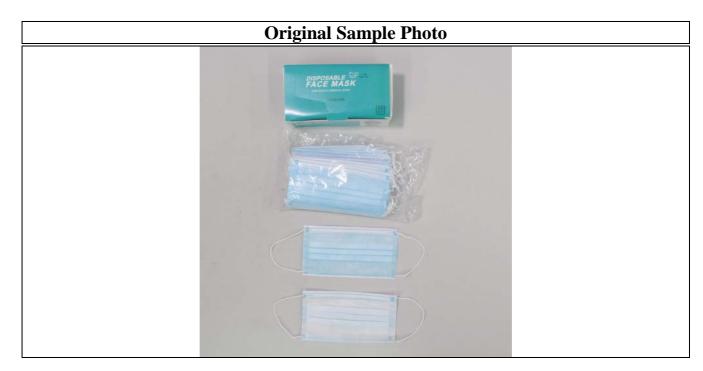


REPORT NUMBER: SHAT06556675





Number: SHAT06556675

Jul 17, 2020

Date:

Applicant: DANYANG SUNMED HEALTHCARE CORP.

NO. 3 NORTH SECOND RING ROAD DANYANG CITY, JIANGSU PROVINCE

Attn: WEI CAIXIA

Sample Description As Declared:

No. Of Sample : Several

Material : Non - Woven + Melt - Blown Fabric

Sample Name : Disposable Face Mask

Finishing : End Uses : Colour : Blue

Style No. : KN001/KN-FM-N01/P265.885

Order No./PO No. : -

Standard : EN 14683: 2019+AC: 2019

Ratings : Type II

Buyer's Name : -

Manufacturer's Name: Hubei Kangning Protective Products Co., Ltd

Ref. : -

Applicant's Provided Care Instruction/Label: -

Date Sample Received : Jul 01, 2020 Date Testing Started : Jul 02, 2020

Conclusion:

# Summary of testing:

# With reference to following standard:

• EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods Type II

Materials Used in The Submitted Sample Were Found To Comply With The Type II Requirements of EN 14683:2019+AC:2019 with respect to Bacterial Filtration Efficiency, Differential Pressure and Microbial Cleanliness tests.

Prepared And Checked By:

For Intertek Testing Services Ltd., Shanghai

Jennifer Ren General Manager





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Tests Conducted (As Requested By The Applicant)

terial Filtration Efficiency (BFE)

As Per EN 14683:2019+AC:2019 Medical face masks – Requirements And Test Methods Annex B.

Test Item		Performance Requirement for Medical Face Mask (%)				
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.7	99.4	99.8	99.6	99.9	Type II: ≥98

### Remarks:

- 1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
- 2. Testing side: Outside of the test specimen was facing towards the challenge aerosol.
- 3. Test area: 78 cm<sup>2</sup>
- 4. Flow rate: 28.3 L/min
- 5. The average plate count results of the positive controls: 2.5x10<sup>3</sup> CFU
- 6. The average plate count results of the negative controls: < 1 CFU
- 7. CFU = Colony Forming Unit

Remark: This Test Was Conducted By Intertek Testing Services Guangzhou Ltd.



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Tests Conducted (As Requested By The Applicant)

2 Differential Pressure (EN 14683:2019+AC:2019 Annex C):

Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm<sup>2</sup>.

<u>Tested</u>		<u>R</u>	Performance			
<u>Sample</u>			Requirement for Medical Face Mask (Pa/cm <sup>2</sup> )			
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	19.2	24.3	24.3	23.0	27.7	
Location 2	23.1	24.3	25.0	22.3	23.7	Type II: < 40
Location 3	25.1	20.3	22.8	25.0	25.4	
Location 4	22.7	20.7	22.4	23.5	25.2	
Location 5	22.6	19.3	21.3	26.0	25.3	
Average	22.5	21.8	23.2	24.0	25.5	
* = All the locations were evenly taken from the main mask body.						

Remark: This Test Was Conducted By Intertek Testing Services Guangzhou Ltd.

#### 3 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods Annex D.

Test Item		<u>Limit</u> (cfu/g)				
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Microbial Cleanliness	2	<1#	<1#	2	2	Type II: ≤30

#### Remark:

cfu = colony forming unit

 $\leq$  = Not more than

# = No colony was detected at the extraction liquid of the samples.

Remark: This Test Was Conducted By Intertek Testing Services Guangzhou Ltd.



Number: SHAT06556675

Tests Conducted (As Requested By The Applicant)

Product Size Measurement:

>10 cm Width

End of Report

Remark: This statement of conformity is only based on the actual measured test result by the laboratory, without taking the influence of uncertainty into accord.

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