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CERTIFICATION

NB 2163

# CERTIFICATE OF CONFORMANCE

## Certificate No: 2163-PPE-971/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**JIFA Group Co., Ltd.**
Jiangnan Development Area, Dongyang, Zhejiang, P.R. China 322121

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

| Model | Class | EU Type Examination Certificate | | |
|---|---|---|---|---|
| | | Serial No | Date | Issuing NB No |
| JIFA / JFM-02 | FFP2 NR | 2163-PPE-971 | 07.07.2020 | 2163 |

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **02/08/2020** and will be valid for one year, until **01/08/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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NB 2163

# EU TYPE EXAMINATION CERTIFICATE

## Certificate No: 2163-PPE-971

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**Jifa Group Co., Ltd.**
Jiangnan Development Area, Dongyang, Zhejiang, P.R. China 322121

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

**Product Definition**

**Brand Name:** JIFA **Model:** JFM02
Filtering half mask
**Classification:** FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **07/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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# TECHNICAL ASSESSMENT REPORT

**REPORT DATE / NO:** 07.07.2020 / 2163-KKD-971

**Manufacturer:** JIFA GROUP CO., LTD.
**Address:** Jiangnan Development Area, Dongyang, Zhejiang, P.R. China 322121

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-10118 for the product identified below, dated 27.06.2020 with Serial Id WSZ FHL 6680 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 29 June 2020 Version 0 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the cient.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

**Product Description:** Particle Filtering Half Mask
**Classification:** FFP2 NR
**Trademark:** JIFA **Model:** JFM02




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## ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

**1.1. Design principles**

**1.1.1. Ergonomics**

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level. The test resuts with human subjects did not report any problem with the ergonomics of the product.

**1.1.2. Levels and classes of protection**

**1.1.2.1. Highest level of protection possible**

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**

**1.2.1. Absence of risks and other inherent nuisance factors**

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use. The manufacturer declares in his technical file that according to the results of risk analysis and the material properties they use in the manufacturing, the product has no hazardous content for health.

**1.2.1.1. Suitable constituent materials**

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users. The material selection is processed in the technical manufacturing process and documented.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries is evaluated and reported in the test report.

**1.2.1.3. Maximum permessible user impediment**

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**

**1.3.1. Adaptation of PPE to user morphology**

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination



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## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

### 2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

### 2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

### 2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions. The product is for single use and tested with simulated wearing conditioning.

### 2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

### 2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

### 2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

### 2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

### 3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.



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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

| Conforming to EN 149:2001 + A1:2009 Standard Requirements | |
|---|---|
| *Article* 5 | **Classification: :** Particle Filtering Half Mask<br>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as;<br>Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2<br>Mask is classified for single shift use, NR |
| *Article* 7.4 | **Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report. |
| *Article* **7.5** | **Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.<br>Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects. |
| *Article* **7.6** | **Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer. |
| *Article* 7.7 | **Practical Performance :**<br>The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues. |

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 2.Head harness comfort | 2 | 0 | Positive results are obtained from the test subjects<br>**No imperfections** |
| 3.Security of fastenings | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |

**Conditioning :** (A.R.) As Received, original

| | |
|---|---|
| *Article* 7.8 | **Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs. |
| *Article* 7.9.1 | **Total Inward Leakage:**<br>The Total Inward Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the condcution of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.<br><br>It was reported that;<br>At least 46 out of the 50 exercise measurement results are smaller or equal to 11%, the values varies between 4,1 % and 6,8 %.<br>At least 8 out of the 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 5,1 % and 6,4 %.<br><br>**According to the reported results, the product meets the limits for FFP1 and FFP2 classification.** |

*Article* 7.9.2

**Penetration of filter material:** Sodium Chloride Testing

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | - | 0.1 | | |
| (A.R.) | - | 0.2 | | |
| (A.R.) | - | 0.1 | FFP1 ≤ 20 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2, FFP3** classes. |
| (S.W.) | - | 0.1 | | |
| (S.W.) | - | 0.1 | FFP2 ≤ 6 % | |
| (S.W.) | - | 0.1 | | |
| (M.S. T.C.) | - | 0.2 | FFP3 ≤ 1 % | |
| (M.S. T.C.) | - | 0.3 | | |
| (M.S. T.C.) | - | 0.2 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$



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*Article* 7.9.2

**Penetration of filter material: :** Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | - | 0.2 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2, FFP3** classes. |
| (A.R.) | - | 0.1 | | |
| (A.R.) | - | 0.1 | | |
| (S.W.) | - | 0.1 | | |
| (S.W.) | - | 0.1 | | |
| (S.W.) | - | 0.2 | | |
| (M.S. T.C.) | - | 0.3 | | |
| (M.S. T.C.) | - | 0.4 | | |
| (M.S. T.C.) | - | 0.4 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

*Article* 7.11

**Flammability :**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | - | 0.1 s | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | **Passed**<br>Filtering half masks fulfill requirements of the standard |
| (A.R.) | - | 0.1 s | | |
| (T.C.) | - | 0.1 s | | |
| (T.C.) | - | 0.1 s | | |

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | - | 0.7224 | 0.72 [%] | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | **Passed**<br>Filtering half masks fulfil requirements of the standard |
| (A.R.) | - | 0.7230 | | | |
| (A.R.) | - | 0.7241 | | | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

*Article* 7.14

**Field of vision:** In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

*Article* 7.15

**Exhalation Valve(s):** The model under inspection have no valves.

*Article* 7.16

**Breathing Resistance:** Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min. The measurement details for each single mask tested are available in the test report.

**Passed.**

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| | |
|---|---|
| *Article* 7.17 | **Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)* |
| *Article* 7.18 | **Demountable Parts:** There are no demountable parts on the product. |
| *Article* 8 | **Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 5.1.1-5.1.2 of the technical file.<br><br>The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing JFM02. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (JIFA) of the manufacturer, Type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model JFM02 drawing exists in the technical file of the manufacturer, Annex 4.1-4.2-4.3 of technical file. |
| *Article* 10 | **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 2. The manufacturer shall include this documented user information text in every smallest commertially available package. |

| PREPARED BY | APPROVED BY |
|---|---|
| **Neslihan EKE BİRTÜRK**<br>PPE Expert | **Suat KAÇMAZ**<br>General Manager |

UNIVERSAL CE 2163 Notified Body



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# EU Declaration of Conformity

## Annex IX PPE Regulation (EU) 2016/425

### This EU Declaration of conformity refers to the following products

| Product Name | Model | Classification/Type | Batch No./Serial No./Identifier |
|---|---|---|---|
| Particle Filtering half mask | JFM02 | FFP2 NR | 202009A |

The Manufacturer's name and address is as follows:

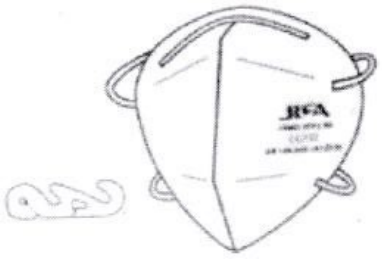
| | |
|---|---|
| Name: | JIFA GROUP CO., LTD. |
| Address: | Jiangnan Development Area, Dongyang, Zhejiang, P.R.China 322121 |

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Model: JFM02 FFP2 NR

White folder half mask without valve

Product Photo:




The article identified in product category has been demonstrated fulfillment essential health and safety requirements set out in Annex II and in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425. our products are References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

| No. | Harmonized standard name |
|---|---|
| 1 | EN 149:2001+A1:2009 |

universal certification and surveillance services trade co (NB 2163) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

| No. | EU Type Examination (Module B) Certificate Number |
|---|---|
| 1 | 2163-PPE-971 |

Product Category:

☐ This product is Category II.

☐ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of universal certification and surveillance services trade co (NB 2163)

☒ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of universal certification and surveillance services trade co (NB 2163)

Signature : Date : 2020.9.4 Company stamp and/or legal signature :

161019130764

中国认可
国际互认
检测
TESTING
CNAS L10118

国检检测
CHINA COMPONENTS TEST

# Test Report

Report No.: [2020] WSZ FHL NO.6680

Product Name Filtering half mask

Applicant UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co.

Manufacturer Jifa Group Co.,Ltd

Test Type Entrusted inspection

江苏国健检测技术有限公司 检验专用章

Jiangsu Guojian Testing Technology Co., Ltd.

3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

# Test Report

| | | | |
|---|---|---|---|
| Product name | Filtering half mask | Model name | JFM02 |
| | | Brand | — |
| Laboratory/ Add. | Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China | | |
| Applicant/ Add/Tel | UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co./—/— | | |
| Manufacturer/ Add/Tel | Jifa Group Co.,Ltd/Jiangnan Development Area, Dongyang, Zhejiang, P.R.China 322121/— | | |
| Sample classification | FFP2 | Sample number | GW6680-2020 |
| Sample quantity | 110 pcs | Date of receipt of sample | 11/06/2020 |
| Test type | Entrusted inspection | Article/Batch/Style number | — |
| Date (s) of performance of tests | 15/06/2020~23/06/2020 | Testing location | Same as the Laboratory |
| Sample state | Meeting the requirements of testing | Sample description | Refer to page 3 |
| Test standard(s) | EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking | | |
| Test items | Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage | | |
| Test conclusion | The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11.<br>Date of issue: 27/06/2020 | | |
| Note | The test results presented in this report relate only to the submitted sample as received. | | |

江苏国健检测技术有限公司 检验专用章

Lu Bing
Approver (name, signature)

Wan Heng
Reviewer (name, signature)

Yang Ying
Chief Tester (name, signature)

| | |
|---|---|
| **Sample description:** | — |
| **Test item particulars:** | |
| Type of use ..... : | ☐ re-useable particle filtering half mask<br>☒ single shift only particle filtering half mask |
| Classes of devices..... : | ☐ FFP1 ☒ FFP2 ☐ FFP3 |
| Exhalation valve(s)..... : | ☐ Yes ☒ No |
| Inhalation valve(s)..... : | ☐ Yes ☒ No |
| Designed to protect against both solid &liquid aerosols. : | ☒ Yes ☐ No |
| **Possible test case verdicts:** | |
| - Test case does not be required to the test object..... : | NRq（Not required） |
| - Test case does not apply to the test object..... : | N/A (Not Applicable) |
| - Test object does meet the requirement..... : | P (Pass) |
| - Test object does not meet the requirement..... : | F (Fail) |

**General remarks:**

The test results presented in this report relate only to the submitted sample as received.
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Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

**Environmental condition of the testing in this report:**

1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;

2) T.C. Temperature conditioned:

a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;

and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | Test result | Single item decision |
|---|---|---|---|---|---|---|
| 1 (7.3) | Visual inspection | Marking/ information | — | Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10 | The clause were not required | NRq |
| 2 (7.4) | Packaging | Visual inspection | — | 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. | Particle filtering half masks packaged and protected against mechanical damage and contamination. | Pass |
| 3 (7.5) | Material | Visual inspection | — | 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. | Materials were suitable withstand handling and wear. | Pass |
| | | | — | After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. | Sample 1: neither facepiece nor straps have mechanical failure | |
| | | | | | Sample 2: neither facepiece nor straps have mechanical failure | |
| | | | | | Sample 3: neither facepiece nor straps have mechanical failure | |
| | | | — | After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse. | Sample 4: no collapse | |
| | | | | | Sample 5: no collapse | |
| | | | | | Sample 6: no collapse | |
| | | | — | Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. | Not constitute a hazard or nuisance for the wearer | |
| 4 (7.6) | Cleaning and disinfecting | | — | Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5. | ☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer | N/A |
| | | | — | With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11. | ☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer | |

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | Test result | | | | Single item decision |
|---|---|---|---|---|---|---|---|---|---|
| 5 (7.7) | Practical performance | Head harness comfort | — | Head harness should be comfort. | Sample 1: has the feeling of comfortable wearing | | | | Pass |
| | | | | | Sample 2: has the feeling of comfortable wearing | | | | |
| | | Security of fastenings | — | Fastenings are safe and reliable | Sample 1: All fastenings are firm | | | | |
| | | | | | Sample 2: All fastenings are firm | | | | |
| | | Field of vision | — | Field of vision is acceptable | Sample 1: Having a wider visual field | | | | |
| | | | | | Sample 2: Having a wider visual field | | | | |
| 6 (7.8) | Finish of parts | Visual inspection | — | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. | Parts of the device have no sharp edges and burrs | | | | Pass |
| 7 (7.9.2) | Leakage— Penetration of filter material | Sodium chloride | — | ≤**6%** | A.R.[1] | 0.1% | 0.2% | 0.1% | Pass |
| | | | | | S.W.[1] | 0.1% | 0.1% | 0.1% | |
| | | | | | M.S+ T.C.[2] | 0.2% | 0.3% | 0.2% | |
| | | Paraffin oil | — | ≤**6%** | A.R.[1] | 0.2% | 0.1% | 0.1% | Pass |
| | | | | | S.W.[1] | 0.1% | 0.1% | 0.2% | |
| | | | | | M.S+ T.C.[2] | 0.3% | 0.4% | 0.4% | |
| | | [1] average penetration over a time of 30s, beginning 3 min after the start of the test reported<br>[2] max. penetration during exposure test reported;<br>Note:<br>The penetration of the filter of the particle filtering half mask shall meet the requirements below:<br>Maximum penetration of sodium chloride aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%<br>Maximum penetration of paraffin oil aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% | | | | | | | |

| S.No. (Cl.No.) | Test item | Unit | Technical requirements | Test result | | Single item decision |
|---|---|---|---|---|---|---|
| 8 (7.10) | 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. | A.R. | 5 pcs all don't cause irritation | Pass |
| | | | | T.C. | 5 pcs all don't cause irritation | |
| 9 (7.11) | Flammability | — | When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame. | A.R. | The Sample is burning. Burning time:0.1s | Pass |
| | | | | | The Sample is burning. Burning time:0.1s | |
| | | | | T.C. | The Sample is burning. Burning time:0.1s | |
| | | | | | The Sample is burning. Burning time:0.1s | |
| 10 (7.12) | 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). Remark: 3 half masks (S1, S2 and S3) A.R. tested. | Sample 1 | 0.7224% | Pass |
| | | | | Sample 2 | 0.7230% | |
| | | | | Sample 3 | 0.7241% | |
| | | | | average | 0.72% | |
| 11 (7.13) | 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 | A.R. | All of 5 pieces particle filtering half mask meet the requirements | Pass |
| | | | | T.C. | All of 5 pieces particle filtering half mask meet the requirements | |
| 12 (7.14) | Field of vision | — | The field of vision is acceptable if determined so in practical performance tests. | The two samples both have a wider visual field | | Pass |

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | Test result | Single item decision |
|---|---|---|---|---|---|---|
| 13 (7.15) | Exhalation valve(s) | Visual inspection | — | A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. | No exhalation valve(s) | N/A |
| | | | — | 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. | No exhalation valve(s) | |
| | | Flow conditioning | — | 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. | No exhalation valve(s) | |
| | | Strength of attachment of exhalation valve housing | — | When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s. | No exhalation valve(s) | |
| 14 (7.17) | Clogging— Breathing resistance & Penetration of filter material | | — | Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3. | ☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask | N/A |
| 15 (7.18) | Demountable parts | | — | All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. | No demountable parts | N/A |

**Table A- Leakage—Total Inward Leakage**

| S.No. (Cl.No.) | Test item | Unit | Technical requirements[1)] | Test result | | | | | | | Single item decision |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 16 (7.9.1) | Leakage—Total inward leakage | — | At least 46 out of the 50 individual exercise results shall be not greater than **11%**; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than **8%.** | Exercises | E1 (%) | E2 (%) | E3 (%) | E4 (%) | E5 (%) | TIL (%) | Pass |
| | | | | A.R. | 4.5 | 5.6 | 5.3 | 5.5 | 4.9 | 5.2 | |
| | | | | | 4.2 | 4.9 | 4.7 | 4.8 | 4.3 | 4.6 | |
| | | | | | 5.1 | 5.0 | 5.4 | 5.9 | 5.5 | 5.4 | |
| | | | | | 4.9 | 5.7 | 6.1 | 5.8 | 5.3 | 5.6 | |
| | | | | | 4.6 | 5.3 | 5.5 | 5.2 | 4.8 | 5.1 | |
| | | | | T.C. | 4.7 | 5.4 | 5.6 | 5.5 | 5.1 | 5.3 | |
| | | | | | 4.5 | 5.4 | 5.6 | 5.3 | 4.9 | 5.1 | |
| | | | | | 4.0 | 4.5 | 4.6 | 4.8 | 4.1 | 4.4 | |
| | | | | | 4.5 | 5.3 | 5.1 | 5.0 | 4.6 | 4.9 | |
| | | | | | 5.0 | 6.0 | 5.9 | 6.1 | 5.8 | 5.8 | |

Note 1:
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
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.

**Table A-1- Test subjects—Facial dimension**

| Test Subject No. | Length of face (mm) | Width of face (mm) | Depth of face (mm) | Width of mouth (mm) |
|---|---|---|---|---|
| 1 | 120 | 130 | 109 | 59 |
| 2 | 122 | 140 | 115 | 65 |
| 3 | 119 | 160 | 139 | 55 |
| 4 | 112 | 122 | 119 | 63 |
| 5 | 110 | 130 | 118 | 60 |
| 6 | 115 | 119 | 110 | 59 |
| 7 | 112 | 123 | 113 | 55 |
| 8 | 103 | 130 | 100 | 50 |
| 9 | 118 | 139 | 130 | 63 |
| 10 | 120 | 135 | 125 | 50 |

**Table B- Breathing Resistance**

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements[1)] | Test result | | | | | | Single item decision |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Exercises | Facing directly ahead | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | |
| 17 (7.16) | Breathing resistance | Inhalation 30 L/min | mbar | ≤0.7 | A.R. | 0.5 | 0.5 | 0.6 | 0.6 | 0.5 | Pass |
| | | | | | | 0.5 | 0.6 | 0.5 | 0.5 | 0.6 | |
| | | | | | | 0.6 | 0.5 | 0.5 | 0.5 | 0.5 | |
| | | | | | S.W. | 0.5 | 0.6 | 0.5 | 0.6 | 0.5 | |
| | | | | | | 0.6 | 0.5 | 0.5 | 0.5 | 0.5 | |
| | | | | | | 0.5 | 0.5 | 0.6 | 0.5 | 0.6 | |
| | | | | | T.C. | 0.6 | 0.5 | 0.5 | 0.5 | 0.5 | |
| | | | | | | 0.5 | 0.5 | 0.6 | 0.5 | 0.6 | |
| | | | | | | 0.5 | 0.6 | 0.5 | 0.6 | 0.5 | |
| | | Inhalation 95 L/min | | ≤2.4 | A.R. | 1.6 | 1.7 | 1.6 | 1.7 | 1.6 | Pass |
| | | | | | | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | |
| | | | | | | 1.7 | 1.6 | 1.7 | 1.6 | 1.7 | |
| | | | | | S.W. | 1.6 | 1.7 | 1.6 | 1.6 | 1.6 | |
| | | | | | | 1.7 | 1.6 | 1.6 | 1.7 | 1.6 | |
| | | | | | | 1.6 | 1.6 | 1.7 | 1.6 | 1.7 | |
| | | | | | T.C. | 1.7 | 1.6 | 1.6 | 1.7 | 1.6 | |
| | | | | | | 1.6 | 1.6 | 1.7 | 1.6 | 1.6 | |
| | | | | | | 1.6 | 1.7 | 1.6 | 1.6 | 1.7 | |
| | | Exhalation 160 L/min | | ≤3.0 | A.R. | 2.3 | 2.3 | 2.3 | 2.2 | 2.3 | Pass |
| | | | | | | 2.3 | 2.2 | 2.3 | 2.3 | 2.2 | |
| | | | | | | 2.2 | 2.3 | 2.2 | 2.3 | 2.2 | |
| | | | | | S.W. | 2.3 | 2.2 | 2.3 | 2.2 | 2.3 | |
| | | | | | | 2.2 | 2.3 | 2.2 | 2.3 | 2.3 | |
| | | | | | | 2.3 | 2.2 | 2.3 | 2.2 | 2.2 | |
| | | | | | T.C. | 2.2 | 2.3 | 2.2 | 2.3 | 2.2 | |
| | | | | | | 2.3 | 2.2 | 2.3 | 2.3 | 2.3 | |
| | | | | | | 2.3 | 2.3 | 2.3 | 2.2 | 2.3 | |

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

**Table C- Clogging Test—Breathing resistance**

| S.No. (Cl.No.) | Test item[1) 2)] | | Unit | Technical requirements[1) 2)] (mbar) | Test result | | | | | | Single item decision |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Exercises | Facing directly ahead | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | |
| 18 (7.17) | Clogging test— Breathing resistance | Inhalation 95 L/min | mbar | — | A.R. | | | | | | N/A |
| | | | | | T.C. | | | | | | |
| | | | | | | | | | | | |
| | | Exhalation 95 L/min | mbar | — | A.R. | | | | | | N/A |
| | | | | | T.C. | | | | | | |
| | | | | | | | | | | | |

Note 1: Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 l/min continuous flow;

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

Note 2: 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 95 l/min continuous flow.

**Table D- Clogging Test—Penetration of filter material**

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | Test result | | Single item decision |
|---|---|---|---|---|---|---|---|
| 19 (7.17) | Clogging test- Penetration of filter material | Paraffin oil | — | — | A.R. | | N/A |
| | | | | | T.C. | | |
| | | | | | T.C. | | |

Note: Maximum penetration of test aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

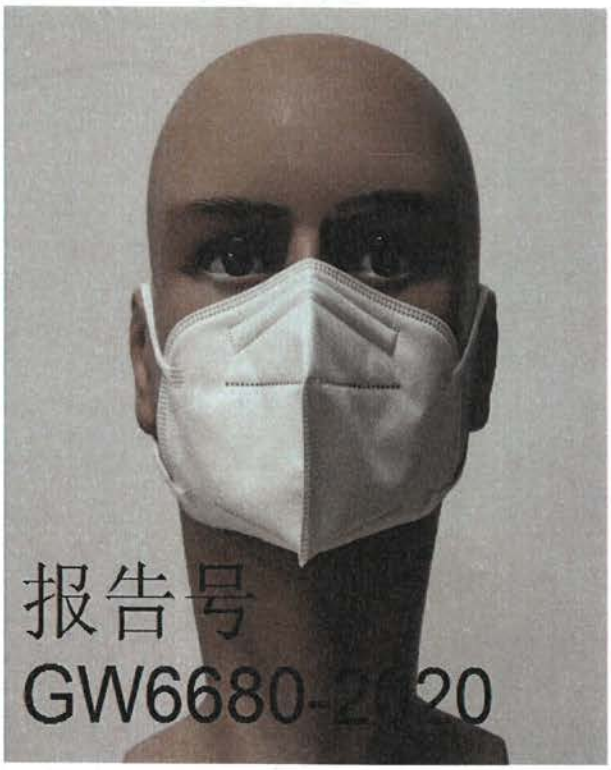
Abbreviations :

| | | |
|---|---|---|
| A.R. As received | M.S. Mechanical strength | S.W. Simulated wearing treatment |
| T.C. Temperature conditioned | F.C. Flow conditioned | C.D. Cleaning and Disinfecting |

## Annex A- Estimates of the uncertainty of measurement

| Test item | Uncertainty |
|---|---|
| Total inward leakage | 2.98% |
| Penetration of filter material | 1.00% |
| Flammability | 1.00% |
| Carbon dioxide content of the inhalation air | 0.93% |
| Breathing resistance | 1.90% |

## Annex B- Sample Photo




The end