

Certificate of CE-Registration

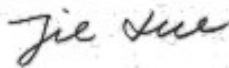
This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, _____ agrees to perform all duties and responsibilities as the Authorized Representative for :

as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's in medical devices and has allocated registration number _____

The Manufacturer has provided Prolinx GmbH with the appropriate Declaration of Conformity confirming that the Disposable Medical Masks with the REF Number _____ and _____ fulfill the applicable requirement of Directive 93/42/EEC and the Standard EN 14683:2019+AC:2019 according to Test Report No. _____ by _____

In compliance with German law, a safety officer has been appointed.

2020-06-22



Jie Xue
Managing Director
Prolinx GmbH



检测报告

(Test Report)

No. _____

样品名称 (Sample Description) 一次性使用医用口罩（非灭菌型）
Disposable Medical Mask (Non-sterile)
委托单位 (Applicant) 温州华盟医药科技有限公司
Co.,LTD.

PONY 谱尼测试
Pony Testing International Group
www.ponytest.com



声明
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This report is invalid without special seal of inspection, cross-page seal and the approver's signatures.
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		厦门实验室: (0592)5568048
		成都实验室: (028) 87702708

检测结果 (Test Results)

No.

第 1 页, 共 2 页 (page 1 of 2)

样品名称 (Sample Description)	一次性使用医用口罩(非灭菌型) Disposable Medical Mask (Non-sterile)	样品规格 (Sample Specification)	规格 Specification: 17.5*9.5cm 型号 Model: 耳挂式 Ear-hanging
委托单位 (Applicant)	温州华盟医药科技有限公司 Wenzhou HuaMeng Medical Technology Co.,LTD.	商标 (Trade Mark)	海威盾 Haveden
到样日期 (Received Date)	2020-06-08	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date: 2020/05/25 生产批号 Manufacturing Lot No.:
检测日期 (Test Date)	2020-06-08~2020-06-19	样品等级 (Sample Grade)	—
样品数量 (Sample Quantity)	80 只 80pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	正常 Normal	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	恒温培养箱 Heating Constant Temperature Incubator、 细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc.		
检测结论 (Test Conclusion)	该样品经检测, 所检项目符合 EN 14683: 2019 IIR 型的要求。 The sample has been tested and the tested items meet the requirements of EN 14683: 2019 Type IIR.		
备注 (Note)	限值标准 Limit Standard: EN 14683: 2019 生产单位 Production: 温州华盟医药科技有限公司 Wenzhou HuaMeng Medical Technology Co.,LTD. 受检单位 Inspection: 温州华盟医药科技有限公司 Wenzhou HuaMeng Medical Technology Co.,LTD. 以上样品信息由委托单位提供 The information of above sample was provided by the applicant.		
	编制人 (Edited by)	黄斌	
	审核人 (Checked by)	郭惠	
	批准人 (Approved by)	戴晴	
	签发日期 (Issued Date)	2020-06-19	

NA
11
PC
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检测结果 (Test Results)

No.

第 2 页, 共 2 页 (page 2 of 2)

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	限值 (Limit)	检测结果 (Test Results)		单项结论 (Evaluation)	检测方法 (Test Methods)
		IIR 型 Type IIR				
一次性使用医用口罩 (非灭菌型) Disposable Medical Mask (Non-sterile)	细菌过滤效率 (BFE), % Bacterial filtration efficiency(BFE)	≥98	No.1	99.9	符合 Conform	EN 14683: 2019
			No.2	99.6		
			No.3	99.8		
			No.4	99.8		
			No.5	99.7		
	压力差, Pa/cm ² Differential pressure	<60	40.6		符合 Conform	EN 14683: 2019
	抗溅压力, kPa Splash resistance pressure	≥16.0	>16.0		符合 Conform	EN 14683: 2019
微生物清洁度, cfu/g Microbial cleanliness	≤30	<1		符合 Conform	EN 14683: 2019	

样品编号和照片 (Sample Number and Photo):



仅对报告照片中的样品负责

Pony authenticate the photo on original report only

——以下空白——

(End of Report)

EN 14683:2019+AC:2019

Clause	Requirement + Test	Result - Remark	Verdict					
5.2.2	TABLE: Bacterial filtration efficiency (BFE)							
Batch/ lot no.:	Test Speci- men no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm ²)	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
	1	15cm×13cm	Φ13cm	28.3	2192	0	99.9	/
	2	15cm×13cm	Φ13cm	28.3	2192	0	99.6	/
	3	15cm×13cm	Φ13cm	28.3	2192	0	99.8	/
	4	15cm×13cm	Φ13cm	28.3	2192	0	99.8	/
	5	15cm×13cm	Φ13cm	28.3	2192	0	99.7	/
Supplementary information:								
1, Each specimen was conditioned at <u>21.1</u> °C and <u>85.0</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing.								
2, The side of the test specimen was facing towards the challenge aerosol: <u>face</u>								

5.2.3	TABLE: Breathability (Differential pressure)				
Batch/ lot no.:	Test Specimen number- Test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks
	1-1	34.9	34.2	8	/
	1-2	34.1		8	/
	1-3	34.6		8	/
	1-4	33.1		8	/
	1-5	34.5		8	/
	2-1	36.1	36.1	8	/
	2-2	35.4		8	/
	2-3	36.3		8	/
	2-4	37.6		8	/
	2-5	35.1		8	/
	3-1	31.3	30.9	8	/
	3-2	31.3		8	/



EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	3-3	30.3	8	/
	3-4	30.5		
	3-5	30.9		
	4-1	39.7	40.6	/
	4-2	40.9		
	4-3	41.4		
	4-4	40.6		
	4-5	40.5		
	5-1	34.2	34.7	/
	5-2	35.9		
	5-3	35.7		
	5-4	33.5		
	5-5	34.0		

Supplementary information:

Each specimen was conditioned at 21.1 °C and 85.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.



5.2.4		TABLE: Splash resistance		
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
	1	/	Pass	/
	2	/	Pass	/
	3	/	Pass	/
	4	/	Pass	/
	5	/	Pass	/
	6	/	Pass	/
	7	/	Pass	/
	8	/	Pass	/
	9	/	Pass	/
	10	/	Pass	/
	11	/	Pass	/
	12	/	Pass	/

EN 14683:2019+AC:2019				
Clause	Requirement + Test	Result - Remark		Verdict
5.2.5	TABLE: Microbial cleanliness (Bioburden)			
Batch/ lot no.:	Mask(under test) no.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks
	1	3.68	<1	/
	2	3.66	<1	/
	3	3.67	<1	/
	4	3.66	<1	/
	5	3.65	<1	/
Supplementary information: /				

Sample Number and Photo:



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 —End of Report—





TEST REPORT

(Electronic version)



VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: _____



No: _____

ISSUE DATE: 2020-05-08

APPLICANT:
ADDRESS:

INFORMATION CONFIRMED BY APPLICANT:

SINGLE-USE MEDICAL FACE MASK

QUANTITY: THIRTY PIECES

BRAND: Haveden

DATE RECEIVED/DATE TEST STARTED: 2020-04-30

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M
COLIFORM GROUP	M
TOTAL AMOUNT OF BACTERIAL COLONY	M
TOTAL AMOUNT OF FUNGUS COLONY	M
PSEUDOMONAS AERUGINOSA	M
STAPHYLOCOCCUS AUREUS	M
HEMOLYTIC STREPTOCOCCUS	M
AIRFLOW RESISTANCE	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"----" -NO COMMENT

REMARK:

THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

THE EXPERIMENT WAS CARRIED OUT AT No. 1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

APPROVED BY:

Nan Ma ENGINEER

马楠



总部: 广州市番禺区珠江路1号

花都实验室: 广州市花都区狮岭镇旗岭河滨西路1号

电话:

电话:

TEST REPORT

(Electronic version)

No:



TEST REPORT

(Electronic version)

No:

BACTERIAL FILTRATION EFFICIENCY (%)

 (YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 40cm², FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0 μm, RESULT OF THE POSITIVE CONTROL: 1.9×10³ CFU, RESULT OF THE NEGATIVE CONTROL: <1CFU)

		REQUIREMENT
BFE ₁	99.4	≥95
BFE ₂	99.2	(YY/T 0969-2013)
BFE ₃	98.9	

COLIFORM GROUP

(GB 15979-2002 ANNEX B)

	NOT DETECTED	REQUIREMENT
		MUST NOT BE DETECTED
		(YY/T 0969-2013)

TOTAL AMOUNT OF BACTERIAL COLONY (CFU/g)

(GB 15979-2002 ANNEX B)

	<20	REQUIREMENT
		≤100
		(YY/T 0969-2013)

TOTAL AMOUNT OF FUNGUS COLONY (CFU/g)

(GB 15979-2002 ANNEX B)

	NOT DETECTED	REQUIREMENT
		MUST NOT BE DETECTED
		(YY/T 0969-2013)

PSEUDOMONAS AERUGINOSA

(GB 15979-2002 ANNEX B)

	NOT DETECTED	REQUIREMENT
		MUST NOT BE DETECTED
		(YY/T 0969-2013)

STAPHYLOCOCCUS AUREUS

(GB 15979-2002 ANNEX B)

	NOT DETECTED	REQUIREMENT
		MUST NOT BE DETECTED
		(YY/T 0969-2013)

HEMOLYTIC STREPTOCOCCUS

(GB 15979-2002 ANNEX B)

	NOT DETECTED	REQUIREMENT
		MUST NOT BE DETECTED
		(YY/T 0969-2013)

AIRFLOW RESISTANCE (Pa/cm²)

(YY/T 0969-2013 5.6)

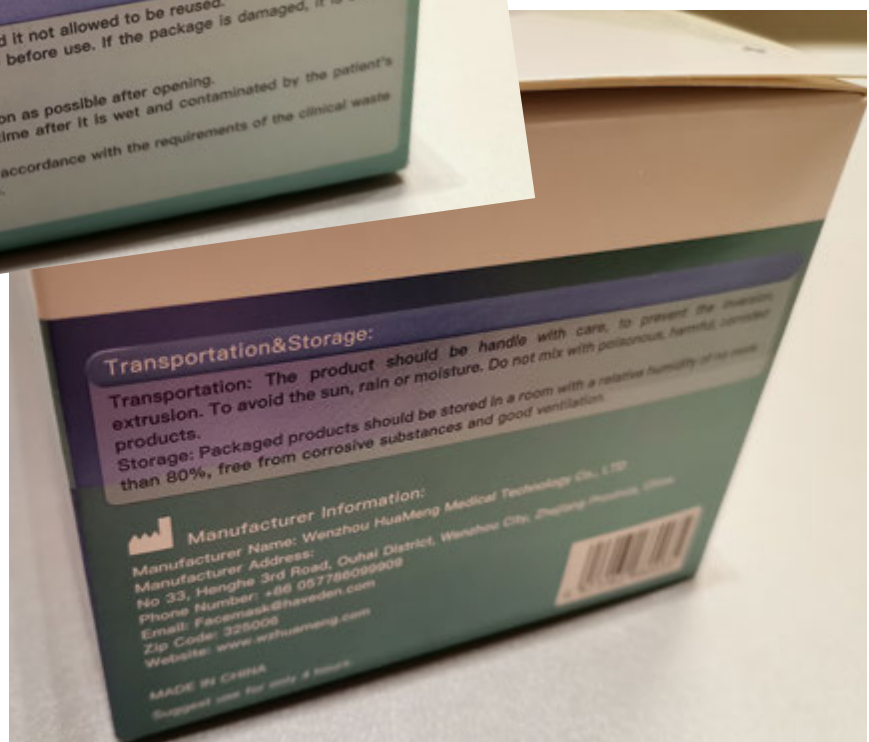
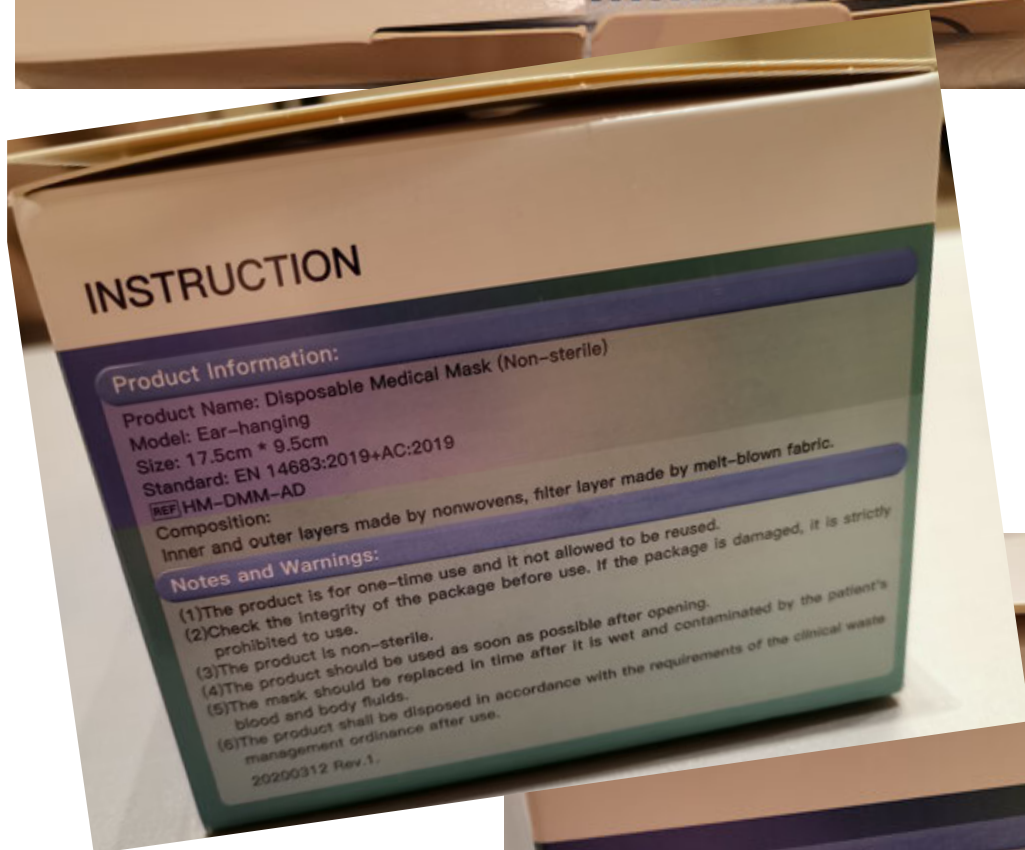
		REQUIREMENT
1#	34.3	≤49
2#	33.5	(YY/T 0969-2013)
3#	36.3	



———End of Report———

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PARCKAGING

Dimension (cm)	Poids net(kg)	Poids brut (kg)	Quantité/Carton
52 X 42 X 34	7,5	8,5	2000

50pcs/Boîte
40boites/Carton

