CE

DECLARATION OF CONFORMITY

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

Manufacturer: Zhengzhou Wanshenshan Healthcare PPE Co., Ltd.

Address: Group 8, Miaozhu Village, Quliang Town, Xinmi City, Zhengzhou, Henan Province, China 452370

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Surgical Mask

Specification: 17.5cm×9.5cm 14.5cm×9cm 12.5cm×7.5cm

Classification : Class I (MDD, Annex IX)

Conformity Assessment Procedure: Annex VII of Medical Device Directive (93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012	EN ISO 15223-1:2016
EN 1041:2008+A1:2013	ISO 10993-1:2018
EN ISO 10993-5:2009	EN ISO 10993-10:2013
EN 14683:2019+AC:2019	

Signature: _____

Name/ Position: Changtai Wang/ General Manager

Date: Nov 20, 2020

Place: CHINA/ZHENGZHOU

On behalf of SUNGO Europe office, I confirmed we are EC REP of the company who issue this document.

Sungo

Authorized Signature (S)

万神山

Final customer: Ergum Asia Ltd.

ADD: Unit B, 3/F Kai Wan House, 146 Tung Choi Street – Kln – Hong Kong

Manufacturer: Zhengzhou Wanshenshan Healthcare PPE Co., Ltd.

Address: Quliang Wanli Industrial Zone, Xinmi city, Zhengzhou, Henan.

Tel: 0086-371-55328658

Product Name: Surgical Mask

Model: WSS-F02

Total QTY: 2520000 pcs

Test Report: SL521052320782O1TX

Conformity: EN14683:2019 and MDD93/42

Declare that:

We hereby confirmed our company Zhengzhou Wanshenshan Healthcare PPE Co., Ltd., is producing 3-ply face masks on behalf of Ergum Asia Ltd. It is non sterile Type IIR product.

Zhengzhou Wanshenshan Healthcare PPE Co., Ltd.

5th, March, 2021

ZHENGZHOU WANSHENSHAN HEALTHCARE PPE CO., LTD.
GROUP 8,MIAOZHU VILLAGE,QULIANG TOWN,XINMI CITY,ZHENGZHOU,HENAN PROVINCE,CHINA

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

Sample Description	:	(A)Surgical Mask (Claimed Type IIR)
Sample Color	:	(A)Blue
Lot No.	:	Not provided
Manufacturer		ZHENGZHOU WANSHENSHAN HEALTHCARE PPE CO., LTD.
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Nov 05, 2020
Testing Period	:	Nov 06, 2020 - Nov 19, 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	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)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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 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	:	~174mm x 150mm
Positive Control Average	:	2764 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)

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 cm^2
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	46.9	45
	1-2	42.3	
	1-3	44.6	
	1-4	48.1	
	1-5	43.4	
2	2-1	43.3	48
	2-2	43.0	
	2-3	48.6	
	2-4	57.4	
	2-5	48.8	
3	3-1	44.2	46
	3-2	44.4	
	3-3	48.7	
	3-4	45.0	
	3-5	47.6	
4	4-1	46.4	45
	4-2	45.0	
	4-3	41.5	
	4-4	45.1	
	4-5	46.2	
5	5-1	40.1	42
	5-2	40.6	
	5-3	41.2	
	5-4	47.1	
	5-5	42.4	

Remark:
1) Performance Requirement: 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)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	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) Test was conducted within 60s after removal from conditioning chamber.
3) 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.

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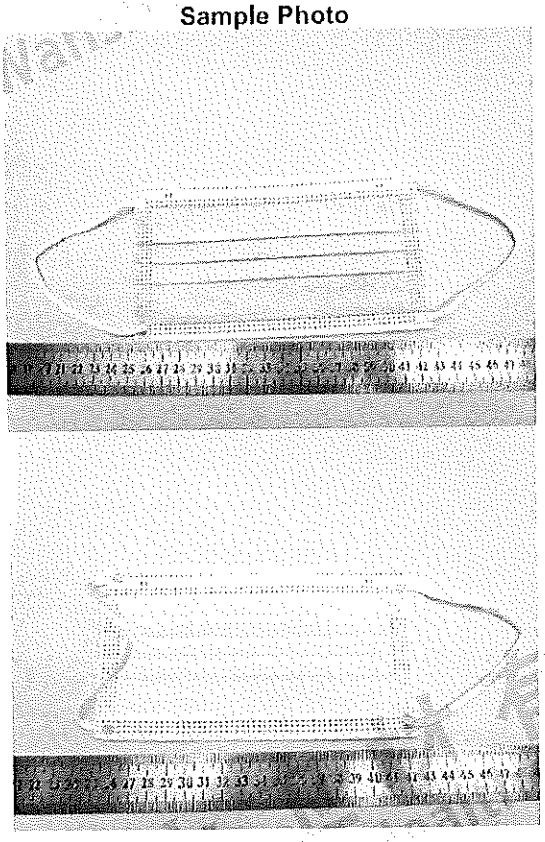
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.54	3	0.85
2#	3.56	9	2.53
3#	3.56	3	0.84
4#	3.53	<3	<0.85
5#	3.51	6	1.71

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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