

FISA TEHNICA PRODUS



Denumire Produs: Masca medicala 3 pliuri tip IIR verde/
negru/roz/albastru/mov/portocaliu/galben 50 buc

Producator: Hubei Ingenuity

EC REP: MedPath GmbH

1. DECLARATIE DE CONFORMITATE

EU DECLARATION OF CONFORMITY	
According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices	
Manufacturer:	Hubei Ingenuity Medical Products Co., Ltd. No. 1 West of Industrial Park Road, Yanglinwei Town, 433000 Xiantao City, Hubei Province, China
Trademark:	
SRN:	Not available yet
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN:	Not available yet
Trade name:	Medical face mask
Product Name:	Medical face mask
Product code / Catalogue number:	INM-3PM
Basic UDI:	Not available yet
Classification acc. to MDR Ax. VIII:	Class I, rule I
Applied Standard & Common Specification:	EN 14683:2019 +AC:2019
Conformity assessment procedure:	Annex II + Annex III of MDR
CE certificate No.:	N.A.
Name and ID of the Notified Body:	N.A.
We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.	
Signature:	Xiantao, 21. 09. 2020
Yu Fu	
General Manager	

2. CONFIRMAREA NOTIFICARII UE



MedPath GmbH, Mies-van-der-Rohe-Straße 8, 80807 Munich, Germany

To whom it may concern

MedPath GmbH

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80807 Munich, Germany

Telefon: +49(0)89 189174474
Telefax: +49(0)89 5485 8884
E-Mail: info@medpath.pro

Munich, 23.04.2021

Confirmation of EU Medical Device(s) Notification

This is to confirm that in accordance of Article 29 of the Regulation (EU) 2017/745 on Medical Devices (MDR), MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the manufacturer

Hubei Ingenuity Medical Products Co., Ltd.

No. 1 West of Industrial Park Road, Yanglinwei Town, 433000 Xiantao City,
Hubei Province, China

as stipulated and demanded by the aforementioned Regulation. The German Competent Authority is notified of the manufacturer's medical device(s)

- Medical face mask
- Surgical gown
- Shoe covers
- Sleeve covers
- Caps
- Scrub suit
- Bed sheet
- Colonoscopy pants

1/2

MedPath GmbH
Mies-van-der-Rohe-Straße 8
80807 Munich, Germany

St.Nr.: 143/161/40603
Ust-IdNr.: DE313841775
HRB 235061

BANK: Postbank
IBAN: DE06 7001 0095 0134 4418 55
BIC: PBNKDEFF



The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity claiming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Regulation.


Safety Officer **MedPath GmbH**
Mies-van-der-Rohe-Straße 8-D-80807 München
Tel 089-189174474 - Fax 089-54858884
MedPath GmbH

2/2

MedPath GmbH
Mies-van-der-Rohe-Straße 8
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IBAN: DE06 7001 0095 0134 4418 55
BIC: PBNKDEFF

4. RAPORT DE TESTARE

PONY 谱尼测试
Pony Testing International Group

Test Report

No.: GOL35EHP062025L1

Issued Date: 2020-10-16

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Summary of Test Results

No.	Test Item	Test Standard	Performance Requirement Type IIR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	BS EN 14683:2019 Appendix B	≥ 98	Pass
2	Differential pressure Test (Pa/cm ²)	BS EN 14683:2019 Appendix C	< 60	Pass
3	Splash resistance pressure Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial cleanliness Test (CFU/g)	BS EN 14683:2019 Appendix D	≤ 30	Pass

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements.

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Hotline 400-819-5688

www.ponytest.com

PONY-BG186-2-013-16-2028A

Pony Testing International Group Co., Ltd.

Address: 101, 5F Building 1, No.66 Jindai Road, Haidian District, Beijing, China Tel: 010-83055000 Fax: 010-82619629

Testing address: Building 1, No.66 Jindai Road, Haidian District, Beijing, China

Test Report
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5.2.2 TABLE: Bacterial filtration efficiency (BFE)								
Sample No.:	Test Specimen No.:	Dimension of the test specimen L x W (mm x mm)	test area	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
P062025L1	1	175×95	Φ11cm	28.3	2107	0	99.76	/
	2	175×95	Φ11cm	28.3	2107	0	99.86	/
	3	175×95	Φ11cm	28.3	2107	0	99.72	/
	4	175×95	Φ11cm	28.3	2107	0	99.95	/
	5	175×95	Φ11cm	28.3	2107	0	99.91	/
Supplementary information:								
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 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>								

Test procedure

- 1.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
- 1.2 Adjust the flow rate through the sampler to 28.3 L/min.
- 1.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
- 1.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles

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being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.

1.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer.

Immediately begin sampling the aerosol using the sampler.

1.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.

1.4.3 Time the air pressure and sampler to run for 2 min.

1.4.4 At the conclusion of the positive control run, remove plates from the sampler.

1.5 Place new agar plates into sampler and clamp the test specimen into the top of the sampler, with the inside of the specimen facing towards the bacterial challenge (test area: $\phi 11$ cm).

1.6 Repeat the challenge procedure for each test specimen.

1.7 Repeat a positive control after completion of the sample set.

1.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.

1.9 Incubate agar plates at $(37 \pm 2)^\circ\text{C}$ for (48 ± 4) h.

1.10 Count each of the six-stage plates of the sampler.

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5.2.3	TABLE: Breathability (Differential pressure)				
Sample 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
P062025L1	1-1	27.3	24.1	8	/
	1-2	22.1		8	/
	1-3	22.7		8	/
	1-4	23.9		8	/
	1-5	24.7		8	/
	2-1	30.3	26.2	8	/
	2-2	25.0		8	/
	2-3	29.5		8	/
	2-4	19.4		8	/
	2-5	26.9		8	/
	3-1	23.3	22.2	8	/
	3-2	22.1		8	/
	3-3	20.7		8	/
	3-4	22.9		8	/
	3-5	22.1		8	/

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Test Results

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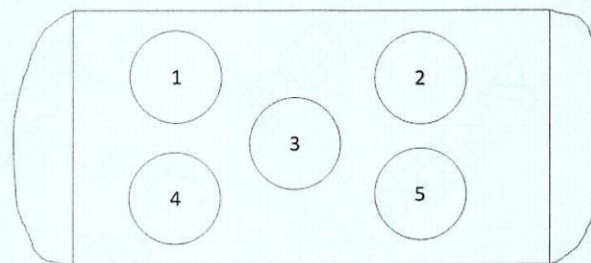
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5.2.3	TABLE: Breathability (Differential pressure)				
Sample No.:	Test Specimen number-Test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks
P062025L1	4-1	28.9	26.1	8	/
	4-2	26.8		8	/
	4-3	27.0		8	/
	4-4	24.2		8	/
	4-5	23.8		8	/
	5-1	30.2	25.0	8	/
	5-2	26.5		8	/
	5-3	23.2		8	/
	5-4	21.5		8	/
	5-5	23.6		8	/

Supplementary information:

Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

Sketch map of test location:



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Test procedure

1.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump

is started and the flow of air adjusted to 8 L/min.

1.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and

clamped into place so as to minimize air leaks.

1.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in

line and across the flow of air.

1.4 The differential pressure is read directly.

1.5 The procedure described in steps 1.1-1.4 is carried out on 5 different areas of the mask and calculate

averaged.

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5.2.4	TABLE: Splash resistance pressure			
Sample No.:	Test mask No.:	The material of tested mask	Test result (Pass/fail)	Remarks
P062025L1	1	/	Pass	/
	2	/	Pass	/
	3	/	Pass	/
	4	/	Pass	/
	5	/	Pass	/
	6	/	Pass	/
	7	/	Pass	/
	8	/	Pass	/
	9	/	Pass	/
	10	/	Pass	/
	11	/	Pass	/
	12	/	Pass	/
	13	/	Pass	/
	14	/	Pass	/
	15	/	Pass	/
	16	/	Pass	/

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5.2.4	TABLE: Splash resistance pressure			
Sample No.:	Test mask No.:	The material of tested mask	Test result (Pass/fail)	Remarks
P062025L1	17	/	Pass	/
	18	/	Pass	/
	19	/	Pass	/
	20	/	Pass	/
	21	/	Pass	/
	22	/	Pass	/
	23	/	Pass	/
	24	/	Pass	/
	25	/	Pass	/
	26	/	Pass	/
	27	/	Pass	/
	28	/	Pass	/
	29	/	Pass	/
	30	/	Pass	/
	31	/	Pass	/
	32	/	Pass	/

Supplementary information:

- Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
- The description of target area tested: The center of outside
- Any technique used to enhance visual detection of synthetic blood: cotton swab
- The temperature and relative humidity for testing: 21 °C and 85 %
- Description of any pre-treatment techniques used: constant temperature and humidity machine was used

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Test procedure

- 1.1 Prepare the synthetic blood (40~44 mN/m) for the test.
- 1.2 Determine the density of the synthetic blood.
- 1.3 Fill the reservoir with new synthetic blood.
- 1.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
- 1.5 Set the reservoir pressure to the approximate pressure.
- 1.6 Place the targeting plate approximately 1 cm away from the mask.
- 1.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 1.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 1.9 Calculate the difference in weight of the two spurts.
- 1.10 Adjust the reservoir pressure and repeat steps 1.7 to 1.9 until the weight difference is within the target range.
- 1.11 Record the weight difference for the spurts exiting the nozzle.
- 1.12 Record the pressure in the reservoir.
- 1.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 1.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 1.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2%~-5% of the difference in weight from the nozzle.

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1.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

1.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 1.7 to 1.11).

1.18 Adjust the timer setting until 2 ml of fluid passes through the hole for three spurts in a row. For a test fluid with a density of 1,005 g/cm³, the output should weigh 2,01 g.

1.19 Record the timer setting to use as the starting point for subsequent testing.

1.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

1.21 Squirrt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

1.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

1.23 Report the results (none/penetration) for each test specimen at the test pressure.

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Test Results

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5.2.5	TABLE: Microbial cleanliness (Bioburden)			
Sample No.:	Mask(under test) No.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks
P062025L1	1	3.4	<1	/
	2	3.4	<1	/
	3	3.3	<1	/
	4	3.4	<1	/
	5	3.3	<1	/
Supplementary information: /				

Test procedure

1.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.

1.2 The mask is weighed and aseptically removed from the packaging and placed in a aseptic container containing 300 mL of extraction liquid, then mix well.

1.3 After extracting, 100 mL of the extraction liquid is filtered through a 0.45 µm filter, wash with 100mL sterile 0.1% peptone water (containing 2g/L Tween 20) each time. Then transfer the filter aseptically to the TSA plate to count the active aerobic microorganisms. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungus count.

1.4 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.

1.5 Calculate the colonies of each agar plate.

Test Report

No.: GPL70D3Z511455L1

Issued Date: 2021-02-22

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Photo:



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—End of Report—

检测结果
(Test Results)

No. GPL739PZ641085L1

第3页, 共3页 (page 3 of 3)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
3	抗液压力 Splash resistance pressure	kPa	≥16.0	>16.0	符合 Pass	ISO 22609:2004
4	微生物洁净度 Microbial cleanliness	cfu/g	≤30	4	符合 Pass	BS EN 14683:2019 附录 D Appendix D
				5		
				6		
				6		
				7		

备注 Note: A-试样编号-测试区域编号 Test Specimen number-Test area number; B-每个测试区域的压力差 Differential pressure for each test area; C-每个试样的平均压差 The averaged differential pressure for each test specimen.

照片 Photo:



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(End of Report)

☎ Hotline 400-819-5688

www.ponytest.com

PONY-BG186-01A-1-B-1-01-2019A

谱尼测试集团股份有限公司 Pony Testing International Group Co., Ltd.

公司地址: 北京市海淀区锦都路66号院1号楼5层101

Address: 101, 5F Building 1, No.66 Jindu Road, Haidian District, Beijing, China

检测地址: 北京市海淀区锦都路66号院1号楼

Testing address: Building 1, No.66 Jindu Road, Haidian District, Beijing, China

电话: 010-83055000 传真: 010-82619629

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Test Report

No.: GOL35EHP062025L1

Issued Date: 2020-10-16

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Photo:



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—End of Report—

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3. Aviz ANMDMR



MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
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Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 09.06.2021
LA AVIZUL DE FUNCȚIONARE
Nr. 7111/19.08.2020 al MEDPLAZA HEALTH SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 7111/19.08.2020 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

Nume producator	Tara
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ALCAN LIFE MEDICAL LTD	INDIA
ALCAN MEDICAL, WINDHOLM, INC.	INDIA
AND SPEND INK STRIAL CO. LTD	INDIA
BEALING PERFORMING NEW TECHNOLOGY CO. LTD	INDIA
BEALING BEAL BAKING/COOKING CO. LTD	INDIA
BEALING L.P. MEDICAL TECHNOLOGY CO. LTD	INDIA
BIANCAUTON, BIL. ANANDA MEDICAL DEVICES CO. LTD	INDIA
CAL DENTAL IND CO. LTD	INDIA
CH. TENG / WINDHOLM (INDIA) CO. LTD	GERMANIA
COMFORT BEALING CO. LTD (INDIA) CO. LTD	INDIA
TRANSBERRY NON BHD	INDIA
EXTRABEAL NON BHD	INDIA
EXTRABEAL DENTAL (INDIA) CO. LTD	GERMANIA
FLORINDIA SPA	ITALIA
FLORINDIA (INDIA) CO. LTD	GERMANIA
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ALCAN MEDICAL LTD CO. LTD	INDIA
HANGUTON, REALITY TECH CO. LTD	INDIA
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HEALAN THAILAND MEDICAL INSTRUMENTS CO. LTD	INDIA

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LIANGHUI FANGYI MESHES FACTORY	CHINA
MASTET GLOVE MANUFACTURING BORN BORN	ISRAEL/21
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MEIPO INTERNATIONAL INC.	U.S.A.
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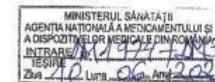
PREȘEDINTE
Agencia Națională a Medicamentului și a
Dispozitivelor Medicale din România
Roxana Ștefania STROE



Pagina 3 de la Anexa din 09.06.2021 de la Avizul de funcționare nr. 7111/19.08.2020



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Către,

MEDPLAZA HEALTH SRL

Tel : 0737.552756

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererilor cu numerele: DM
1974/22.03.2021 și DM 3475/21.05.2021.

Cu stimă,

PREȘEDINTE

Agencia Națională a Medicamentului și a
Dispozitivelor Medicale din România

Roxana Ștefania STROE



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