





#### CERTIFICATE OF CONFORMITY

EU - Medical devices Regulation (MDR) No. CIC200309003-ZJ-ZS

Applicant : BeijingYimed TechnologyCo. ,Ltd.

Address : Room 504,5<sup>th</sup> floor,Nailunbuilding,No.1,LiuliBridge,Fengtai District,Beijing

Manufacturer : BeijingYimedTechnologyCo. ,Ltd.

Address: Room 504,5<sup>th</sup> floor, Nailunbuilding, No.1, LiuliBridge, Fengtai District, Beijing

Product : Surgical Mask

Trade Name : N/A

Model(s) : YMD-188

Test Report No. : CIC200309003-ZJ

Test Standards : EN 14683:2019

The tests that base on the above designated product Complies with the essential requirements of Regulation 2017/745/EU.

The test results apply only to the particular sample tested and to the specific tests carried out.

Specifically to the sample investigated in our test reference number only.

The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed..

 $\epsilon$ 

Hale Zhao (Chief engineer) March 11, 2020

Shenzhen CIC Testing Technology Co., Ltd

Add: No.102, Floor 1, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China.

Web: http://www.soncap-saso.com Tel: 0755-23593247 E-mail: admin@cic-test.com



# **TEST REPORT**

# MEASUREMENT AND TEST REPORT For

BeijingYimed TechnologyCo. ,Ltd.

Room 504,5th floor,Nailunbuilding,No.1,LiuliBridge,FengtaiDistrict,Beijing

Models: YMD-188

March 11, 2020

erns:	Equipment Type:		
	Surgical Mask		
Dana Hum	<u> </u>		
CIC200309003-ZJ			
March 09-10, 2020			
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and and and	esting Technology Co., Ltd.  Ilding A, No. 26 of Xinhe Road, Xinqiao Community,		
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	March 09-10, 2020  Shenz. 10 MC  No.102, Floor 1, Bui Xinqiao Street, Baox Tel: 0755-23593247		

**Note:** This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen CIC Testing Technology Co., Ltd.

### TEST REPORT EN 14683

#### Medical face masks - Requirements and test methods

Report reference No. ..... : CIC200309003-ZJ

Tested by (+signature).....: Dana Huang .....see cover page.....

Approved by (+ signature)... : Hale Zhao .....see cover page.....see

Date of issue .....: March 11, 2020

**Testing laboratory** 

Name.....: Shenzhen CIC Testing Technology Co., Ltd

Address.....: No.102, Floor 1, Building A, No. 26 of Xinhe Road, Xinqiao Community,

Xinqiao Street, Baoan District, Shenzhen, Guangdong, China.

Test location .....: (Same as above)

Client

Name.....: BeijingYimed TechnologyCo.,Ltd.

Test specification

Standard.....: EN 14683:2019

Test procedure..... : CE- MDR

Procedure deviation......: N.A.
Non-standard test method.: N.A.

Test Report Form No...... EN\_14683

**Test item** 

Description .....: Surgical Mask

Model No. ..... : YMD-188

Trade Mark.....: N/A

Manufacturer.....: BeijingYimed TechnologyCo.,Ltd.

Address...... Room 504,5th floor,Nailunbuilding,No.1,LiuliBridge,FengtaiDistrict,Beijing

Classification..... : Type II

#### Test case verdicts

Test case does not apply to the test object .....: N(.A.)

Test item does meet the requirement .....: P(ass)

Test item does not meet the requirement.....: F(ail)

Testing

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item tested.

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

#### Remark:

The EUT complies with the standard EN 14683 requirement.

#### Copy of marking plate:

# Disposable medical mask

Model: N/A
Classification: Type II

EN 14683: 2019





Beijing Hongfang Medical Equipment co.,Ltd.

Made In China

Table 1 — Performance requirements for medical face masks

Table 1	The performance test				Result
Test		Type I a	Type II	Type IIR	Type II
Bacterial filtration efficiency (BFE), (%)		≥95	≥98	≥98	99
Differential pressure (Pa/cm 2)		<40	<40	<60	37.9
Splash resistance pressure (kPa)		Not required	Not required	≥16,0	
Microbial clea (cfu/g)	nliness	≤30	≤30	≤30	28.54

Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

# Appendix Photo documentation



\*\*\*\*\*\* End of this report \*\*\*\*\*\*\*