### **EU DECLARATION OF CONFORMITY**

### Manufacturer

Name: SANMEN SANMEI CRAFT CO., LTD

Address: TINGPANG INDUSTRY ZONE,SANMEN,TAIZHOU, ZHEJIANG,CHINA 317103

declares that the new PPE described hereafter

*Product, type* Filtering Half Mask, ZDFM002 Brand Name: ZIDAI



is in conformity with the provisions of regulation (EU) 2016/425 of the European parliament and of the council of 9 March 2016 on Personal protective equipment, and Conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications:

EN 149: 2001+A1:2009

Is identical to the PPE which is the subject of EU type-examination for Regulation (EU) 2016/425 issued by SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland, Notified Body number: 0598, the certificate FI20/966545

Is identical to the PPE which is subject to the procedure set out in C2 of Regulation(EU)2016/425 Personal Protective Equipment under the supervision of the notified body SGS Fimko Oy, Takomotie 8,FI-00380 Helsinki, Finland, Notified Body number:0598, the certificate FI20/966545

The product(s) of the declaration described above is in conformity with the requirement of following test reports:

Report No. :SL52035260792001TX

SGS-CSTC Standards Technical Services(Shanghai) Co., Ltd Testing Center *Place : ZHEJIANG* 

DATE : July 3th, 2020





Certificate FI20/966545

# SANMEN SANMEI CRAFT CO.,LTD

Tingpang Industry Zone, Sanmen, Taizhou, 317103 Zhejiang, China

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 08 September 2020 until 08 September 2025 1. Certified since 08 September 2020

Authorised by

Finnish Accreditation Service S003 (EN ISO/IEC 17065)

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Certificate FI20/966545, continued

# SANMEN SANMEI CRAFT CO.,LTD

# Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

ZIDAI (logo) ZDFM002 particle filtering half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene / ethylene-propylene / polypropylene) disposable face mask, with nose clip, polyester/spandex ear strap and polyethylene hook

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

SS-TCF-01, dated: 2020-04-12.

SGS Reference Number UK/CRS 241688.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request.



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Certificate CN20/42326

The management system of

# SANMEN SANMEI CRAFT CO., LTD

Tingpang Industry Zone, Sanmen, Taizhou, 317103 Zhejiang, China

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module C2

For the following activities

Manufacture of ZIDAI (logo) ZDFM002 particle filtering half mask. (Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of Directive 89/686/EEC.)

> This certificate is valid from 25 September 2020 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 25 September 2020

> > Authorised by

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Test Report SL52035260792001TX

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SANMEN SANMEI CRAFT CO.,LTD TINGPANG INDUSTRY ZONE, SANMEN, TAIZHOU, ZHEJIANG, CHINA 317103

The following sample(s) was/were submitted and identified on behalf of the client as: Sample Description : (A)Filtering Half Mask

| Style No.<br>Sample Color<br>Manufacturer<br>Supplier     | ::     | ZDFM002<br>(A)WHITE<br>ZIDAI<br>SANMEN SANMEI CRAFT CO.,LTD   |
|---|--------|---|
| Test Performed  | :      | Selected test(s) as requested by applicant  |
| Sample Receiving Date<br>Testing Period<br>Test Result(s) | :<br>: | Jun 17, 2020<br>Jun 18, 2020 - Jul 02, 2020<br>Unless otherwise stated the results shown in this test report refer only to the<br>sample(s) tested, for further details, please refer to the following page(s). |

| ~     |       |       |
|-------|-------|-------|
| ( 'Ar |       | non   |
| 001   | เษเนง | sion: |
|       |       |       |

| Sample No. | Recommendation Level |  |
|------------|----------------------|--|
| (A)        | FFP2 NR              |  |

Signed for and on behalf of SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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Test Result

#### Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

EN 149:2001+A1:2009

#### Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

| Test Requirement   | Results | Comment |
|--|---------|---------|
| 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. | Comply  | Pass    |

#### Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

| Test Requirement  | Results | Comment |
|---|---------|---------|
| 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.                | Comply  |         |
| 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. | Comply  | Pass    |
| When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.  | Comply  |         |
| Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.                          | Comply  |         |

#### Clause 7.6 Cleaning and Disinfecting

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

| Test Requirement   | Results   | Comment |
|--|---|---------|
| If the particle filtering half mask is designed to be re-usable, the materials<br>used shall withstand the cleaning and disinfecting agents and procedures to<br>be specified by the manufacturer.<br>With reference to 7.9.2, after cleaning and disinfecting the re-usable particle<br>filtering half mask shall satisfy the penetration requirement of the relevant<br>class. | Not applicable<br>(Not designed to<br>be re-usable) | N.A.    |

### Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

| Test Requirement   | Results          | Comment |
|--|------------------|---------|
| The particle filtering half mask shall undergo practical performance tests<br>under realistic conditions. These general tests serve the purpose of<br>checking the equipment for imperfections that cannot be determined by the<br>tests described elsewhere in this standard. | No imperfections | Pass    |



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#### Clause 7.8 Finish of Parts

(EN 149:2001+A1:2009, Clause 8.2)

| Test Requirement  | Results        | Comment |
|---|----------------|---------|
| Parts of the device likely to come into contact with the wearer shall have no | No sharp       | Pass    |
| sharp edges or burrs.   | edges or burrs |         |

#### Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009, Clause 8.5)

| Test Requirement   | Results                       | Comment                 |
|--|-------------------------------|-------------------------|
| The total inward leakage consists of three components: face seal leakage,<br>exhalation value leakage(if exhalation value fitted) and filter penetration.<br>For particle filtering half masks fitted in accordance with the manufacturer's<br>information, at least 46 out of the 50 individual exercise results (i.e. 10<br>subjects x 5 exercises) for total inward leakage shall be not greater than:<br>25% for FFP1, 11% for FFP2, 5% for FFP3<br>and, in addition, at least 8 out of the 10 individual wearer arithmetic means<br>for the total inward leakage shall be not greater than:<br>22% for FFP1, 8% for FFP2, 2% for FFP3 | Detail refer to<br>Appendix 1 | Meet FFP1,<br>Meet FFP2 |

#### Appendix 1: Summarization of Test Data

#### Inward Leakage Test Data

| Subject | Sample | Condition | Walk(%) | Head         | Head       | Talk(%) | Walk(%) | Mean(%) |
|---------|--------|-----------|---------|--------------|------------|---------|---------|---------|
| _       | No.    |           |         | Side/side(%) | up/down(%) |         |         |         |
| Zhou    | 1      | A.R.      | 5.17    | 6.32         | 7.04       | 5.26    | 4.60    | 5.68    |
| Luo     | 2      | A.R.      | 5.68    | 6.19         | 7.14       | 5.13    | 5.88    | 6.00    |
| Lu      | 3      | A.R.      | 6.02    | 6.57         | 4.88       | 5.82    | 5.60    | 5.78    |
| Wang    | 4      | A.R.      | 4.61    | 3.97         | 3.86       | 3.66    | 5.22    | 4.26    |
| Bao     | 5      | A.R.      | 5.07    | 6.58         | 5.90       | 7.35    | 6.02    | 6.18    |
| Ding    | 6      | T.C.      | 3.58    | 5.37         | 4.75       | 4.53    | 4.21    | 4.49    |
| Li      | 7      | T.C.      | 7.54    | 5.73         | 6.52       | 5.40    | 7.11    | 6.46    |
| Chen    | 8      | T.C.      | 4.38    | 4.54         | 4.91       | 4.66    | 3.48    | 4.39    |
| Song    | 9      | T.C.      | 4.76    | 5.59         | 7.31       | 6.55    | 5.32    | 5.91    |
| Ye      | 10     | T.C.      | 7.32    | 5.92         | 5.88       | 6.72    | 6.29    | 6.43    |

#### Facial Dimension(mm)

| <u>Subject</u> | Face length | Face Width | Face Depth | Mouth Width |
|----------------|-------------|------------|------------|-------------|
| Chen           | 125         | 150        | 120        | 58          |
| Lu             | 115         | 132        | 107        | 48          |
| Zhou           | 115         | 135        | 106        | 52          |
| Li             | 125         | 130        | 107        | 46          |
| Luo            | 125         | 136        | 100        | 43          |
| Zheng          | 128         | 140        | 112        | 55          |
| Wang           | 120         | 147        | 103        | 48          |
| Song           | 120         | 140        | 100        | 50          |
| Bao            | 130         | 134        | 104        | 50          |



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|--------------------|-----|----------------|-------------------|--------------|
| Ding               | 134 | 150            | 110               | 52           |
| Liu                | 120 | 135            | 117               | 50           |
| Ye                 | 126 | 137            | 105               | 52           |

#### Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

|      |            | Test Requirement   |                            | Results | Comment                       |                          |
|------|------------|--|----------------------------|---------|-------------------------------|--------------------------|
|      |            | of the filter of the particle filte<br>he following table. | he                         |         |                               |                          |
| requ | Classifica | Maximum penetratio   |                            |         |                               |                          |
|      | tion       | Sodium chloride test 95                                    | Paraffin oil test 95 l/min |         |                               | Meet FFP1,<br>Meet FFP2, |
|      |            | l/min<br>%   | %                          |         | Detail refer to<br>Appendix 2 |                          |
|      |            | max.   | max.                       |         |                               | Meet FFP3                |
|      | FFP1       | 20   | 20                         |         |                               |                          |
|      | FFP2       | 6  | 6                          |         |                               |                          |
|      | FFP3       | 1  | 1                          |         |                               |                          |

#### Appendix 2: Summarization of Test Data

Penetration of filter material

| Aerosol              | Condition                             | Sample No.      | Penetration<br>(%) |
|----------------------|---------------------------------------|-----------------|--------------------|
|                      |                                       | 1               | 0.081              |
|                      | As received                           | 2               | 0.123              |
|                      |                                       | 3               | 0.092              |
|                      |                                       | 4               | 0.109              |
| Sodium chloride test | Simulated wearing treatment           | 5               | 0.117              |
|                      |                                       | 6               | 0.097              |
|                      | Machanical strength . Towns water     | 7               | 0.083              |
|                      | Mechanical strength +Temperature      | 8               | 0.099              |
|                      | conditioned                           | 9               | 0.118              |
|                      |                                       | 10              | 0.125              |
|                      | As received                           | 11              | 0.134              |
|                      |                                       | 12              | 0.126              |
|                      |                                       | 13              | 0.146              |
| Paraffin oil test    | Simulated wearing treatment           | 14              | 0.134              |
|                      |                                       | 15              | 0.145              |
|                      | Marchanical sture with Tanan sustains | 16              | 0.194              |
|                      | Mechanical strength +Temperature      | 17              | 0.186              |
|                      | conditioned                           | 18              | 0.176              |
|                      | Flow conditioning: Single fil         | ter: 95.0 L/min |                    |



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Clause 7.10 Compatibility with Skin (EN 149:2001+A1:2009, Clause 8.4 & 8.5)

| Test Requirement   | Results   | Comment |
|--|---|---------|
| 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. | No irritation or<br>any other adverse<br>effect to health | Pass    |

#### Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

| Test Requirement  | Results         | Comment |
|---|-----------------|---------|
| The material used shall not present a danger for the wearer and shall not be of highly flammable nature                                 | Detail refer to | Daga    |
| 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. | Appendix 3      | Pass    |

#### Appendix 3: Summarization of Test Data

Flammability

| Condition               | Sample No. | Result |
|-------------------------|------------|--------|
|                         | 1          | NIL    |
| As received             | 2          | NIL    |
|                         | 3          | NIL    |
| Temperature conditioned | 4          | NIL    |

#### Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

| Test Requirement   | Results                       | Comment |
|--|-------------------------------|---------|
| The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) | Detail refer to<br>Appendix 4 | Pass    |

#### Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

| Condition   | Sample No. | Result(%) |                 |  |
|-------------|------------|-----------|-----------------|--|
|             | 1          | 0.4729    |                 |  |
| As received | 2          | 0.4714    | Mean value:0.47 |  |
| ASTECEIVEU  |            | 0.4733    | Wear value.0.47 |  |
|             | 3          |           |                 |  |



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#### Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

| Test Requirement  | Results | Comment |
|---|---------|---------|
| The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.   | Comply  |         |
| The head harness shall be adjustable or self-adjusting and shall be<br>sufficiently robust to hold the particle filtering half mask firmly in position and<br>be capable of maintaining total inward leakage requirements for the device. | Comply  | Pass    |

#### Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

| Test Requirement   | Results | Comment |
|--|---------|---------|
| The field of vision is acceptable if determined so in practical performance tests. | Comply  | Pass    |

#### Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

| Test Requirement  | Results   | Comment |
|---|---|---------|
| (a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.  | Not applicable<br>due to No<br>exhalation valve |         |
| (b) 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. | Not applicable<br>due to No<br>exhalation valve | N.A.    |
| (c) 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.  | Not applicable<br>due to No<br>exhalation valve |         |
| (d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.   | Not applicable<br>due to No<br>exhalation valve |         |



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#### Clause 7.16 Breathing Resistance

(EN 149:2001+A1:2009, Clause 8.9)

| Test Requirement  |                                     |                    |           |                 | Results         | Comment    |
|---|-------------------------------------|--------------------|-----------|-----------------|-----------------|------------|
| The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table. |                                     |                    |           |                 |                 |            |
| Classification  | Maximum permitted resistance (mbar) |                    |           |                 | Deteil vefev te | Meet FFP1, |
|   | Inh                                 | alation Exhalation |           | Detail refer to | Meet FFP2,      |            |
|   | 30 l/min                            | 95 l/min           | 160 l/min |                 | Appendix 5      | Meet FFP3  |
| FFP1  | 0.6                                 | 2.1                | 3.0       |                 |                 |            |
| FFP2  | 0.7                                 | 2.4                | 3.0       |                 |                 |            |
| FFP3  | 1.0                                 | 3.0                | 3.0       |                 |                 |            |

#### Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

|                                   | Flow rate(l/min) |     | 1   |     |     |     | 2   |     |     |     | 3   |     |     |     |     |     |     |
|-----------------------------------|------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| As received                       |                  |     | Α   | В   | С   | D   | E   | Α   | В   | С   | D   | E   | Α   | В   | С   | D   | E   |
|                                   | Inhalation       | 30  | 0.3 | 0.3 | 0.4 | 0.3 | 0.3 | 0.3 | 0.2 | 0.2 | 0.3 | 0.4 | 0.4 | 0.3 | 0.3 | 0.3 | 0.3 |
|                                   |                  | 95  | 0.9 | 0.9 | 1.0 | 0.9 | 1.0 | 1.0 | 0.9 | 0.8 | 1.0 | 0.9 | 0.8 | 0.9 | 0.8 | 1.0 | 1.0 |
|                                   | Exhalation       | 160 | 2.0 | 2.0 | 2.1 | 1.9 | 2.0 | 2.0 | 1.9 | 1.9 | 2.0 | 2.0 | 1.9 | 1.9 | 2.0 | 1.9 | 2.0 |
| Simulated<br>wearing<br>treatment | Flow rate(l/min) |     | 4   |     |     |     | 5   |     |     |     | 6   |     |     |     |     |     |     |
|                                   |                  |     | Α   | В   | С   | D   | Е   | Α   | В   | С   | D   | Е   | Α   | В   | С   | D   | Е   |
|                                   | Inhalation       | 30  | 0.4 | 0.5 | 0.4 | 0.4 | 0.3 | 0.4 | 0.4 | 0.3 | 0.4 | 0.5 | 0.4 | 0.5 | 0.5 | 0.4 | 0.3 |
|                                   |                  | 95  | 1.1 | 1.2 | 1.2 | 1.1 | 1.2 | 1.0 | 1.2 | 1.2 | 1.2 | 1.0 | 1.2 | 1.2 | 1.2 | 1.0 | 1.2 |
|                                   | Exhalation       | 160 | 2.1 | 2.1 | 2.1 | 2.2 | 2.2 | 2.1 | 2.1 | 2.2 | 2.2 | 2.2 | 2.1 | 2.1 | 2.2 | 2.1 | 2.2 |
|                                   | Flow rate(l/min) |     | 7   |     |     |     | 8   |     |     |     | 9   |     |     |     |     |     |     |
| Temperature conditioned           |                  |     | Α   | В   | С   | D   | E   | Α   | В   | С   | D   | E   | Α   | В   | С   | D   | E   |
|                                   | Inhalation       | 30  | 0.2 | 0.2 | 0.3 | 0.2 | 0.2 | 0.3 | 0.2 | 0.2 | 0.2 | 0.3 | 0.2 | 0.2 | 0.3 | 0.3 | 0.2 |
|                                   |                  | 95  | 0.7 | 0.7 | 0.8 | 0.7 | 0.7 | 0.8 | 0.7 | 0.7 | 0.7 | 0.8 | 0.7 | 0.7 | 0.8 | 0.8 | 0.7 |
|                                   | Exhalation       | 160 | 1.9 | 1.8 | 1.8 | 1.9 | 1.9 | 1.8 | 1.8 | 1.9 | 1.9 | 1.8 | 1.8 | 1.9 | 1.9 | 1.9 | 1.8 |

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



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Clause 7.17 Clogging

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

|  | Test Requirement  | Results                               | Comment                               |      |
|--|---|---------------------------------------|---------------------------------------|------|
| Valved particle fill<br>After clogging the<br>FFP1: 4 mbar, FF<br>The exhalation re<br>flow.<br>Valveless particle<br>After clogging the | eathing resistance<br>tering half masks:<br>a inhalation resistances shall not<br>P2: 5 mbar, FFP3: 7 mbar at 95<br>asistance shall not exceed 3 mb<br><u>e filtering half masks:</u><br>a inhalation and exhalation resis<br>FP2: 4 mbar, FFP3: 5 mbar at 95 | Optional for single shift device only | N.A.                                  |      |
| All types (valved  | netration of filter material<br>and valveless) of particle filte<br>prequirement shall also meet th<br>Maximum penetration<br>Sodium chloride test 95 l/min<br>%<br>max.<br>20  | e requirements.                       | Optional for single shift device only | N.A. |
| FFP2   | 6   | 6                                     |                                       |      |
| FFP3   | 1   | 1                                     |                                       |      |

#### Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

| Test Requirement   | Results | Comment |  |
|--|---------|---------|--|
| All demountable parts (if fitted) shall be readily connected and secured, where possible by hand | Comply  | Pass    |  |

| Test   | Uncertainty |
|--|-------------|
| Total inward leakage                         | 3.4%        |
| Penetration of filter material               | 4.8%        |
| Carbon dioxide content of the inhalation air | 3.9%        |
| Breathing resistance (30L/min)               | 5.9%        |
| Breathing resistance (95L/min)               | 4.9%        |
| Breathing resistance (160L/min)              | 4.3%        |



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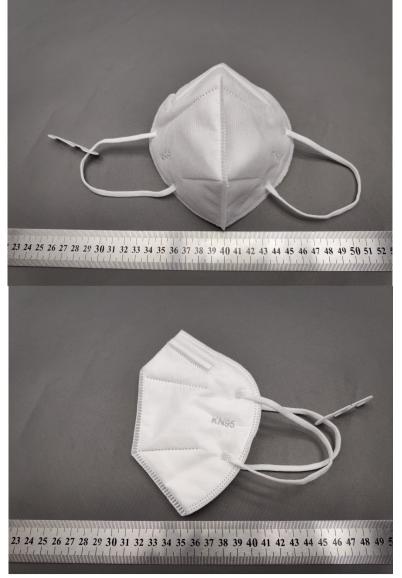
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Sample Photo





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