# TEST REPORT

**2020EC0614**

**DATE OF RECEPTION**
04/05/2020

**DATE TESTS**
Starting: 04/05/2020
Ending: 22/05/2020

**APPLICANT**

YANGZHOU MEDLINE INDUSTRY CO, LTD
No.108 JINSHAN ROAD, ECONOMIC DEVELOPMENT ZONEYANGZHOU
CN-225009 JIANGSU

Att. *

## IDENTIFICATION AND DESCRIPTION OF SAMPLES

| REFERENCES |
|---|
| Respiratory protective mask, Model: I N9501 |
| Description:<br><br>Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour |

## TESTS CARRIED OUT

- VISUAL INSPECTION.
- PRACTICAL BEHAVIOR.
- FILTER PENETRATION WITH PARAFFIN OIL.
- FILTER PENETRATION WITH SODIUM CHLORIDE.
- CO2 CONTENT IN INHALED AIR.
- BREATHING RESISTANCE.

Tests marked with * are not included within the scope of the ENAC accreditation

**Rev.1** This revision cancels and replaces the previous
Reference error







AITEX - Plaza Emilio Sala, 1
E-03801 ALCOY (Alicante) SPAIN
Tel.:+34 96 554 22 00
www.aitex.es
info@aitex.es

# DESCRIPTION OF SAMPLES

## PHOTOGRAPHY

**Reference**

Respiratory protective mask, Model: I N9501




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# RESULTS

## VISUAL INSPECTION

**Standard**

EN 149:2001+A1:2009 modified by RfU PPE-R/02.075.

**Reference**

Respiratory protective mask, Model: I N9501

Requirements of visual inspection to evaluate the filtering half mask against particles according to standard EN 149:2001 + A1:2009.

| **Packing (Requirement according to the point 7.4)** | |
|---|---|
| Filtering half mask shall be packaged to protect them from mechanical damage, thermal and contaminant conditions during storage. | **NOT EVALUATED** |

| **Materials (Requirement according to the point 7.5)** | |
|---|---|
| The materials used shall withstand handling and use during the period of time for which the half-mask filter has been designed, and it shall not constitute a danger or damage to the user. | **PASS** |
| Any material in the filter that is released by the passage of the air flow through the filter shall not be a danger or damage to the user. | **PASS** |

| **Finished of parts (Requirement according to the point 7.8)** | |
|---|---|
| Parts of the equipment that can come into contact with the user shall not have sharp edges or burrs. | **PASS** |

| **Exhalation valve (Requirement according to the point 7.15)** | |
|---|---|
| If an exhalation valve is available, it shall be protected against dirt and mechanical damage and shall include any other device necessary to meet the requirements for leakage into the interior. | **N.A.** |

| **Removable parts (Requirement according to the point 7.18)** | |
|---|---|
| All removable parts (if any) shall be easily connected and secured and, wherever possible, manually. | **N.A.** |

N.A. Does not apply

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# RESULTS

## PRACTICAL BEHAVIOR

**Standard**

EN 149:2001+A1:2009 (point 8.4) modified by RfU PPE-R/02.075.

**Testing conditioning**

| Test date | Initial | Final |
|---|---|---|
| 05/04/2020 | 24,7 ºC and 49,0 % RH. | 24,7 ºC and 48,8 % RH. |

**Observation or deviation of the standard**

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**Description of the simple**

Particle filtering half mask without exhalation valve covering mouth and chin, white colour

**Test uncertainty**

The expanded uncertainty is ± 18% of the value of the measured for a probability of coverage of 95%.



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# RESULTS

**Reference**

Respiratory protective mask, Model: I N9501

| TESTER<br>1 | Sample No.<br>1 |
|---|---|
| **Does the respiratory protective device fit well?** | |
| YES | |

**Walk test**

| **Walk for 10 min at a speed of 6 km / h.** | **Acceptance by tester** |
|---|---|
| **The finishing of filtering half mask that are in contact with the user must be free of sharp edges and burrs. Materials likely to be in contact with the user's skin shall not present a known risk of irritation or other adverse health effects.** | |
| The user has not suffered any damage by edges. The materials of the mask have not irritated the user. | YES |
| **The head harness shall be designed so that it can be easily put on and removed.** | |
| The tester has been able to put on and take off his half mask without problems. | YES |
| **The head harness shall be adjusted or self-adjusted and hold the full facepiece in its position firmly and comfortably.** | |
| The half mask has been easily adjusted. | YES |
| **The filtering half mask has not hindered the field of vision during its use.** | |
| The user's vision has not been hindered. | YES |
| **The filter half mask has a good facial seal during use** | |
| **The half mask has been maintaining a good faceseal.** | YES |
| **Other comments** | |
| **---** | |



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# RESULTS

**Work simulation test**

| 1. Walking for 5 min.at a free height of (1,3 ± 0,2) m;<br>2. Crawling on all fours for 5 min. at a free height of (0,7 ± 0,05) m.; and<br>3. Filling a 1.5 m hopper, about 20 times. | Acceptance by tester |
|---|---|
| **The finishing of filtering half mask that are in contact with the user must be free of sharp edges and burrs. Materials likely to be in contact with the user's skin shall not present a known risk of irritation or other adverse health effects.** | |
| The user has not suffered any damage by edges. The materials of the mask have not irritated the user. | YES |
| **The head harness shall be designed so that it can be easily put on and removed.** | |
| The tester has been able to put on and take off his half mask without problems. | YES |
| **The head harness shall be adjusted or self-adjusted and hold the full-face piece in its position firmly and comfortably.** | |
| The half mask has been easily adjusted. | YES |
| **The filtering half mask has not hindered the field of vision during its use.** | |
| The user's vision has not been hindered. | YES |
| **The filter half mask has a good facial seal during use** | |
| **The half mask has been maintaining a good faceseal.** | YES |
| **Other comments** | |
| **---** | |



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# RESULTS

**Requirements to be met according to EN 149:2001+A1:2009, point 7.7 and according to RfU PPE-R / 02.075.**

| |
|---|
| The respiratory protective equipment shall not have imperfections related to user acceptance.<br><br>Requirement added RfU PPE-R/02.075: During the practical performance test, the test subject should pay particular attention to the ability of the product to maintain a good faceseal. If the wearer observes that a good faceseal is not maintained, they shall be instructed to readjust the filtering half mask according to the user instructions. Should the test subject experience further difficulties with maintaining a good faceseal during the practical performance test, the filtering half mask shall be considered unsatisfactory. |

The test was carried out at APPE Laboratory located at Polígono Industrial Santiago Payá C/ Filá Benimerines, 25 B – 03801 Alcoy (Alicante).

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# RESULTS

## FILTER PENETRATION WITH PARAFFIN OIL

**Standard**

EN 149:2001+A1:2009 (point 8.11) modified by RfU PPE-R/02.075

**Apparatus**

Paraffin generator equipment.

**Testing conditioning**

| Test date | Initial | Final |
|---|---|---|
| 04/05/2020 | 23,8 ºC and 43,4 % RH. | 23,8 ºC and 45,3 % RH. |

**Sample Conditioning**

- Samples: as received.

**Observation or deviation of the standard**

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**Sample description**

Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour

**Test uncertainty**

The expanded uncertainty is ± 18% of the value of the measurand for a probability of coverage of 95%.

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# RESULTS

**Reference**

Respiratory protective mask, Model: I N9501

| Paraffin oil penetration test (3 min.) | |
|---|---|
| **Sample No.** | **Average value of penetration %** |
| **1** | 0,76 |
| **2** | 0,50 |

| Exposure to 120mg of Paraffin oil | |
|---|---|
| **Sample No.** | **Max. value of penetration %** |
| **1** | 1,64 |

**Requirements to be met according to RfU PPE-R/02.075**

**Maximum penetration to the paraffin oil of the filter material:**

| Classification (*) | Paraffin oil test 95 l/min % Max. |
|---|---|
| **FFP2** | **6** |
| **FFP3** | **1** |

(*) The levels FFP2 or FFP3 are guidance parameters from the standard EN 149: 2001 + A1: 2009, not applicable for RfU PPE-R / 02.075 since the final validity for COVID 19 certification method is according to a PASS / NOT PASS.

The test was carried out at APPE Laboratory located at Polígono Industrial Santiago Payá C/Filá Benimerines, 25 B – 03801 Alcoy (Alicante).

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# RESULTS

## FILTER PENETRATION WITH SODIUM CHLORIDE

**Standard**

EN 149:2001+A1:2009 (point 8.11) modified by RfU PPE-R/02.075.

**Apparatus**

Sodium chloride penetration equipment.

**Test Conditioning**

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**Test date**

20/05/2020

**Sample Conditioning**

- As received.

**Observation or deviation of the standard**

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**Description of the simple**

Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour

**Test uncertainty**

The expanded uncertainty is ± 0,002 % for a probability of coverage of 95%.



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# RESULTS

**Reference**

Respiratory protective mask, Model: I N9501

| Sodium chloride penetration test (3 min) | |
|---|---|
| **Sample No.** | **Average value of penetration %** |
| **1** | 0,328 |
| **2** | 0,423 |

| Exposure to 120mg of sodium chloride | |
|---|---|
| **Sample No.** | **Max. value of penetration %** |
| **1** | 0,304 |

**Requirements to be met according to RfU PPE-R/02.075.**

**Maximum penetration to the sodium chloride of the filter material:**

| Classification (*) | Sodium chloride test 95 l/min % Max. |
|---|---|
| **FFP2** | **6** |
| **FFP3** | **1** |

(*) The levels FFP2 or FFP3 are guidance parameters from the standard EN 149: 2001 + A1: 2009, not applicable for RfU PPE-R / 02.075 since the final validity for COVID 19 certification method is according to a PASS / NOT PASS.

**Remark**

Test covered by accreditation number No. 0159, emitted by ENAC.

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# RESULTS

## CO2 CONTENT IN INHALED AIR

**Standard**

EN 149:2001+A1:2009 (punto / *point* 8.7)

**Apparatus**

Dynamic Breathing equipment, Sheffield test head, Measured CO2 flow and CO2 analyzer.

**Testing conditioning**

| Test date | Initial | Final |
|---|---|---|
| 05/05/2020 | 23,3 ºC and 45,2 % RH. | 24,3 ºC and 45,0 % RH. |

**Observation or deviation of the standard**

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**Description of the simple**

Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour

**Test uncertainty**

The expanded uncertainty is ± 12% of the value of the measured for a probability of coverage of 95%.

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# RESULTS

**Reference**

Respiratory protective mask, Model: I N9501

| Sample No. | Average value of $CO_2$ contained in inhaled air (%) |
|---|---|
| **1** | 0,42 |
| **2** | 0,47 |
| **3** | 0,47 |
| **Average** | 0,45 |

**Requirements to be met according to EN 149:2001+A1:2009, point 7.12.**

Carbon dioxide content in inhalation air (dead space) should not exceed an average of 1.0% (by volume).

The test was carried out at APPE Laboratory located at Polígono Industrial Santiago Payá C/ Filá Benimerines, 25 B – 03801 Alcoy (Alicante).

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# RESULTS

## BREATHING RESISTANCE

**Standard**

EN 149:2001 + A1:2009 (point 8.9) modified by RfU PPE-R/02.075

**Apparatus**

Sheffield test head, constant breathing equipment and digital flowmeter.

**Test conditioning**

| Test date | Initial | Final |
|---|---|---|
| 04/05/2020 | 23,9 ºC and 44,9 % RH. | 23,5 ºC and 44,7 % RH. |

**Sample Conditioning**

- Samples: as received.

**Observation or deviation of the standard**

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**Sample description**

Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour

**Uncertainty**

The expanded uncertainty is ± 10 % of the value of the measurand for a probability of coverage of 95%.

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# RESULTS

**Reference**

Respiratory protective mask, Model: I N9501

| Sample No. | Resistance to inhalation (30l/min) mbar | Resistance to inhalation (95l/min) mbar |
|---|---|---|
| 1 | 0,29 | 1,29 |
| 2 | 0,26 | 1,26 |
| 3 | 0,24 | 1,15 |

| Sample No. | Resistance to exhalation (160 l/min) mbar | | | | |
|---|---|---|---|---|---|
| | Forward | Upwards | Down | Towards the left side | Towards the right side |
| 1 | 2,04 | 2,03 | 2,10 | 1,96 | 1,97 |
| 2 | 2,23 | 2,10 | 2,14 | 2,03 | 2,04 |
| 3 | 2,20 | 2,07 | 2,03 | 2,12 | 2,0 |

**Requirements to be met according to RfU PPE-R/02.075**

| Classification (*) | Maximum resistance permitted (mbar) | | |
|---|---|---|---|
| | Inhalation | | Exhalation |
| | 30 l/min | 95 l/min | 160 l/min |
| FFP2 | 0.7 | 2.4 | 3.0 |
| FFP3 | 1.0 | 3.0 | 3.0 |

(*) The levels FFP2 or FFP3 are guidance parameters from the standard EN 149: 2001 + A1: 2009, not applicable for RfU PPE-R / 02.075 since the final validity for COVID 19 certification method is according to a PASS / NOT PASS.

The test was carried out at APPE Laboratory located at Polígono Industrial Santiago Payá C/Filá Benimerines, 25 B – 03801 Alcoy (Alicante).

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**Israel Soriano**
**Head of Advance Personal Protective Equipment Lab.**

Digitally signed by SANTIAGO GARCIA SANTONJA - NIF:15420772P
Date: 2020.06.08 11:45:34 +02:00
Reason: Autorizado
Location: Alcoy

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