# Test Report

**Customer Information:**

Customer..... : Nanjing Honney Medical Apparatus and Instruments Co.,Ltd.

Address.....: No.68, Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing,China

**Sample Information:**

Sample Name..... : Filtering half mask

Sample Specification.. : ZD03

Sample Classification..: FFP3

Sample Description... . : Samples in good condition

Sampled Method..... : All parts were received from customer

Receipt Date..... : 2020-06-07

**Testing Information:**

Test Items..... : Total inward leakage, Penetration of filter material , etc.

Test Reference..... : EN 149: 2001+A1: 2009

Test Result. ..... : Please refer to the following pages

Test Conclusion..... : The test completed project meets EN149: 2001 + Al: 2009 standard FFP3 grade

Written by: Arzi Gwl Inspected by: Shuteng Wu Approved by: Steven Zhu

Date: 2020-06-18 Date: 2020-06-18 Date: 2020-06-18

**BEFITLAB TEST TECHNOLOGY SHANGHAI CO.,LTD.**

Member of International Standards Certification (ISC)Group

# Test Report



## 1、Sample List

| Manufacturer | Sample Name | Specification | Material | Lot |
|---|---|---|---|---|
| Nanjing Honney Medical Apparatus and Instruments Co.,Ltd. | Filtering half mask | ZD03 | NON-WOVEN(INNER LAYER,OUTER LAYER)/ MELT BLOWN FABRIC/ FILTER SPUNLACE NONWOVEN | 20200607 |

## 2、Sample Photos

# Test Report



**Appendix 1: Visual inspection**

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| **1.1. Visual inspection:** The visual inspection shall include the marking and information supplied by the manufacturer. |
| **1.2. Result**: Not tested |
| **1.3. Note:** As requested by the client, marking and information supplied by the manufacturer was not inspected. |

**Appendix 2: Package**

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|---|
| **2.1. Package:** Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. |
| **2.2. Result:** Pass |
| **2.3. Note:** In accordance with the requirement. |

**Appendix 3: Material**

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|---|
| **3.1. Material:** Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. |
| **3.2. Result:** Pass |
| **3.3. Note:** No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2. |

**Appendix 4: Cleaning and disinfecting**

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|---|
| **4.1. Cleaning and disinfecting:** If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. |
| **4.2. Result:** N/A |
| **4.3. Note:** Single shift use only. |

**Appendix 5: Practical performance**

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|---|
| **5.1. Practical performance:** The particle filtering half mask shall undergo practical performance tests under realistic conditions. |
| **5.2. Result:** Pass |
| **5.3. Note:** No imperfections. |

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**Appendix 6: Finish of parts**

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|---|
| **6.1. Finish of parts:** Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. |
| **6.2. Result:** Pass |
| **6.3. Note:** No sharp edges or burrs. |

**Appendix 7: Total inward leakage**

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|---|
| **7.1. Total inward leakage:** For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e.10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greaterthan22% for FFP1, 8% for FFP2, 2% for FFP3 |
| **7.2. Result:** Pass |

**7.3. Note:**

| Subject | Sample No. | Condition | Walk (%) | Head Side/side (%) | Head up/down (%) | Talk (%) | Walk (%) | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| Li | 1 | A.R. | 1.96 | 2.80 | 2.28 | 1.31 | 1.98 | 1.50 |
| Zhang | 2 | A.R. | 2.82 | 4.07 | 4.72 | 3.45 | 3.35 | 3.68 |
| Yang | 3 | A.R. | 3.16 | 2.08 | 3.72 | 3.03 | 2.11 | 2.82 |
| Liu | 4 | A.R. | 1.97 | 2.30 | 1.70 | 2.82 | 1.25 | 2.00 |
| Xu | 5 | A.R. | 2.53 | 3.20 | 4.39 | 3.79 | 3.40 | 3.46 |
| Sun | 6 | T.C. | 3.19 | 4.27 | 1.89 | 2.24 | 3.69 | 3.05 |
| Shen | 7 | T.C. | 1.55 | 2.11 | 1.52 | 1.43 | 1.25 | 1.57 |
| Zhu | 8 | T.C. | 2.37 | 3.74 | 2.97 | 2.98 | 3.93 | 3.20 |
| Wu | 9 | T.C. | 2.85 | 3.88 | 2.82 | 1.99 | 2.20 | 2.75 |
| Xie | 10 | T.C. | 1.64 | 1.20 | 1.71 | 0.94 | 1.44 | 1.38 |
| 50 out of the 50 individual exercise results ≤ 5%<br>10 of the 10 individual arithmetic means ≤ 2 % | | | | | Pass | | | |

| Subject | Face length | Face length | Face Depth | Mouth Width |
|---|---|---|---|---|
| Li | 128 | 133 | 109 | 48 |
| Zhang | 115 | 146 | 113 | 55 |
| Yang | 109 | 126 | 109 | 51 |
| Liu | 108 | 120 | 113 | 51 |
| Xu | 114 | 135 | 113 | 54 |
| Sun | 126 | 153 | 119 | 56 |
| Shen | 112 | 138 | 121 | 59 |
| Zhu | 119 | 146 | 120 | 53 |
| Wu | 123 | 150 | 115 | 53 |
| Xie | 119 | 141 | 118 | 58 |

## Appendix 8: Penetration of filter material

**8.1. Penetration of filter material:** The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

| | Sodium chloride test 95 l/min | Paraffin oil test 95 l/min |
|---|---|---|
| FFP1 | ≤20% | ≤20% |
| FFP2 | ≤6% | ≤6% |
| FFP3 | ≤1% | ≤1% |

**8.2. Result:** Pass

**8.3. Note:**

| Aerosol | Condition | Sample No. | Penetration (%) | Assessment |
|---|---|---|---|---|
| Sodium Chloride test | As received | 11 | 0.25 | |
| | | 12 | 0.44 | |
| | | 13 | 0.38 | |
| | Simulated wearing treatment | 14 | 0.29 | |
| | | 15 | 0.35 | |
| | | 16 | 0.23 | |
| | Mechanical strength+ Temperature conditioned | 17 | 0.58 | |
| | | 18 | 0.67 | |
| | | 19 | 0.62 | |

| | | | | |
|---|---|---|---|---|
| Paraffin oil test | As received | 20 | 0.68 | |
| | | 21 | 0.79 | |
| | | 22 | 0.71 | |
| | Simulated wearing treatment | 23 | 0.76 | |
| | | 24 | 0.85 | |
| | | 25 | 0.73 | |
| | Mechanical strength+ Temperature conditioned | 26 | 0.88 | |
| | | 27 | 0.97 | |
| | | 28 | 0.96 | |
| Flow conditioning: Single filter: 95.0 L/min | | | | |

## Appendix 9: Compatibility with skin

**9.1. Compatibility with skin:** Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

**9.2. Result:** Pass

**9.3. Note:** No irritation or any other adverse effect to health.

## Appendix 10: Flammability

**10.1. Flammability:** When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

**10.2. Result:** Pass

**10.3. Note:**

| Condition | Sample No. | Result | Assessment |
|---|---|---|---|
| As received | 29 | No Burn | Pass |
| | 30 | No Burn | |
| Temperature conditioned | 31 | No Burn | |
| | 32 | No Burn | |

## Appendix 11: Carbon dioxide content of the inhalation air

**11.1. Carbon dioxide content of the inhalation air:** The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

**11.2. Result:** Pass

**11.3. Note:**

| Condition | Sample No. | Result | | Assessment |
|---|---|---|---|---|
| As received | 33 | 0.5% | Mean value 0.4% | Pass |
| | 34 | 0.4% | | |
| | 35 | 0.4% | | |

## Appendix 12: Head harness

**12.1. Head harness:** The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

**12.2. Result:** Pass

**12.3. Note:** Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

## Appendix 13: Field of vision

**13.1. Field of vision:** The field of vision is acceptable if determined so in practical performance tests.

**13.2. Result:** Pass

**13.3. Note:** Pass the practical performance tests.

## Appendix 14: Exhalation valve

**14.1. Exhalation valve:** A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s),if fitted, shall continue to operate correctly after continuous exhalation flow of 300 l/min over a period of 30s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10s.

**14.2. Result:** N/A

**14.3. Note:** No exhalation valve.

**Appendix 15: Breathing resistance**

**15.1. Breathing resistance:** The breathing resistance apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.

| Classification | Maximum permitted resistance (mbar) | | |
|---|---|---|---|
| | Inhalation | | Exhalation |
| | 30 l/min | 95 l/min | 160l /min |
| FFP1 | 0.6 | 2.1 | 3.0 |
| FFP2 | 0.7 | 2.4 | 3.0 |
| FFP3 | 1.0 | 3.0 | 3.0 |

**15.2. Result:** Pass

**15.3. Note:**

| | Flow rate | | 36 | | | | | 37 | | | | | 38 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| As received | Inhalation | 30 l/min | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 | 0.4 | 0.5 | 0.5 |
| | | 95 l/min | 1.8 | 1.7 | 1.7 | 1.7 | 1.6 | 1.8 | 1.8 | 1.7 | 1.7 | 1.8 | 1.6 | 1.6 | 1.7 | 1.6 | 1.6 |
| | Exhalation | 160 l/min | 2.5 | 2.4 | 2.4 | 2.4 | 2.4 | 2.3 | 2.4 | 2.5 | 2.5 | 2.3 | 2.5 | 2.5 | 2.4 | 2.5 | 2.4 |
| Simulated wearing treatment | Flow ate | | 39 | | | | | 40 | | | | | 41 | | | | |
| | | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| | Inhalation | 30 l/min | 0.5 | 0.5 | 0.4 | 0.5 | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 |
| | | 95 l/min | 1.7 | 1.7 | 1.8 | 1.6 | 1.8 | 1.8 | 1.7 | 1.6 | 1.8 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 |
| | Exhalation | 160 l/min | 2.3 | 2.5 | 2.5 | 2.4 | 2.5 | 2.4 | 2.5 | 2.4 | 2.4 | 2.4 | 2.5 | 2.3 | 2.3 | 2.4 | 2.3 |
| Temperature conditioned | Flow rate | | 42 | | | | | 43 | | | | | 44 | | | | |
| | | | A | B | C | D | E | A | B | C | D | E | A | B | C | D | E |
| | Inhalation | 30 l/min | 0.5 | 0.5 | 0.5 | 0.4 | 0.5 | 0.4 | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.4 |
| | | 95 l/min | 1.7 | 1.7 | 1.7 | 1.6 | 1.6 | 1.7 | 1.6 | 1.6 | 1.8 | 1.6 | 1.8 | 1.7 | 1.7 | 1.8 | 1.7 |
| | Exhalation | 160 l/min | 2.5 | 2.4 | 2.4 | 2.3 | 2.4 | 2.4 | 2.4 | 2.4 | 2.5 | 2.5 | 2.4 | 2.4 | 2.5 | 2.4 | 2.5 |
| Assessment | Pass | | | | | | | | | | | | | | | | |

A: facing directly ahead, B: facing vertically upwards. C: facing vertically downwards, D: lying on the left side, E: lying on the right side