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:	InMed Healthcare&PPE
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:	Disposable medical face mask
Product code / Catalogue number:	INM-3PM/4PM 17.5x9.5cm,14.5x9.5cm
Basic UDI:	697442339
Classification acc. to MDR Ax. VIII:	Class I, rule I
Applied Standard & Common Specification:	EN 14683:2019
Conformity assessment procedure:	Annex II + Annex III of MDR
Registration number:	DE/CA61/00167698

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:

Yu Fu

General Manager

Xiantao, 21. 09. 2020

MedPath

Appendix A: Product Category(ies)

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

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

CE

MedPath

EU- Compliance Review Certificate

Regulation (EU) 2017/745 on Medical Devices (MDR), Article 19

Class I non-sterile and without measuring function

No. A0476K001

Manufacturer: Hubei Ingenuity Medical Products Co., Ltd
No. 1, West of Industrial Park Road,
Yanglinwei Town,Xiantao City,
Hubei Province,China

CE

Product Category(ies): See Appendix A

This is to certify that, MedPath GmbH has verified the aforementioned manufacturer declares to conform with all applicable requirements set in the Medical Device Regulation (EU) 2017/745 for the product category(ies) listed in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Regulation.
When the manufacturer affixes CE mark to the product category(ies) listed above, it remains the manufacturer's responsibility to ensure continuous compliance with all applicable requirements of the aforementioned Regulation.

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

Issued Date: 2020-09-12 MedPath GmbH

Expiration Date: 2025-09-12

中国认可
国际互认
检测
TESTING
CNAS L0612

Test Report

No.: GOL35EHP062025L1 Issued Date: 2020-10-16

Applicant: HUBEI INGENUITY MEDICAL PRODUCTS CO.,LTD

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Name: Disposable Medical Face Mask

Sample Specification: 175mm×95mm

Manufacturing Date or Lot No.: 2020-09-28/202010

Model: INM-3PM

Manufacturer/Tested company: HUBEI INGENUITY MEDICAL PRODUCTS CO.,LTD

Trade Mark: INMED

Sample Received Date: 2020-09-30

Testing Period: 2020-09-30~2020-10-16

Test Requested: BS EN 14683:2019

Testing Results: Please refer to next page(s)

Edited by:

Checked by:

Approved by:

PONY TESTING INTERNATIONAL GROUP CO., LTD. 谱尼测试集团股份有限公司 PONY 检验检测专用章

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

Summary of Test Rusults

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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5.2.2		TABLE: Bacterial filtration efficiency (BFE)						
Sample No.:	Test Speci-men No.:	Dimensio-n 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: face

Test procedure

1.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately $5x10^5$ 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 specime 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 ran, 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: ø11cm).

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±2)℃ for (48±4) h.

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

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Test Results

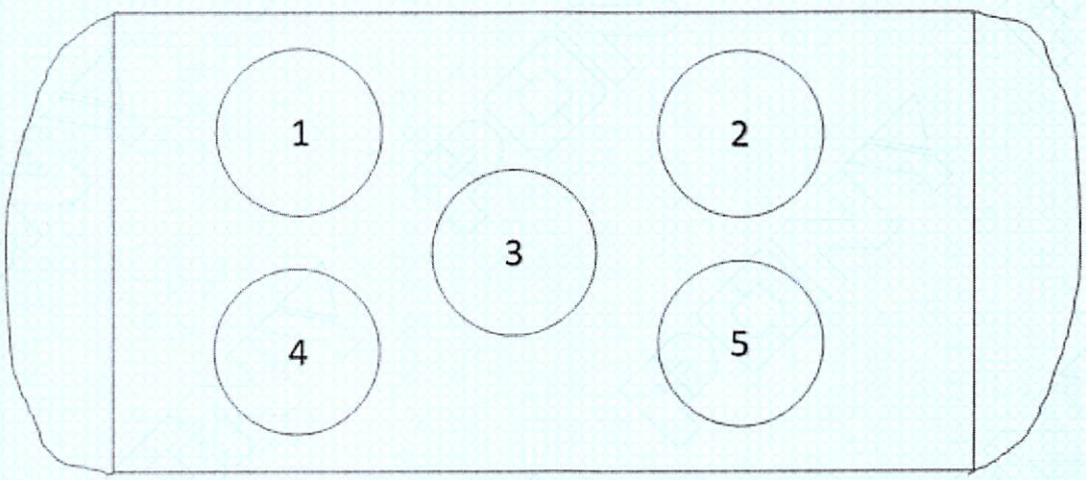
5.2.3	TABLE: Breathability (Differential pressure)				
Sample No.:	Test Specimen number-Test area number	Differential pressure for each test area (Pa/cm^2)	The averaged differential pressure for each test specimen (Pa/cm^2)	Flow rate (l/min)	Remarks
P062025L1	1-1	27.3	24.1	8	/
	1-2	22.1		8	/
	1-3	22.7		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	/

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 4.9cm^2, 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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Test Report No.：GOL35EHP062025L1 Issued Date：2020-10-16 Page 8 of 13
Test Results

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	/

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:

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 description of target area tested: The center of outside

3, Any technique used to enhance visual detection of synthetic blood: cotton swab

4, The temperature and relative humidity for testing: 21 °C and 85 %

5, 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 salve 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.

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/cm^3, 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 Squirt 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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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℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively.

1.5 Calculate the colonies of each agar plate.

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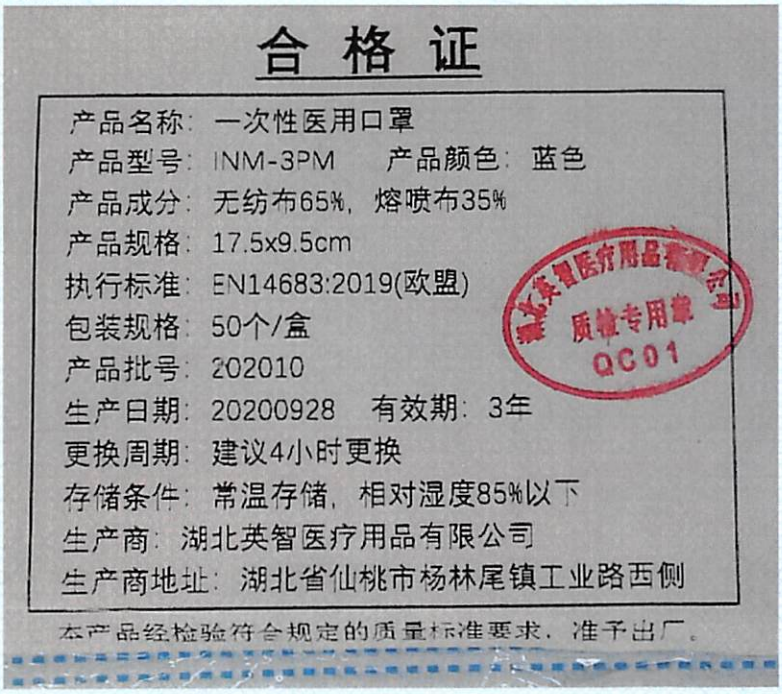
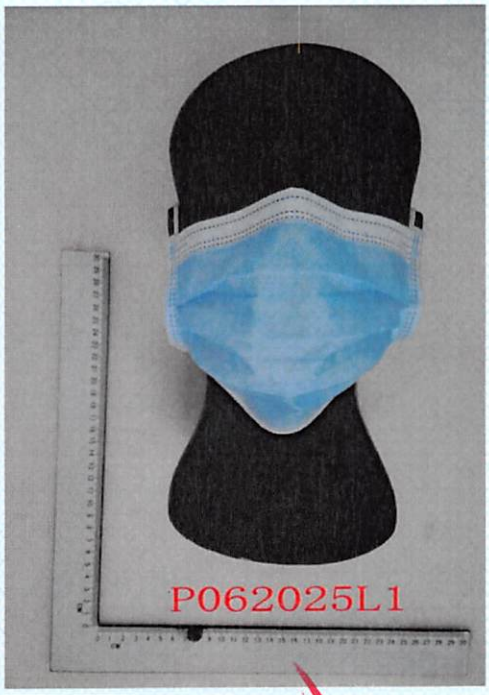
Photo:





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———End of Report———

PONY 谱尼测试
Pony Testing International Group

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