

REPORT NUMBER:

SHAT06471864



TEST REPORT

Number : SHAT06471864

Applicant : ZHEJIANG HAIPAI PHAMACEUTICAL CO.,LTD  
1ST AND 2ND FLOOR NO.2,NO.3  
BUILDING,XIXIANG JINYUANNANBAIXIANG,  
OUHAI, WENZHOU,ZHEJIANG  
PROVICE CHINA  
Attn : LIUHUI

Date : May 07, 2020

Sample Description As Declared :

No. Of Sample : Several  
Material : Disposable Medical Mask Is Composed Of Mask Body, Nose Clip And Mask Belt.  
The Body Of The Mask Is Made Of Non-Woven Fabric And Melt Blown Fabric.  
The Nose Clip Is Made Of PVC And Iron Wire.  
The Ear Band Is Made Of Spandex And Tapestry.  
Sample Name : Disposable Medical Mask (Non-Sterile)  
Finishing : -  
End Uses : It Is Used For One-Time Hygienic Care In Ordinary Environment, And Is Not Used For  
Special Protection During Surgical Operations.  
Colour : Blue/White  
Style No. : 175mm×95mm (±5%)  
Order No./PO No. : -  
Standard : EN 14683:2019+AC:2019  
Rating : Type I  
Buyer's Name : -  
Manufacturer's Name : Zhejiang Haipai Pharmaceutical Co.,Ltd.  
Ref. : -

Applicant's Provided Care Instruction/Label : -

Date Sample Received : Apr 16, 2020

Date Testing Started : -

Prepared And Checked By:  
For Intertek Testing Services Ltd.,Shanghai



Jennifer Ren  
General Manager



**Intertek Testing Services Ltd., Shanghai**

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Attention is drawn to the terms and conditions printed overleaf

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**Conclusion:**

**Summary of testing:**

With reference to following standard:

- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type I.

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

1 Microbial Cleanliness

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

Test Item	Result ( cfu/g )	Requirement ( cfu/g )
	Test component	
	(1)	
Total Plate Count (30°C)	4	-
Total Plate Count (20 to 25°C)	<1#	-
Microbial cleanliness	4	Type I: ≤30

cfu = Colony Forming Unit

≤ = Not More Than

# = No Colony Was Detected At The Extraction Liquid Of The Samples.

Sample received condition: Sample in unopened plastic bag.

Tested Component:

(1) Blue/ white Face Mask

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

- 2 Bacterial Filtration Efficiency (EN 14683:2019+AC:2019, Clause 5.2.2, Testing Refer To Annex B):  
Flow rate: 28.3L/min, Test area: 77 cm<sup>2</sup>, Test bacteria: Staphylococcus aureus ATCC 6538, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.2 X 10<sup>3</sup> CFU, The average plate count results of the negative controls: <1 CFU.

<u>Tested Sample</u>	<u>Result (%)</u>	<u>Performance Requirement for Medical Face Mask</u>
Specimen (1)	98.6	Type I: ≥ 95%
Specimen (2)	98.0	
Specimen (3)	98.2	
Specimen (4)	98.2	
Specimen (5)	98.3	

Remark : Test was conducted by external provider

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Tests Conducted (As Requested By The Applicant)

- 3 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 Sample</u>	<u>Result (Pa/cm<sup>2</sup>)</u>	<u>Performance Requirement for Medical Face Mask</u>
Specimen (1)	32.3	Type I < 40 Pa/cm <sup>2</sup>
Specimen (2)	37.7	
Specimen (3)	38.3	
Specimen (4)	39.9	
Specimen (5)	39.6	
Average	37.6	

Remark : Test was conducted by external provider

- 4 Product Size Measurement:

		<u>Marked</u>
Length	9.7cm	9.5 cm ±5%
Width	17.3cm	17.5 cm ±5%

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 account.*

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