欧盟检测报告 EN14683-Type IIR

Number: GZHT02285211

CE EN14683 Test report-Type IIR

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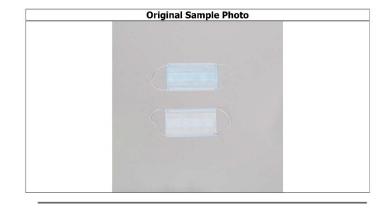
Test Report

Number: GZHT02285211

Report Ref:	GZHT02285211			
Date Received:	Apr 26, 2020	Date Issued:	May 07, 2020	

Company Name: Address:	ZAIDTEK ELECTRONIC TECHNOLOGY (XIAMEN) CO LTD NO. 285,WENGJIAO ROAD,XINYANG STREET, HAICANG DISTRICT XIAMEN, FUJIAN, CHINA	
Contact Name:	Michael Lan	

End Uses	: Non-Sterile Medical Face Mask
Ratings	: Type IIR
Sample Name	: Disposable Medical Face Mask
Size	: 17.5*9.5cm
Colour	: Blue
Standard	: EN 14683:2019+AC:2019
Band Name	: Yafox
Manufacturer	: ZAIDTEK ELECTRONIC TECHNOLOGY (XIAMEN) CO LTD
Date received/ Test Started	: Apr 26, 2020
Ref	HFM-002
	闽横注准 20202140216 (临时)



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.

Prepared And Checked By:

For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin

General Manager

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/ pennytao

Intertek Testing Services Shienzhen Ltd. Guangzhou Branch 深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8 F & Room 01, E101/E201/E301/E401/E501/E601/F 75/ 76901, No.7-2, Calpin Road, Guangzhou Science City, GETDD, Guang And, China 中国广州经济技术开发区科学就采购路 7 号之二第 1—8 层 02 房 Hengyun Building, 235 Kaifa Ave., Guangzhou Egneomic & Technological Development District, Guangzhou, China 程單广州经济技开发区开发大道 235 号恒运大厦 3 模 整整调号用型 256 +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

E201, E301, E401, E501, E601, E701, E801

For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin General Manager

/ pennytao

Intertek Testing Services Strenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有规公司广州分公司

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Number: GZHT02285211

For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin General Manager

/ pennytao

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E201, E301, E401, E501, E601, E701, E801

Room 02: 1-8F & Room 01: E010E201E201E401E501E801E701e801 サインフィース (Bungying Building, 235 Kaifa Ave., Guangying No.7-2, Cajan Road, Guangying Olyekpraer District, Guangying China 中のアルス (Bungying China Hangying China Ha 使可广州经济技开发区开发大道 235 号恒运大厦 3 楼 经营设置专用。 2015: +86 20 8396 8888 Fax: +86 20 8222 8169 Postoode: 510730

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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.

Sel Care September (1997)	Result (cfu/g)	Requirement
Test Item	Test component	(cfu/g)
	(1)	
Total Plate Count (30°C)	22	-
Total Plate Count (20 to 25°C)	3	-
Microbial cleanliness	25	Type IIR: <30

cfu = Colony Forming Unit ≤ = 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: 28.3L/min, Test area:77 cm², 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: 2.6×103CFU, The average plate count results of the negative controls:<1CFU.

Tested Sample	Result (%)	Performance Requirement for Medical Face Mask
Specimen (1)	98.0	
Specimen (2)	98.3	Type IIR : ≥ 98%
Specimen (3)	98.4	
Specimen (4)	98.6	
Specimen (5)	98.6	

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 cm2

Tested Sample	Result (Pa/cm²)	Performance Requirement for Medical Face Mask
Specimen (1)	49.6	
Specimen (2)	46.6	
Specimen (3)	48.8	Type IIR < 60
Specimen (4)	41.2	Pa/cm ²
Specimen (5)	51.2	
Average	47.5	
Remark : Test was conducted b	y external provider.	

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Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E70/E801, No.7-2, Calpin Road, Guangzhou Solence City, GETDD, Guangzhou, China 中国广州经济技术开发区科学维彩频路 7 号之二第 1 —8 层 02 层 Hengyun Building, 235 Kaifa Ave., Guangzhou omic & Technological Development District, Guangzhou, China +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730 E301 E301 E401 E501 E801 E701 E801

/ pennytao

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Hengyun Building, 235 Kaifa Ave., Guangzhou comic & Technological Development District, Guangzhou, China 保育广州经济技开发区开发大道 235 号恒运大厦 3 楼 機整備専用章 3 号 - 186 20 8396 6888 Fax: 186 20 8222 8169 Prosto +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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Tests Conducted (As Requested By The Applicant)

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.

Tested Sample	Result	Performance Requirement for Medical Face Mask Type IIR: No penetration at 16.0 kPa
Specimen (1)	None Seen	10.0 KF4
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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Number:

This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report(except for full text copy) shall be made without the written approval by

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EC符合性声明 EC Declaration of Conformity for Type I, Type II and Type IIR

EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

Zaidtek Electronic Technology (Xiamen) Co., Ltd. M/s CMC Medical Devices & Drugs S.L. No. 285, Wengjiao Road, Xinyang Street, Haicang C/ Horacio Lengo Nº 18, CP 29006, Málaga, District, Xiamen, Fujian

The peoples republic of China

We, the manufacturer, herewith declare that the products Medical surgical face mask (non-sterile)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to

The above mentioned declaration of conformity is exclusively under the responsibility of

Zaidtek Electronic Technology (Xiamen) Co., Ltd.

No. 285, Wengjiao Road, Xinyang Street, Haicang District, Xiamen, Fujian

EC Declaration of Conformity

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医用外科口罩欧洲代理证书及产品注册号 (Type IIR) Medical surgical face mask European Representative Certificate & Registration No. (Type IIR)



(Appendix A): [Disposable medical mask (non-sterile)] [Medical surgical face mask (non-sterile)]

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee:

Validity of Agreement: This agreement shall stand valid up to May 28, 2025. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

COMPANY NAME

Zaidtek Electronic Technolog (Xiamer) Conditable Con Manual Land CMC MEDICAL DEVICES & DRUGS S.L.

Authorized Signatury

Spain on May 29, 202



EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/01062020.27

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Zaidtek Electronic Technology (Xiamen) Co., Ltd No. 285, Wengjiao Road, Xinyang Street, Haicang District, Xiamen, Fujian, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number RPS/1154/2020



Issued on: 01/06/2020

Author or di Signatory

Valid until: 31/05/2021

CMC Medical Devices & Drugs SL

EC REP CERTIFICATE



ANNEX I Medical Device Produ

Medical surgical face Mask (Non sterile)

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