欧盟检测报告 EN14683-Type IIR　　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

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	:	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 闽械注准 20202140216（临时）

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

Lin Lin
General Manager

/ pennytao

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Original Sample Photo

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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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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) Test component	Requirement (cfu/g)
	(1)	
Total Plate Count (30℃)	22	-
Total Plate Count (20 to 25℃)	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 cm^2, 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: 2.6×10^3CFU, 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.

/ pennytao

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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^2.

Tested Sample	Result (Pa/cm^2)	Performance Requirement for Medical Face Mask
Specimen (1)	49.6	
Specimen (2)	46.6	
Specimen (3)	48.8	Type IIR < 60 Pa/cm^2
Specimen (4)	41.2	
Specimen (5)	51.2	
Average	47.5	

Remark : Test was conducted by external provider.

/ pennytao

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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	
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

/ pennytao

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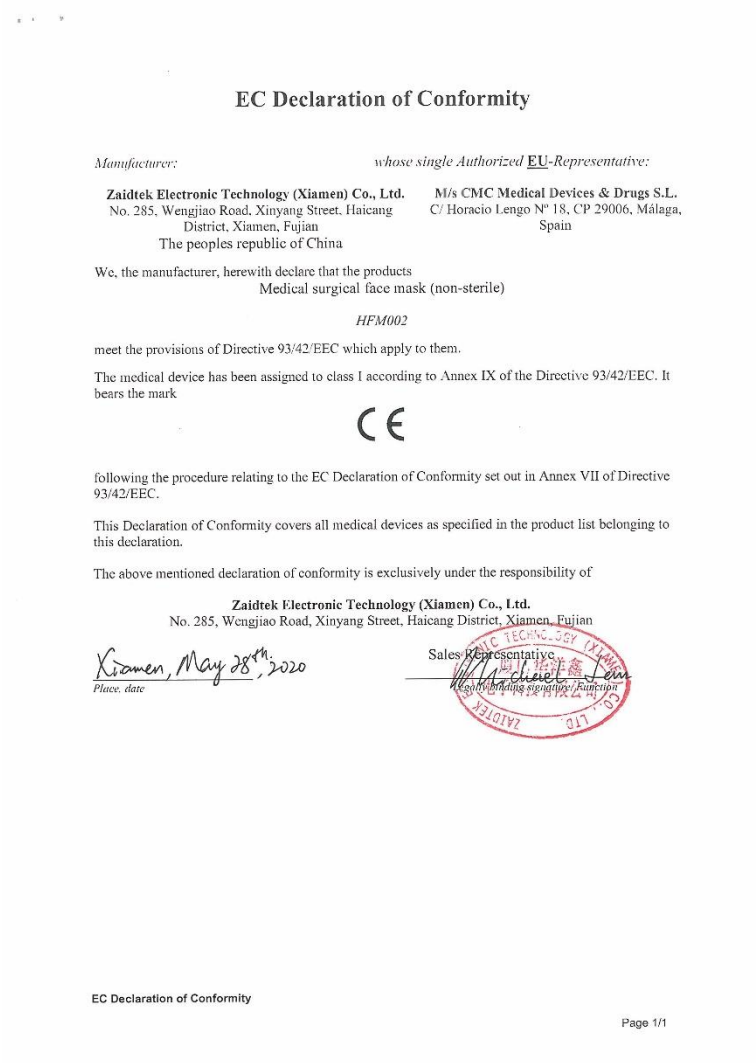
EC符合性声明 EC Declaration of Conformity for Type I, Type II and Type IIR



EC Declaration of Conformity

Manufacturer:

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

whose single Authorized **EU**-*Representative:*

M/s CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

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

HFM002

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

CE

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 this declaration.

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

Xiamen, May 28th, 2020
Place, date

Sales Representative
Legally binding signature / Function

EC Declaration of Conformity

Page 1/1

Type IIR-HFM002

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 Technology (Xiamen) Co., Ltd

Authorized Signatory

Country on May 28, 2020.

CMC MEDICAL DEVICES & DRUGS S.L.
(EC REP AUTHORIZED REPRESENTATIVE)

Authorized Signatory

Spain on May 29, 2020.

Page 5 of 5

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**

CE

Issued on: 01/06/2020

Valid until: 31/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Medical surgical face Mask (Non sterile)

CE

www.cmcmedicaldevices.com