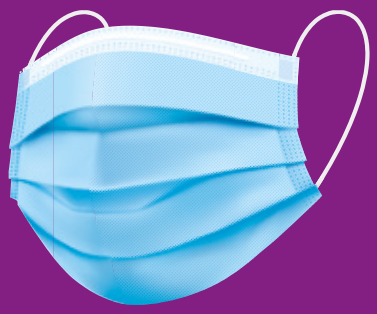
DIAMOND MEDICAL

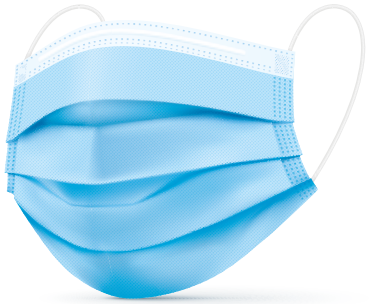


MEDICAL **FACE MASK**

Type IIR

3-ply • Latex-free
Disposable

DIAMOND MEDICAL



Brand Name :	Diamond Medical
Product Type:	Medical Face mask, 3-Ply with earloop
Ratings:	Type IIR
Product Dimension:	17.5 x 9.5 cm
Colour:	Blue
Product code:	DM2020180
Package Quantity:	50 pieces/pack, 2000 pieces/box
European Standard:	EN14683:2019 + AC:2019 Annex 2019 Type IIR, ISO 22609:2004
Expire Date:	The storage temperature is -20C - 40C, the storage humidity is <80%, valid for 3 years in a dry indoor environment.
Product Registration Certificate:	Intertek testing services Shenzhen Ltd. Ref. GZHT02337145
Manufacturer:	Hubei Wanli Protective Products Co.LTD Yuanshi, Ganhe Town, Xiantao City, Hubei province China
EC REP:	SUNGO Europe B.V. Olympisch stadion 24, 1076DE Amsterdam, The Netherlands
Distributed by	De Boer Dental, The Netherlands www.deboerdental.nl

DIAMOND MEDICAL

INNERBOX

SHIPPING CARTON

DIAMOND MEDICAL

CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ ZERTIFIKAT

Sungo global service

To whom it may concern

SUNGO Europe B.V. located in Olympisch Stadion 24, 1076DE Amsterdam, Netherlands is appointed as the European Representative by Hubei Wanli Protective Products Co., Ltd located in Yuanshi, Ganhe, Xiantao, Hubei, China

The “Business Area” and “Product Categories” for the EU REP are Face Mask, Coverall, Surgical Gown, Lab Coat, Isolation Gown, Cap, Shoe/Boot Cover, Oversleeve, Short Pants, Bed Sheet, CPE Gown in Europe market. And the formal contact of SUNGO Certification Company Limited is as following:

Contact: SUNGO Secretary
Tel: +31 (0)20 21 11 106
E-mail: ec.rep@sungoglobal.com

SUNGO CERTIFIED

Issued: Mar. 25 2020
Expiration Date: Mar. 24 2025

Signature and Stamp
SUNGO Europe B.V.

DIAMOND MEDICAL

XIAN WANLI

Hubei Wanli Protective Products Co., Ltd

Add: Yuanshi, Ganhe Town, Xiantao City, Hubei, China

Tel: 0086-27-85513916 Email: info@hbwanli.com

CE EC DECLARATION OF CONFORMITY

Manufacturer:	Name: Hubei Wanli Protective Products Co. Ltd.
Address:	Yuanshi, Ganhe Town, Xiantao City, Hubei Province, China.

We declare under our sole responsibility that the Disposable Face mask 3-ply, non sterile.

Brand Name:	Diamond Medical
Product Type:	Face mask Disposable 3-Ply earloop
Ratings :	Type IIR
Product code:	WLM2002
European Standard:	EN14683:2019 + AC:2019 Annex 2019 Type IIR, ISO 22609:2004
EC REP:	SUNGO Europe B.V. Olympisch stadion 24, 1076DE Amsterdam, The Netherlands
Distributed by:	De Boer Dental, The Netherlands

Meets the provisions of the ASTM F2101-19 and EN 14683:2019, Annex B and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC**

The above mentioned declaration of Conformity is exclusively under the responsibility of Hubei Wanli Protective Products Co. Ltd.

European Representative: SUNGO Europe B.V. (see original certificate on 2nd page)

Place and date:

China
20/03/2020

Name, position and stamp:

Manager

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TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0220

Number: GZHT02337145

Report Ref:	GZHT02337145		
Date Received:	Sep 10, 2020	**Date Issued:**	Sep 21, 2020

Company Name:	DE BOER DENTAL
Address:	BOLSTER 2/ 9281KK HARKEMA/ THE NETHERLANDS
Contact Name:	Thomas de Boer

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Non-Sterile Medical Face Mask
Ratings	:	Type IIR
Sample Name	:	Non-Sterile Medical Face Mask Disposable 3-PLY
No. Of Sample	:	One(110 pieces)
Size	:	17.5x9.5cm
Colour	:	Blue/White
Standard	:	EN 14683:2019+AC:2019
Brand Name	:	Diamond Medical
Manufacturer	:	HUBEI WANLI PROTECTIVE PRODUCTS CO., LTD
Buyer	:	DE BOER DENTAL
Date received/ Test Started	:	Sep 10, 2020
Ref	:	Type No.: DM2020180 EU-Authorized Representative: SUNGO Europe BV/Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Test was conducted on specific items, at our client's request.

Approved by:

Sr. Manager Assistant Supervisor

AL / hilaryxu

Intertek Testing Services Shenzhen 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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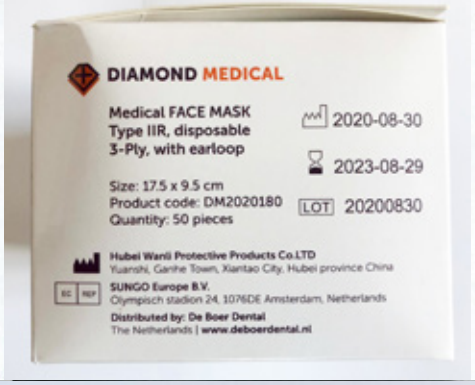
Number: GZHT02337145

Original Sample Photo



Approved by:

Sr. Manager Assistant Supervisor

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AL / hilaryxu

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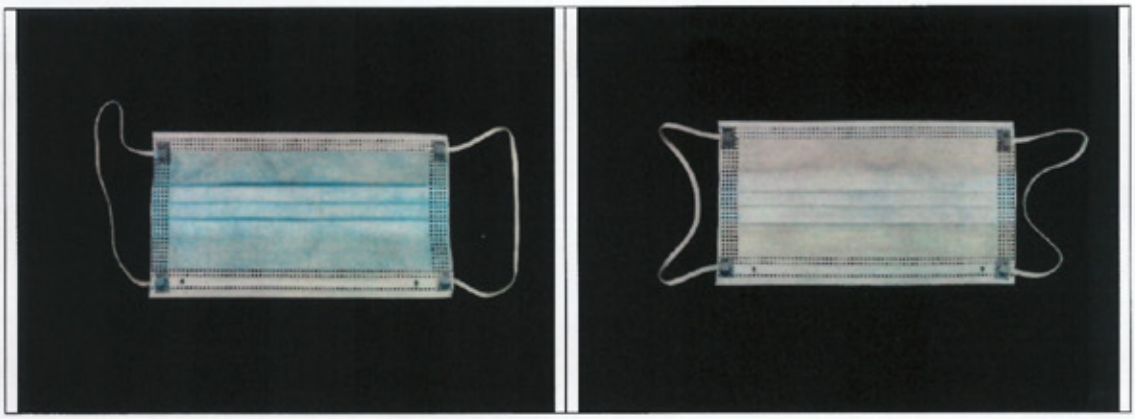
CNAS L0220

Number: GZHT02337145



Approved by:

Sr. Manager Assistant Supervisor

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CNAS L0220

Number: GZHT02337145

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.

Approved by:

Sr. Manager Assistant Supervisor

AL / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
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Number: GZHT02337145

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)					Limit (cfu/g)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Microbial Cleanliness	<1#	<1#	<1#	<1#	<1#	Type IIR: ≤30

Remark:
cfu = colony forming unit
≤ = Not more than
= No colony was detected at the extraction liquid of the samples.

Remark: This test item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

AL / hilaryxu

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Number: GZHT02337145

Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)

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

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.8	>99.9	99.8	>99.9	>99.9	Type IIR: ≥98
Conclusion:	**Pass**					

Remarks:
1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
2. Testing side: Inside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78.5 cm^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2.5 x 10^3 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit
8. Particle Diameter: (3.0±0.3) μm

Remark: This test item is subcontracted to a CNAS accredited organization with Registration No.: L7673

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Number: GZHT02337145

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^2.

Tested Sample	Result (Pa/cm^2)					Performance Requirement for Medical Face Mask (Pa/cm^2)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	34.7	45.3	36.9	41.0	38.0	Type IIR: < 60
Location 2	34.1	40.8	44.7	39.8	42.9	
Location 3	48.6	39.0	39.8	43.9	38.8	
Location 4	43.7	46.1	36.1	41.2	45.1	
Location 5	38.4	40.0	34.5	38.6	40.2	
Average	39.9	42.2	38.4	40.9	41.0	
Conclusion:	**Pass**					

Remark: This test item is subcontracted to a CNAS accredited organization with Registration No.: L7673

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

Synthetic Blood Surface Tension: 0.042N/m, Distance Between Blow Head Front End And Target Area: 305 mm, Artificial Blood Volumes: 2 mL, Blood Pressure: 16.0 kPa, Velocity: 550 cm/s, Without Targeting-plate Used Condition test specimens for a minimum of 4 hours in an environment of temperature (21±5) °C and relative humidity (85±5)% and conduct the test within 1 minute of removal from conditioning chamber.
Test Environment Condition: Temperature (21±5) °C, Relative Humidity (85±5)%

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask
Specimen (1)	Resistance to penetration of liquid splashes>16kPa	Pass	Type II R No Penetration at 16.0 kPa
Specimen (2)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (3)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (4)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (5)	Resistance to penetration of liquid splashes>16kPa	Pass	

AL / hilaryxu

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CNAS L0220

Number: GZHT02337145

Tests Conducted (As Requested By The Applicant)

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask
Specimen (6)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (7)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (8)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (9)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (10)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (11)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (12)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (13)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (14)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (15)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (16)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (17)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (18)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (19)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (20)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (21)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (22)	Resistance to penetration of liquid splashes>16kPa	Pass	

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Number: GZHT02337145

Tests Conducted (As Requested By The Applicant)

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask
Specimen (23)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (24)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (25)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (26)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (27)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (28)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (29)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (30)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (31)	Resistance to penetration of liquid splashes>16kPa	Pass	
Specimen (32)	Resistance to penetration of liquid splashes>16kPa	Pass	
Conclusion*:	**Accepted**		
* = 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.			

Remark: This test item is subcontracted to a CNAS accredited organization with Registration No.: L7673

End of Report

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