



DIAMOND MEDICAL



MEDICAL FACE MASK

Type IIR

3-ply • Latex-free
Disposable



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

INNERBOX



SHIPPING CARTON



ZERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE ◆



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

Signature and Stamp
SUNGO Europe B.V.





Hubei Wanli Protective Products Co., Ltd

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

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



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



TEST REPORT

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 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



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AL / hilaryxu

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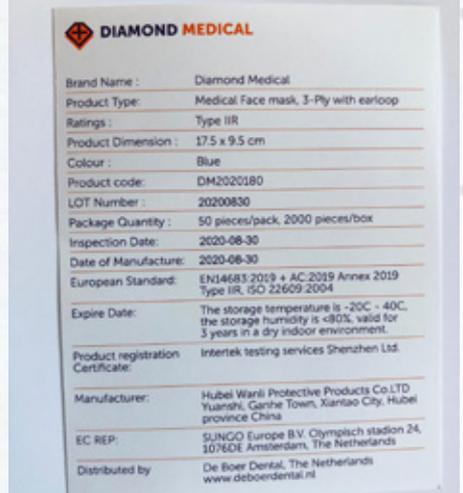
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TEST REPORT

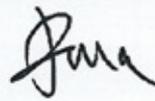
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Number: GZHT02337145

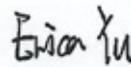
Original Sample Photo

 <p>DIAMOND MEDICAL Medical FACE MASK Type IIR 3-ply - Latex-free Disposable CE EN14683 2019 ISO 22609:2004 50 PCS</p>	 <p>DIAMOND MEDICAL Medical FACE MASK Type IIR, disposable 3-Ply, with earloop Size: 17.5 x 9.5 cm Product code: DM2020180 Quantity: 50 pieces Hubei Wanli Protective Products Co.LTD Yuanshi, Ganhe Town, Xiaotao City, Hubei province China SUNGO Europe B.V. Olympisch stadion 24, 1076DE Amsterdam, Netherlands Distributed by: De Boer Dental The Netherlands www.deboerdental.nl</p>																																
 <p>DIAMOND MEDICAL</p> <p>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 LOT Number : 20200830 Package Quantity : 50 pieces/pack, 2000 pieces/box Inspection Date : 2020-08-30 Date of Manufacture : 2020-08-30 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. Manufacturer: Hubei Wanli Protective Products Co.LTD Yuanshi, Ganhe Town, Xiaotao 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</p>	 <p>产品合格证</p> <table border="1"> <tr><td>产品名称:</td><td>一次性使用医用口罩</td></tr> <tr><td>产品规格:</td><td>一次性使用医用口罩, 9.5cm(卫生级别为普通级)</td></tr> <tr><td>成分比例:</td><td>无纺布, 无纺布, 无纺布66%</td></tr> <tr><td>型号:</td><td>WLX200</td></tr> <tr><td>医疗器械生产许可证:</td><td>鄂食药监生产许20180820号</td></tr> <tr><td>医疗器械注册证:</td><td>鄂械注准20182142554</td></tr> <tr><td>医疗器械执行标准:</td><td>YY 0589-2013</td></tr> <tr><td>医疗器械技术要求编号:</td><td>鄂械注准20182142554</td></tr> <tr><td>注册地址:</td><td>湖北省仙桃市王刘办事处四居委会</td></tr> <tr><td>生产单位:</td><td>湖北万利防护用品有限公司</td></tr> <tr><td>生产地址:</td><td>湖北省仙桃市西流河镇塘湾街</td></tr> <tr><td>生产批号:</td><td>20200830</td></tr> <tr><td>生产日期:</td><td>2020-08-30</td></tr> <tr><td>有效期:</td><td>2023-08-29</td></tr> <tr><td>检验员:</td><td>001</td></tr> <tr><td>售后服务:</td><td>0728-3227299</td></tr> </table>	产品名称:	一次性使用医用口罩	产品规格:	一次性使用医用口罩, 9.5cm(卫生级别为普通级)	成分比例:	无纺布, 无纺布, 无纺布66%	型号:	WLX200	医疗器械生产许可证:	鄂食药监生产许20180820号	医疗器械注册证:	鄂械注准20182142554	医疗器械执行标准:	YY 0589-2013	医疗器械技术要求编号:	鄂械注准20182142554	注册地址:	湖北省仙桃市王刘办事处四居委会	生产单位:	湖北万利防护用品有限公司	生产地址:	湖北省仙桃市西流河镇塘湾街	生产批号:	20200830	生产日期:	2020-08-30	有效期:	2023-08-29	检验员:	001	售后服务:	0728-3227299
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Approved by:



Sr. Manager



Assistant Supervisor



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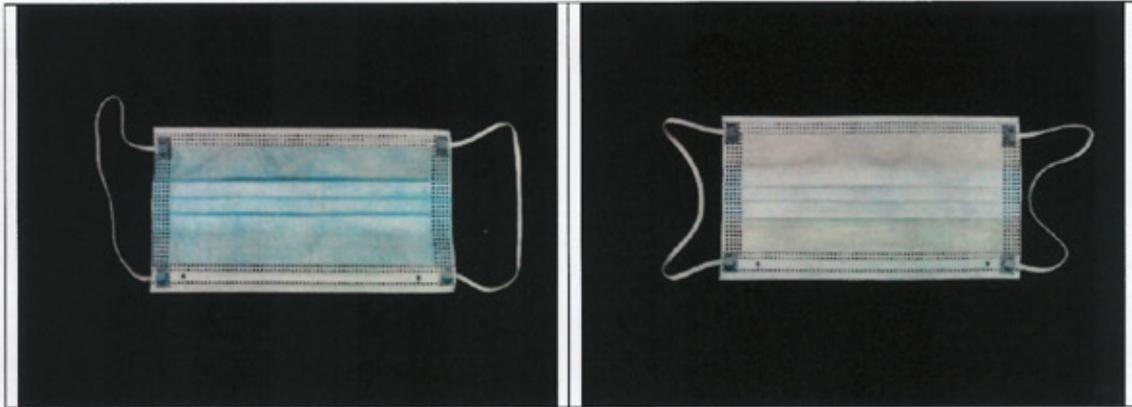
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Number: GZHT02337145

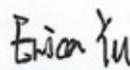


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CNAS L0220

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.

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Sr. Manager

Assistant Supervisor



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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.

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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 cm²
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2.5 x 10³ 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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TEST REPORT

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 CNAS L0220

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 cm².

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	

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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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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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