

Test Report

SL52045313257901TX

Date: December 04, 2020

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SICHUAN ZHENGNING MEDICAL EQUIPMENT CO., LTD
NO. 3. BUILDING 2. NO. 388, FOOD AVENUE, JUNTUN TOWN, XINDU DISTRICT, CHENGDU, SICHUAN.
CHINA

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

Sample Description : (A) Disposable Mask (Claimed Type II)

SGS Internal Ref.No. : GZHL2011058201MD

Sample Color : (A) Blue

Style No. : WS-MED-II

Model No. : WS-MED-II

Lot No. : Not provided

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

Sample Receiving Date : Nov 24, 2020

Testing Period : Nov 24, 2020 - Dec 04, 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).

Comment:

| | |
|---|----------|
| EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods | (A) |
| Clause 5.2 Performance Requirement | |
| Clause 5.2.2 Bacterial filtration efficiency (BFE) | M |
| Clause 5.2.3 Breathability | M |
| Clause 5.2.4 Splash Resistance | EXCLUDED |
| Clause 5.2.5 Microbial Cleanliness | M |
| Clause 5.2.6 Biocompatibility | EXCLUDED |

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type II)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type II)

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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Test Result

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
 Test Side : Inside
 Test Area : Approximately 60 cm²
 Flow Rate : 28.3 L/min
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : ~174mm x 150mm
 Positive Control Average : 2452.5 CFU
 Negative Monitor Count : < 1 CFU
 Mean Particle Size : 3.0 ±0.3µm
 Test bacteria : Staphylococcus aureus ATCC 6538

| Test Item | Specimen No. | Result |
|---------------------------------------|--------------|--------|
| Bacterial Filtration Efficiency (BFE) | 1 | 99.9% |
| | 2 | 99.9% |
| | 3 | 99.8% |
| | 4 | 99.9% |
| | 5 | 99.8% |

Remark:

- 1) Performance Requirement: Type I ≥ 95%, Type II ≥ 98%, Type IIR ≥ 98%
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm²

Flow Rate : 8 l/min

| Specimen No. | Test Area No. | Different Pressure for each tested area (Pa/cm ²) | The average value for each test specimen (Pa/cm ²) |
|--------------|---------------|---|--|
| 1 | 1-1 | 37.2 | 37 |
| | 1-2 | 37.0 | |
| | 1-3 | 35.7 | |
| | 1-4 | 38.9 | |
| | 1-5 | 36.0 | |
| 2 | 2-1 | 35.5 | 37 |
| | 2-2 | 34.6 | |
| | 2-3 | 38.8 | |
| | 2-4 | 37.1 | |
| | 2-5 | 38.0 | |
| 3 | 3-1 | 32.9 | 37 |
| | 3-2 | 39.9 | |
| | 3-3 | 34.7 | |
| | 3-4 | 38.7 | |
| | 3-5 | 39.6 | |
| 4 | 4-1 | 30.8 | 35 |
| | 4-2 | 38.7 | |
| | 4-3 | 37.6 | |
| | 4-4 | 30.8 | |
| | 4-5 | 36.7 | |
| 5 | 5-1 | 30.7 | 34 |
| | 5-2 | 33.0 | |
| | 5-3 | 33.1 | |
| | 5-4 | 31.8 | |
| | 5-5 | 39.6 | |

Remark:

- 1) Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Clause 5.2.5 Microbial Cleanliness

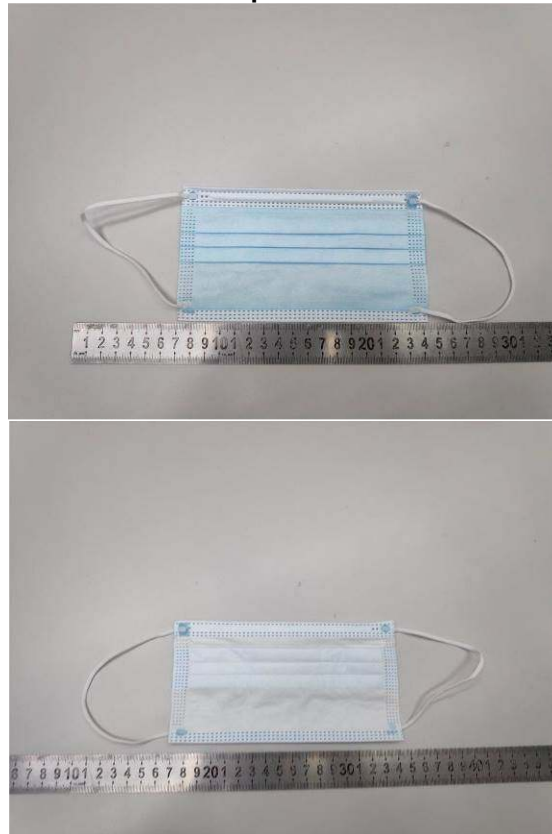
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

| Test Specimen# | Mask Weight(g) | Total Bioburden, (CFU/mask) | Total Bioburden, (CFU/g) |
|----------------|----------------|-----------------------------|--------------------------|
| 1# | 3.26 | 81 | 24.85 |
| 2# | 3.28 | 87 | 26.52 |
| 3# | 3.26 | 93 | 28.53 |
| 4# | 3.28 | 78 | 23.78 |
| 5# | 3.31 | 78 | 23.56 |

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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