# Test Report –TYPE IIR standard

中国认可
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检测
TESTING
CNAS L0599

**Test Report** **SL52025269352301TX** **Date:June 24,2020** 

JIANGXI HEYING PHARMACEUTICAL CO., LTD.
HUANGJINBU TOWN, YUGAN COUNTY, SHANGRAO CITY, JIANGXI PROVINCE, CHINA

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

| | | |
|---|---|---|
| Sample Description | : | (A) Disposable medical mask |
| Sample Color | : | (A)Blue |
| Manufacturer | : | JIANGXI HEYING PHARMACEUTICAL CO., LTD. |
| Lot No./Batch No. | : | 20200501 |
| Test Performed | : | Selected test(s) as requested by applicant |
| Sample Receiving Date | : | Jun 02, 2020 |
| Testing Period | : | Jun 02, 2020 - Jun 24, 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 / Hailian Xuan (Authorized Signatory)



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

**Clause 5.2 Performance Requirement**

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

Sample: A

| | | |
|---|---|---|
| Conditioning Parameters | : | Minimum of 4 hours at 21±5°C and 85±5% R.H. |
| Dimensions of test specimen | : | 165 mm x 145 mm |
| Test Area | : | ~60 $cm^2$ |
| Test Side | : | Inside |
| Flow Rate | : | 28.3 l/min |
| Positive Control Average | : | 2729 CFU |
| Negative Monitor Count | : | < 1 CFU |

| | 1# | 2# | 3# | 4# | 5# |
|---|---|---|---|---|---|
| (BFE), % | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%

**Clause 5.2.3 Breathability**
(EN 14683 :2019+AC:2019 Annex C)

Sample: A

| | | |
|---|---|---|
| Test number and location | : | 5 random areas for each specimen (face mask) |
| Conditioning Parameters | : | Minimum of 4 hours at 21±5°C and 85±5% R.H. |
| Test Area | : | 4.9 $cm^2$ |
| Flow Rate | : | 8 l/min |

| | 1# | 2# | 3# | 4# | 5# |
|---|---|---|---|---|---|
| Differential pressure △P ($Pa/cm^2$) | 57 | 58 | 58 | 50 | 53 |

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

**Clause 5.2.4 Splash Resistance**
(ISO 22609 :2004, Pressure 16.0 kPa)

Sample: A

| 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 | Pass | 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: | | | 32 | | | | |
| Overall result: | | | Acceptable | | | | |

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±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

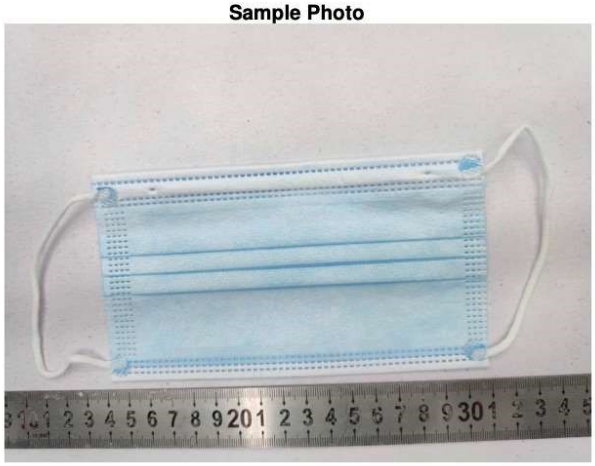
**Clause 5.2.5 Microbial Cleanliness**
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

| | 1# | 2# | 3# | 4# | 5# |
|---|---|---|---|---|---|
| CFU/g | 5 | 2 | 3 | <1 | <1 |

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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