ZHEJIANG TAISILK FASHION CO.,LTD.
NO. 588, EAST SECTION OF TIYUCHANG ROAD, TAIZHOU CITY, ZHEJIANG PROVINCE

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 |
| Claimed Type/Level | : | EN 14683 Type IIR |
| Style No. | : | FH003 |
| Lot No. | : | C20220530 |
| Factory | : | Zhejiang TAISILK Fashion Co.,LTD. |
| Proposed Care Instruction | : | - |
| Test Performed | : | Selected test(s) as requested by applicant |
| Sample Receiving Date | : | Nov 11, 2022 |
| Testing Period | : | Nov 14, 2022 - Nov 25, 2022 |
| 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**<br><br>**Clause 5.2 Performance Requirement** | (A) |
|---|---|
| Clause 5.2.2 Bacterial filtration efficiency (BFE) | M |
| Clause 5.2.3 Breathability | M |
| Clause 5.2.4 Splash Resistance | M |
| Clause 5.2.5 Microbial Cleanliness | M |
| Clause 5.2.6 Biocompatibility | EXCLUDED |

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

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 $cm^2$ |
| 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 | : | ~175mm x 150mm |
| Positive Control Average | : | 2027 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 | 99.9% |
| | 4 | 99.9% |
| | 5 | 99.9% |

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;Test number and location: Test in different location on each of the 5 masks;
Pre-Conditioning: Minimum of 4 hours at 21±5°C(70±10°F) and 85±5% R.H.;
Test Area: 4.9 $cm^2$;
Flow Rate: 8 l/min.)

**A**

| As Received | No. 1 | No. 2 | No. 3 | No. 4 | No. 5 |
|---|---|---|---|---|---|
| Differential Pressure | | | | | |
| Top Centre(Pa/cm²) | 40.0 | 46.9 | 50.1 | 53.1 | 54.4 |
| Centre Left(Pa/cm²) | 42.7 | 46.3 | 52.1 | 52.7 | 57.3 |
| Centre(Pa/cm²) | 43.3 | 54.8 | 57.3 | 50.6 | 57.4 |
| Centre Right(Pa/cm²) | 41.3 | 54.3 | 49.2 | 55.2 | 50.8 |
| Bottom Centre(Pa/cm²) | 44.2 | 47.6 | 51.1 | 55.5 | 49.9 |
| Average Differential Pressure(Pa/cm²) | 42 | 50 | 52 | 53 | 54 |

Remark:
1) Performance Requirement for EN 14683 :2019+AC:2019 Annex C: Type I<40 Pa/$cm^2$, Type II<40 Pa/$cm^2$, Type IIR<60 Pa/$cm^2$

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 5.2.4 Splash Resistance**

(ISO 22609:2004)

**A**

| Type IIR- 16.0kPa | No. 1 | No. 2 | No. 3 | No. 4 | No. 5 | No. 6 | No. 7 |
|---|---|---|---|---|---|---|---|
| Resistance to Penetration by Synthetic Blood(Grade) | Pass | Pass | Pass | Pass | Pass | Pass | Pass |

| Type IIR- 16.0kPa | No. 8 | No. 9 | No. 10 | No. 11 | No. 12 | No. 13 | No. 14 |
|---|---|---|---|---|---|---|---|
| Resistance to Penetration by Synthetic Blood(Grade) | Pass | Pass | Pass | Pass | Pass | Pass | Pass |

| Type IIR- 16.0kPa | No. 15 | No. 16 | No. 17 | No. 18 | No. 19 | No. 20 | No. 21 |
|---|---|---|---|---|---|---|---|
| Resistance to Penetration by Synthetic Blood(Grade) | Pass | Pass | Pass | Pass | Pass | Pass | Pass |

| Type IIR- 16.0kPa | No. 22 | No. 23 | No. 24 | No. 25 | No. 26 | No. 27 | No. 28 |
|---|---|---|---|---|---|---|---|
| Resistance to Penetration by Synthetic Blood(Grade) | Pass | Pass | Pass | Pass | Pass | Pass | Pass |

| Type IIR- 16.0kPa | No. 29 | No. 30 | No. 31 | No. 32 |
|---|---|---|---|---|
| Resistance to Penetration by Synthetic Blood(Grade) | Pass | Pass | Pass | Pass |

Number of Test Specimen Passed:32
Conclusion: Pass
Remark:
1. Pre-Conditioning: Minimum of 4 hours at 21±5°C and 85±5% R.H.
2. Distance of the mask to the tip of cannula: 300±10mm.
3. Test was conducted within 60s after removal from conditioning chamber.
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.
5. Pass: No Penetration on inside surface
   Fail: Penetration on inside surface


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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 | 3.21 | 26.46 | 8.24 |
| 2 | 3.07 | 15.12 | 4.93 |
| 3 | 3.09 | 18.90 | 6.12 |
| 4 | 3.09 | 15.12 | 4.89 |
| 5 | 3.11 | 7.56 | 2.43 |

Recovery Efficiency : 79.1%
Correction Factor : 1.3

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



SGS-CSTC Standards Technical Services (Shanghai) Co.,Ltd. Testing Center
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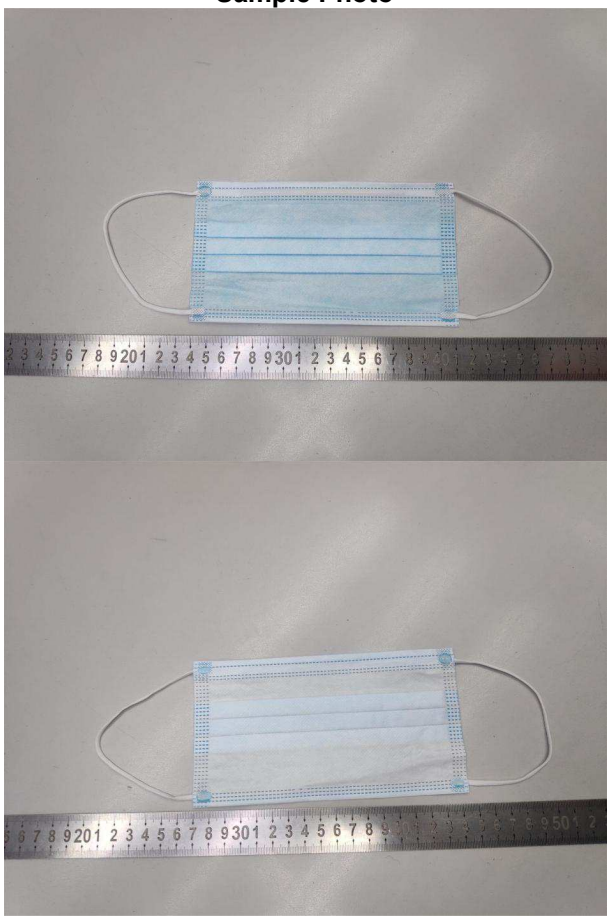
**Sample Photo**



***Product information is provided by applicant without verification or authentication of the brand.***

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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