

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Manufacturer: Sichuan Ai Doctor Medical Technology Co., Ltd
Address: No.333, Yongke Road, Yongsheng Town, Chengdu Cross-strait
Science and Technology Industrial Development Park,
Wenjiang
District, Chengdu, Sichuan, China

EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Surgical mask (Non-sterile) **HYGISUN**[®]
Specification: Earloop Type 170*95MM

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment: Annex VII



We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC)
and the following harmonized standards.

EN ISO 14971:2012

EN ISO 10993-5:2009

EN ISO 15223-1:2016

EN ISO 10993-10:2013

EN 1041:2013

EN 14683:2019

EN ISO 10993-1:2009/AC:2010

On behalf of SUNGO Europe office, I confirmed we are

Title: CEO

Title: CEO

Name: Yingbo Tang

Name: Chen Lan

Signature:

Signature:

Date: 2020年6月3日

Date: 2020年6月3日

Authorized Signature(S)

Test Report No.: 721654378
Report Date: 14 May 2020



SUBJECT Physical & Microbiological Test

TEST LOCATION TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME Sichuan Ai Doctor Medical Technology Co.,Ltd.

CLIENT ADDRESS No.333, Yongke Road, Yongsheng Town, Chengdu Cross-strait Science And
Technology Industrial Development Park, Wenjiang District, Chengdu, Sichuan,
China

TEST PERIOD 26-Apr-2020-08-May-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By



(LeoLiu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co.,
Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
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201108
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Phone : +86 (21) 6037 6375
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Regional Head Office:
TÜV SÜD Certification and Testing
(China) Co., Ltd.
No.151 Heng Tong Road Shanghai
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TEST REPORT

Sample Description : Surgical Mask
Sample Quantity : 50 pieces
Lot Number/Batch Code : 20200401
Specification : Earloop Type
Size : /
Brand Name : /

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type II R	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm ²)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
= No comment;
N.D. = Not detected.

Photo of Samples





Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 98.2% Specimen 2#: 98.0% Specimen 3#: 98.1% Specimen 4#: 98.1% Specimen 5#: 98.1%
2	Differential Pressure Test	26.6 Pa/cm ²
3	Synthetic Blood Penetration Test	Specimen 1#-32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: <1 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical Mask
Specification : Earloop Type
Lot Number : 20200401
Sample Receiving Date : 2020-04-26

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

- 4.1 *Staphylococcus aureus* ATCC 6538.
- 4.2 Peptone water.
- 4.3 Tryptic Soy Broth(TSB).
- 4.4 Tryptic Soy Agar(TSA).
- 4.5 Bacterial filtration efficiency test apparatus.
- 4.6 Six-stage viable particle Anderson sampler.
- 4.7 Flow meters.

5. Test specimen

- 5.1 As requested by client, take a total of 5 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

