

Report Ref:	GZHT02279529		
Date Received:	Apr 10, 2020	Date Issued:	May 06, 2020

Company Name: Address:	BYD PRECISION MANUFACTURE CO., LTD NO.3001 BAOHE ROAD,BAOLONG INDUSTRIAL AREA, LONGGANG SHENZHEN, GUANGDONG, P.R.CHINA
Contact Name:	古淑芬

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
Non-Sterile Medical Face Mask		
Type IIR		
Single-Use Surgical Mask		
-		
Blue		
EN 14683:2019+AC:2019		
BYD PRECISION MANUFACTURE CO., LTD		
BYD		
Apr 10, 2020		
FE2311		

Prepared And Checked By: For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch

Lin Lin General Manager

doris / pennytao



Intertek Testing Services Stielizhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

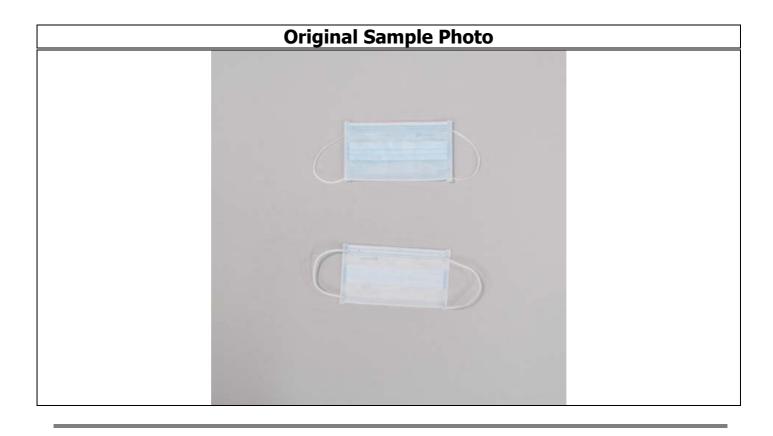
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Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E70/4601, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China 中国广州经济技术开发区科学城彩频路 7 号之二第 1-8 层 02 房 01 原 101、

E201、E301、E401、E501、E601、E701、E801 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663 Hengyun Building, 235 Kaifa Ave., Guangzhou Repomic & Technological Development District, Guangzhou, China 使了广州经济技开发区开发大道 235 号恒运大厦 3 楼 dei: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



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Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/**E**01, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou China 中国广州经济技术开发区科学城彩频路 7 号之二第 1-8 层 02 房、01 房 101、 24 24

E201、E301、E401、E501、E601、E701、E801 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663 任, Hengyun Building, 235 Kaifa Ave., Guangzhou Foromic & Technological Development District, Guangzhou, China 中一广州经济技开发区开发大道 235 号恒运大厦 3 楼 1: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



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Summary of testing:

With reference to following standard:

• EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

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

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Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E01/E01/E01, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou China 中国广州经济技术开发区科学城彩频路 7 号之二第 1-8 层 02 房 91 房 101.

E201、E301、E401、E501、E601、E701、E801 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663 94. Hengyun Building, 235 Kaifa Ave., Guangzhou Foromic & Technological Development District, Guangzhou, China 中口广州经济技开发区开发大道 235 号恒运大厦 3 楼 1: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Tests Conducted (As Requested By The Applicant)

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## 1 Microbial Cleanliness

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

Test Item	<u>Result ( cfu/g )</u> <u>Test component</u>	<u>Requirement</u> <u>( cfu/g )</u>
	(1)	
Total Plate Count (30°C)	1	-
Total Plate Count (20 to 25°C)	1	-
Microbial cleanliness	2	Type IIR: ≤30

cfu = Colony Forming Unit  $\leq$  = Not More Than

Sample received condition: Sample in closed plastic bag.

Tested Component: (1) Blue Face Mask

2 Bacterial Filtration Efficiency (EN 14683:2019+AC:2019, Clause 5.2.2, Testing Refer To Annex B): Flow rate: 28.3 L/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: 2.5×10<sup>3</sup> CFU, The average plate count results of the negative controls:<1 CFU.</p>

Tested Sample	<u>Result (%)</u>	Performance Requirement for Medical Face Mask (%)
Specimen (1)	99.1	<b>*</b>
Specimen (2)	99.1	Type IIR: ≥ 98
Specimen (3)	99.2	
Specimen (4)	99.1	
Specimen (5)	99.1	

Remark: Test was conducted by external provider.

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3 Differential Pressure (EN 14683:2019+AC:2019 Annex C): Air flow: 8 L/min, Test area diameter 25 mm, Test area: 4.9 cm<sup>2</sup>.

Tested Sample	Result (Pa/cm <sup>2</sup> )	Performance
		Requirement for
		Medical Face Mask
		<u>(Pa/cm²)</u>
Specimen (1)	43.4	
Specimen (2)	47.6	Type IIR: < 60
Specimen (3)	40.6	
Specimen (4)	46.3	
Specimen (5)	49.1	
Average	45.4	

Remark: Test was conducted by external provider.

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#### 4 Splash Resistance Pressure (ISO 22609:2004):

Synthetic Blood Surface Tension: 0.040 N/m, Distance Between Blow Head Front End And Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

<u>Tested Sample</u>	<u>Result</u>	Performance <u>Requirement for</u> <u>Medical Face Mask</u> Type IIR: No penetration at 16.0 kPa
Specimen (1)	None seen	
Specimen (2)	None seen	
Specimen (3)	None seen	
Specimen (4)	None seen	
Specimen (5)	None seen	
Specimen (6)	None seen	
Specimen (7)	None seen	
Specimen (8)	None seen	
Specimen (9)	None seen	
Specimen (10)	None seen	
Specimen (11)	None seen	
Specimen (12)	None seen	
Specimen (13)	None seen	

Remark : Test was conducted by external provider.

End of Report

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