



National Quality Supervision and Testing Center for Personal  
Protective Equipment (Beijing)  
(Testing Laboratory for Labour Protection Products of Beijing  
Municipal Institute for Labour Protection)

No.55 Taoranting Street, Xicheng District, Beijing, China.  
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311  
Fax: +86 10 63519250 +86 10 63520770

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## TEST REPORT

### Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles —  
Requirements, testing, marking

**Product:** Particle filtering half mask  
**Report No:** 2020 (D) - 0291  
**Client:** CCQS Certification Services Limited  
**Model (s):** K8201  
**Date(s) of tests:** 2020.04.12-2020.05.02

## DESCRIPTION OF SAMPLES

| General Information         | Classification   | Main Components    |
|-----------------------------|--|--------------------|
| <b>Manufacturer</b>         | FFP2 NR  | White folding mask |
| <b>Manufacturer Address</b> | Carte Medical Equipment (Suzhou) Co., Ltd<br>No., 1978 Fenhu national Road, Wujiang City, Suzhou City, Jiangsu Province, China |                    |

Signed:

Issued: 2020.5.2

陈倬为 Chen Zhuowei

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Authorized Signatory, Lab Director



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国家劳动防护用品质量监督检验中心(北京)

**Conditions:**

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## Test Results

### 7.3 Visual inspection

Not tested<sup>1</sup>

The visual inspection shall include the marking and information supplied by the manufacturer.

**Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.**

### 7.4 Package

Pass<sup>2</sup>

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.

**Note2: In accordance with the requirement.**

### 7.5 Material

Pass<sup>3</sup>

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.

**Note3: 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.**

### 7.6 Cleaning and disinfecting

N/A<sup>4</sup>

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.

**Note4: Single shift use only.**

### 7.7 Practical performance

Pass<sup>5</sup>

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

**Note5: No imperfections.**

### 7.8 Finish of parts

Pass<sup>6</sup>

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

**Note6: No sharp edges or burrs.**

### 7.9.1 Total inward leakage

Pass<sup>7</sup>

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 greater than

22% for FFP1, 8% for FFP2, 2% for FFP3

**Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.**

### 7.9.2 Penetration of filter material

Pass<sup>8</sup>

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 | $\leq 20\%$                   | $\leq 20\%$                |

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FFP2  $\leq 6\%$  $\leq 6\%$ FFP3  $\leq 1\%$  $\leq 1\%$ **Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.****7.10 Compatibility with skin****Pass<sup>9</sup>**

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.

**Note9: No irritation or any other adverse effect to health.****7.11 Flammability****Pass<sup>10</sup>**

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.

**Note10: Test results are shown in Annex A Table 7.11.****7.12 Carbon dioxide content of the inhalation air****Pass<sup>11</sup>**

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

**Note11: Test results are shown in Annex A Table 7.12.****7.13 Head harness****Pass<sup>12</sup>**

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.

**Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.****7.14 Field of vision****Pass<sup>13</sup>**

The field of vision is acceptable if determined so in practical performance tests.

**Note13: Pass the practical performance tests.****7.15 Exhalation valve****N/A<sup>14</sup>**

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 a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

**Note14: No exhalation valve.****7.16 Breathing resistance****Pass<sup>15</sup>**

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

**Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.****7.17 Clogging****N/A<sup>16</sup>**

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**7.17.2 Breathing resistance**

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

**7.17.3 Penetration of filter material**

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

**Note16: Single shift use only.**

**7.18 Demountable parts**

**Pass<sup>17</sup>**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

**Note17: In accordance with the requirement.**

**9 Marking**

**Not tested**

**9.1 Packaging**

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

**9.1.1** The name, trademark or other means of identification of the manufacturer or supplier.

**9.1.2** Type-identifying marking.

**9.1.3** Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.

Example: FFP2 R D.

**9.1.4** The number and year of publication of this European Standard.

**9.1.5** At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

**9.1.6** The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

**9.1.7** The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

**9.1.8** The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

**9.2 Particle filtering half mask**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

**9.2.1** The name, trademark or other means of identification of the manufacturer or supplier.

**9.2.2** Type-identifying marking.

**9.2.3** The number and year of publication of this European Standard.

**9.2.4** Classification

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The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

**9.2.5** If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

**9.2.6** Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

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### **End of Test Results**

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**Annex A: Summarization of Test Data****Table 7.9.1-A Inward leakage test data**

Test specification: EN 149-2001 Clause 8.5

| Subject  | Sample No. | Condition | Walk(%) | Head Side/side(%) | Head up/down(%) | Talk(%) | Walk(%) | Mean(%) |
|--|------------|-----------|---------|-------------------|-----------------|---------|---------|---------|
| Yu   | 1          | A.R.      | 6.22    | 6.30              | 6.30            | 6.29    | 6.58    | 6.3     |
| Hu   | 2          | A.R.      | 7.66    | 8.20              | 7.84            | 8.10    | 7.87    | 7.9     |
| Xu   | 3          | A.R.      | 7.23    | 7.61              | 7.58            | 7.60    | 7.62    | 7.5     |
| Deng   | 4          | A.R.      | 8.88    | 9.03              | 9.26            | 9.15    | 9.02    | 9.1     |
| Zhang  | 5          | A.R.      | 7.55    | 7.78              | 7.61            | 7.64    | 7.74    | 7.7     |
| Liu  | 6          | T.C.      | 5.83    | 6.25              | 5.84            | 5.89    | 6.05    | 6.0     |
| Zhi  | 7          | T.C.      | 5.43    | 5.91              | 5.84            | 5.53    | 5.43    | 5.6     |
| Fang   | 8          | T.C.      | 6.48    | 6.77              | 6.61            | 6.73    | 6.49    | 6.6     |
| Chen   | 9          | T.C.      | 7.22    | 7.78              | 7.50            | 7.43    | 7.52    | 7.5     |
| Lv   | 10         | T.C.      | 8.04    | 8.12              | 8.12            | 8.48    | 8.35    | 8.2     |
| All 50 individual exercise results were not greater than 11 %<br>8 out of 10 individual wearer arithmetic means were not greater than $\leq$ 8 % |            |           |         |                   |                 | Pass    |         |         |

**Table 7.9.1-B Facial dimension**

| Subject | Face length | Face Width | Face Depth | Mouth Width |
|---------|-------------|------------|------------|-------------|
| Yi      | 120         | 130        | 109        | 59          |
| Gong    | 122         | 140        | 115        | 65          |
| Hu      | 112         | 122        | 119        | 63          |
| Xu      | 110         | 130        | 118        | 60          |
| Deng    | 115         | 119        | 110        | 59          |
| Liu     | 103         | 130        | 100        | 50          |
| Zhi     | 118         | 139        | 130        | 63          |
| Fang    | 115         | 129        | 120        | 50          |
| Chen    | 116         | 150        | 132        | 56          |
| Lv      | 110         | 121        | 110        | 53          |

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**Table -7.9.2 Penetration of filter material**

Test specification: EN 149-2001 Clause 8.11

| Test 3: Penetration: EN 143 2004 Class C1A         |  |            |                 |            |
|--|--|------------|-----------------|------------|
| Aerosol  | Condition                                    | Sample No. | Penetration (%) | Assessment |
| Sodium chloride test                               | As received                                  | 11         | 0.032           | Pass       |
|  |  | 12         | 0.055           |            |
|  |  | 13         | 0.042           |            |
|  | Simulated wearing treatment                  | 14         | 0.096           |            |
|  |  | 15         | 0.091           |            |
|  |  | 16         | 0.112           |            |
|  | Mechanical strength+ Temperature conditioned | 17         | 0.217           |            |
|  |  | 18         | 0.262           |            |
|  |  | 19         | 0.278           |            |
| Paraffin oil test                                  | As received                                  | 20         | 1.65            |            |
|  |  | 21         | 1.82            |            |
|  |  | 22         | 1.71            |            |
|  | Simulated wearing treatment                  | 23         | 1.97            |            |
|  |  | 24         | 2.11            |            |
|  |  | 25         | 2.29            |            |
|  | Mechanical strength+ Temperature conditioned | 26         | 3.11            |            |
|  |  | 27         | 2.89            |            |
|  |  | 28         | 2.96            |            |
| Flow conditioning:    Single filter:    95.0 L/min |  |            |                 |            |

**Table 7.11 Flammability**

Test specification: EN 149-2001 Clause 8.6

| Condition               | Sample No. | Result       | Assessment |
|-------------------------|------------|--------------|------------|
| As received             | 29         | Burn for 1 s | Pass       |
|                         | 30         | Burn for 1 s |            |
| Temperature conditioned | 31         | Burn for 1 s |            |
|                         | 32         | Burn for 1 s |            |

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**Table 7.12 Carbon dioxide content of the inhalation air**

Test specification: EN 149-2001 Clause 8.7

| Condition   | Sample No. | Result |                    | Assessment |
|-------------|------------|--------|--------------------|------------|
| As received | 33         | 0.43%  | Mean value<br>0.4% | Pass       |
|             | 34         | 0.42%  |                    |            |
|             | 35         | 0.44%  |                    |            |

**Table 7.16 Breathing resistance (mbar)**

Test specification: EN 149-2001 Clause 8.9

|                             | 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 | 0.7 | 0.7 | 0.6 | 0.6 | 0.6 | 0.5 | 0.5 | 0.6 | 0.7 | 0.5 | 0.6 | 0.7 | 0.6 | 0.7 |
|                             |            | 95 l/min  | 1.8 | 1.8 | 2.0 | 1.9 | 2.0 | 1.8 | 1.9 | 1.9 | 2.0 | 1.9 | 2.0 | 1.9 | 1.9 | 1.9 | 1.9 |
|                             | Exhalation | 160 l/min | 1.9 | 2.0 | 2.0 | 2.1 | 1.9 | 2.0 | 2.0 | 2.1 | 2.1 | 2.1 | 2.0 | 1.9 | 2.0 | 2.0 | 2.0 |
| Simulated wearing treatment | Flow rate  |           | 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 | 0.6 | 0.7 | 0.6 | 0.5 | 0.6 | 0.7 | 0.6 | 0.6 | 0.7 | 0.6 | 0.6 | 0.5 | 0.5 |
|                             |            | 95 l/min  | 1.9 | 1.9 | 1.8 | 2.0 | 1.8 | 1.9 | 1.9 | 1.9 | 1.8 | 1.8 | 1.9 | 2.0 | 2.0 | 2.0 | 1.9 |
|                             | Exhalation | 160 l/min | 2.0 | 1.9 | 2.0 | 2.0 | 1.9 | 2.1 | 1.9 | 2.0 | 2.0 | 2.0 | 1.9 | 2.0 | 1.9 | 2.0 | 2.0 |
| 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  | 0.6 | 0.7 | 0.6 | 0.6 | 0.6 | 0.7 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.7 | 0.7 | 0.5 | 0.6 |
|                             |            | 95 l/min  | 2.0 | 1.8 | 1.9 | 2.0 | 1.8 | 1.9 | 1.9 | 1.8 | 1.8 | 1.9 | 1.9 | 1.9 | 2.0 | 2.0 | 2.0 |
|                             | Exhalation | 160 l/min | 2.0 | 1.9 | 1.9 | 1.9 | 2.0 | 2.0 | 1.9 | 2.0 | 2.1 | 2.1 | 2.1 | 2.0 | 2.0 | 2.0 | 2.1 |
| Flow conditioned            | Flow rate  |           | 45  |     |     |     |     | 46  |     |     |     |     | 47  |     |     |     |     |
|                             |            |           | A   | B   | C   | D   | E   | A   | B   | C   | D   | E   | A   | B   | C   | D   | E   |
|                             | Inhalation | 30 l/min  | 0.6 | 0.6 | 0.7 | 0.6 | 0.6 | 0.6 | 0.6 | 0.5 | 0.7 | 0.7 | 0.6 | 0.7 | 0.6 | 0.6 | 0.6 |
|                             |            | 95 l/min  | 1.9 | 1.8 | 1.8 | 1.9 | 2.0 | 1.8 | 1.9 | 1.9 | 1.9 | 1.9 | 1.8 | 1.9 | 1.8 | 1.9 | 1.9 |
|                             | Exhalation | 160 l/min | 2.1 | 2.0 | 1.9 | 1.9 | 1.9 | 2.1 | 2.0 | 1.9 | 1.9 | 2.1 | 2.1 | 2.0 | 2.0 | 2.1 | 2.0 |
| 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

**End of Annex A**

**ANNEX B PHOTOS OF SAMPLES**



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**End of Annex B**

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