

**Documentation No.:** *Face mask / CNJW-2020*

**Creation Date:** *2020-10-20*

**Revision No.:** *Version 1*

**Revision Date:** /

# Technical File to comply with the requirements of the Personal Protective Equipment Regulation (EU) 2016/425

Respiratory protective devices - Filtering half masks to protect against particles

EN 149:2001 +A1:2009

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**Section 2**

**Applicant/Manufacture & Product General Information**

1. Manufacturer General Information

Manufacturer Name	Cangnan County Jiawei Bag Making Factory
Manufacturer Address	No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China
Supplier/Factory Name	Cangnan County Jiawei Bag Making Factory
Supplier/Factory Address	No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China
Destination Country	European countries
Brand name	 "JW"

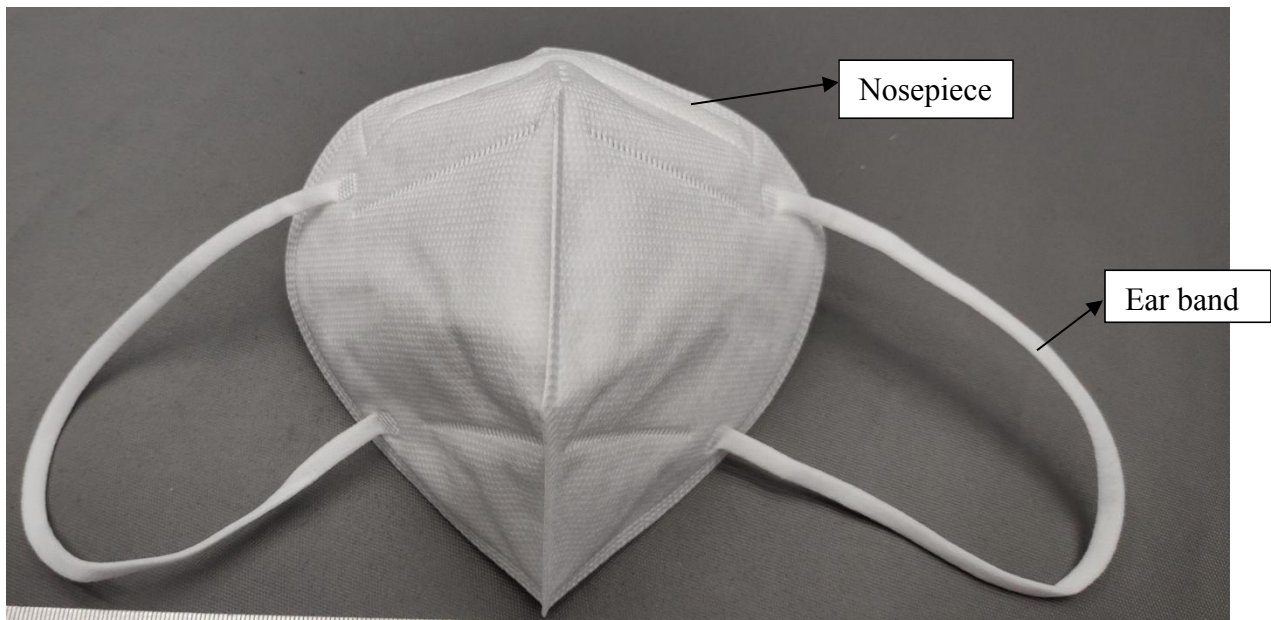
**Section 3**

**Product Specifications**

1. Product General Information

Description of products	Face mask
Products Colour	WHITE
Product style/order No	CNJW-2020
Product Type	Non-reusable, folded, particle filtering half mask
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

2. Product Photograph(s)





## Product Details

Outer Layer 1: 100% polypropylene non-woven fabric, white, 50gsm Middle

Layer 2: 100% polypropylene hot air cotton, white, 50gsm

Middle Layer 3: 100% polypropylene melt-blown fabric, white, 25gsm

Middle Layer 4: 100% polypropylene melt-blown fabric, white, 25gsm

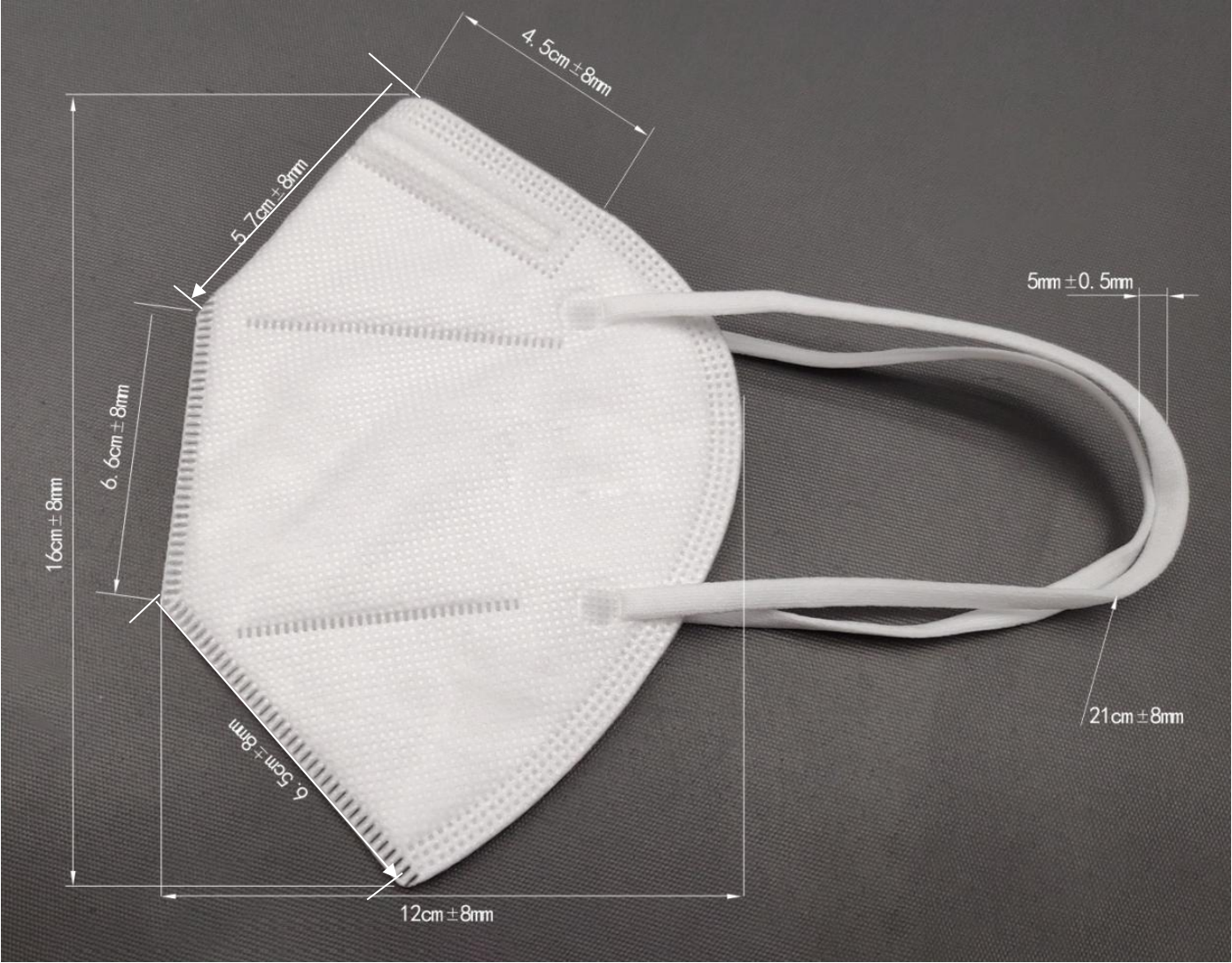
Inner Layer 5: 100% polypropylene non-woven fabric, white, 25gsm



## 3. Parts List

<b>Parts</b>	<b>Components</b>	<b>Supplier name and address</b>
Filtering facepiece	Out layer (first layer): 50g/m <sup>2</sup> 100%Polypropylene non-woven fabric white color	Wenzhou Yuzhe Technology Co., Ltd. No.35 of Taoyuan Road, Xiaojiang Town, Pingyan County, Wenzhou City, Zhejiang Province, China
	Second layer: 50 g/m <sup>2</sup> 100% polypropylene hot air cotton, white color	Wenzhou Yinfeng Fibre Products Co., Ltd. No. 1 of Daqiao Industrial Are, Canna County, Wenzhou City, Zhejiang Province, China
	Middle Layer (third layer): 25 g/m <sup>2</sup> 100% polypropylene melt-blown fabric, white color	Qingdao Guoen Meltblown Industry Co., Ltd. No.2 Road of Qingda Industrial Park, Jihongtang Street, Chengyang District, Qingdao City, Shangdong Province, China.
	Fourth layer: 25 g/m <sup>2</sup> 100%polypropylene melt-blown fabric, white color	Qingdao Guoen Meltblown Industry Co., Ltd. No.2 Road of Qingda Industrial Park, Jihongtang Street, Chengyang District, Qingdao City, Shangdong Province, China
	Inside layer (fifth layer): 25 g/m <sup>2</sup> 100%Polypropylene non-woven fabric white color	Wenzhou Yuzhe Technology Co., Ltd. No.35 of Taoyuan Road, Xiaojiang Town, Pingyan County, Wenzhou City, Zhejiang Province, China
Ear band	85%nylon, 15%Spandex white color	Pingyang County Jinyu Textile Co., Ltd. No.1-5, Building 11, Xinya Garden, Xinya Village, Mabu Town, Pingyang County, Wenzhou City, Zhejiang Province, China.
Nosepiece	40% polypropylene + 60% iron wire white color	Yiwu City Fengxing Technology Co., Ltd. 1/F, No. 70, Xiazhang Village, Fotang Town, Yiwu City, Zhejiang Province, China.

4. Product(s) Dimension

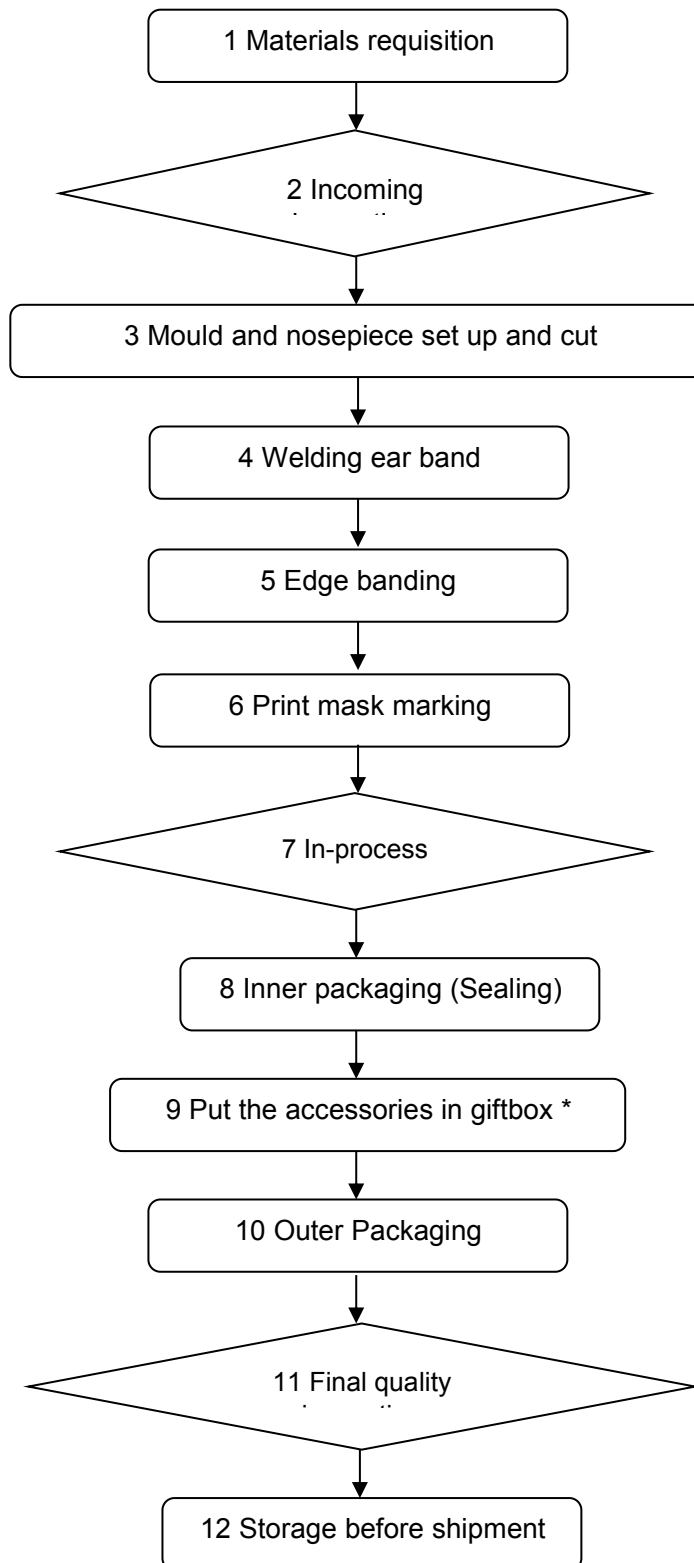


Nosepiece: L=82mm±5mm, W=5mm±0.5mm

## **Section 4**

### **Manufacture Information**

#### 1. Sequence of Manufacture



Remark: \* means: the accessories including as user information and 10pcs masks/ giftbox.  
Packaging: Each one by inner packaging, 10 inner packaging in one giftbox

## 2. Quality Control Procedure

No.	Procedure	Quality Control
1	Raw material control	The 3rd party testing under EN 149 report should be submitted for the filter materials. Supplier should also submit the "Declaration of Innocuousness" of raw materials. Bulk production products will be sent to 3rd party lab to retest EN 149, from batch to batch/year to year to ensure performance. Rework the problem goods. Make sure all the goods are in good quality.
2	In house lab testing	The basic testing e.g. Penetration of filter material, breathing resistance will be checked by own lab. The test method is EN 149. Reject the raw materials and products if they cannot meet the minimum requirement.
3	Mould and cut	Mould and cut as per the specification, make sure the working site is clear to avoid pollution.
4	Nosepiece set up	Set up the nosepiece and check the strength of the attachment. Adjust the procedure if any failure.
5	Seal the ear band	The ear band should be sealed with durability. For tensile test of the samples, each ear band of the folding mask must conform to the requirements. No slippage or fracture shall occur when each ear band bear the tension of 10N and 10S. And take notes.
6	Breath Inspiratory resistance, filtration efficiency	Check reference to EN 149, Breath resistance and filtration efficiency meet the product specification. Filtration efficiency is the most critical index of masks, once there is an unqualified situation, immediately seal this batch of goods, is strictly prohibited to send to the customer. Analyse the causes and find solutions.
7	Total inward leakage	Total inward leakage is the critical criteria for final respirator, bulk production respirator will be sent to 3rd party lab to test TIL according to EN 149 from each year.
8	Appearance inspection	the basic structure, surface and parts of the product shall be inspected in detail, and all information provided by the manufacturer shall be complete.
9	Ergonomics	The QC will carry out the fitting test for the final products. Make sure the fitting is correct.
10	Packaging	check the outgoing products against the production specifications to see if the packaging method is correct. Including pp bag, color box, outer box and packing quantity is correct.
11	Identification	check whether the name, trademark, model, production date and other information is complete and correct.
12	Finished product inspection report	all inspections must be conducted according to the requirements and the finished product inspection report must be filled in. Place in the specified area.

**The Third Party Tests**

Material performance and final products performance (especially the filtration efficiency, breathability, Total inward leakage) will be carried out batch to batch/year to year by an external independent ISO 17025 accredited test house (or equivalent). See Section 8: Test reports.



**Section 5****Essential Health and Safety Requirements**

In accordance with Personal Protective Equipment Regulation (EU) 2016/425 - Annex II

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
1. General requirements applicable to all PPE (PPE must provide adequate protection against the risks against which it is intended to protect)	See section 6, Manufacturer`s Instructions and Information
1.1. Design principles	-
1.1.1. Ergonomics	5, 7.7, 7.9
1.1.2. Levels and classes of protection	See section 2, Product Specifications
1.1.2.1. Optimum level of protection possible	5, 7.7, 7.9, 7.12
1.1.2.2. Classes of protection appropriate to different levels of risk	7.9
1.2. Innocuousness of PPE	-
1.2.1. Absence of inherent risk and other nuisance factors	7.6; 7.12; 7.14; 7.16
1.2.1.1. Suitable constituent materials	7.5; 7.6; 7.7; 7.10; 7.11
1.2.1.2. Satisfactory surface conditions of all PPE parts in contact with the User	7.7; 7.8
1.2.1.3. Maximum permissible user impediment	7.7; 7.14
1.3. Comfort and effectiveness	-
1.3.1. Adaptation of PPE to user morphology	7.7
1.3.2. Lightness and design strength	7.4; 7.5; 7.7
1.3.3. Compatibility of different classes or types of PPE designed for simultaneous use	N/A
1.3.4. Protective clothing containing removable protectors	N/A
1.4. Manufacturer`s instructions and information	10
2. Additional Requirements Common to Several Types of PPE	-
2.1. PPE incorporating adjustment systems	7.13
2.2. PPE enclosing the parts of the body to be protected	N/A
2.3. PPE for the face, eyes and respiratory system	7.14
2.4. PPE subject to ageing	7.6; 9; 10
2.5. PPE which may be caught up during use	N/A
2.6. PPE for use in potentially explosive atmospheres	10
2.7. PPE intended for rapid intervention or to be put on or removed	N/A

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
rapidly	
2.8. PPE for intervention in very dangerous situations	10
2.9. PPE incorporating components which can be adjusted or removed by the user	7.13; 7.18
2.10. PPE for connection to complementary equipment external to the PPE	N/A
2.11. PPE incorporating a fluid circulating system	N/A
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	9
2.13. PPE capable of signaling the user's presence visually	N/A
2.14. 'Multi-risk' PPE	N/A
3. Additional Requirements Specific to Particular Risks	-
3.1. Protecting against mechanical impact	-
3.1.1. Impact caused by falling or ejected objects and collision of parts of the body with an obstacle	N/A
3.1.2. Falls	N/A
3.1.2.1. Prevention of falls due to slipping	N/A
3.1.2.2. Prevention of falls from a height	N/A
3.1.3. Mechanical vibration	N/A
3.2. Protection against static compression of a part of the body	N/A
3.3. Protection against mechanical injuries (abrasion, perforation cuts, bites)	N/A
3.4. Protection in liquids	-
3.4.1. Prevention of drowning	N/A
3.4.2. Buoyancy aids	N/A
3.5. Protection against the harmful effects of noise	N/A
3.6. Protection against heat and/or fire	-
3.6.1. PPE constituent materials and other components	N/A
3.6.2. Complete PPE ready for use	N/A
3.7. Protection against cold	-
3.7.1. PPE constituent materials and other components	N/A
3.7.2. Complete PPE ready for use	N/A

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
3.8. Protection against electric shock	-
3.8.1. Insulating equipment	N/A
3.8.2. Conductive equipment	N/A
3.9. Radiation protection	-
3.9.1. Non-ionising radiation	N/A
3.9.2. Ionising radiation	N/A
3.9.2.1. Protection against external radioactive contamination	N/A
3.9.2.2. Protection against external irradiation	N/A
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents	-
3.10.1. Respiratory protection	7.6; 7.7; 7.8; 7.9; 7.12; 7.16; 7.17; 9; 10
3.10.2. Protection against cutaneous and ocular contact	N/A
3.11. Diving equipment	N/A

## **Section 6**

### **Instruction for use**

Please read this User Information Sheet carefully before using this product. This product complies with the requirements of EU Regulation (EU) 2016/425 for Personal Protective Equipment and meets the requirements of European standard EN 149:2001+A1:2009.

### **CHECK PRIOR TO USE**

The respirator must be selected properly for intended application. An individual risk assessment must be evaluated. Check the respirator that it is undamaged with no visible defects. Check that the expiry date has not been reached (see the packaging). Check the protection class (FFP1 NR/ FFP2 NR/ FFP3 NR) is appropriate for the product used and its concentration. Do not use the mask if a defect is present or the expiry date has been exceeded.

### **INTEND USE OF THIS PPE:**

These devices are designed to protect against both solid and liquid aerosols. And be used in industries such as Textile, abattoirs, metallurgy, construction, iron and steel industries, etc. To Protects against dusts, mists and fumes containing calcium carbonate, clay, kaolin, cellulose, cotton, flour, ferrous metals, vegetal and mineral oils, metal-working fluids.

### **THIS PRODUCT IS DESIGNED TO PROTECTIVE AGAINST THE RISKS:**




<b>Risk</b>	<b>Standard Clause</b>	<b>Assessment method</b>
Penetration of particle	EN 149:2001+A1:2009, clause 7.9.1 and 7.9.2	Total inward leakage test, Penetration of filter material

### **APPLICATION/ LIMITATIONS**

This respirator is suitable for use in protection against the non-toxic solid and liquid aerosols. Do not use out of the scope of use defined in the warnings. Failure to properly use this product may result in serious health damage or death.

**FFP2 NR:** Filter Efficiency 94%; Allocated Protection Factor (FPA) is 10, Examples of applications are Sanding of soft wood, composite materials, rust, putty, plaster, plastics / cutting, deburring, grinding, drilling of metal.

**EXPLANATION OF MARKING**

Marking	Description on label	Explanation
		Brand name
	CNJW-2020	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification Filter Efficiency 94%, non reusable
		CE marking & notified body number

**EASY TO USE/DONNING AND FITTING**



Keep the front outside, and hang ear band over ears.

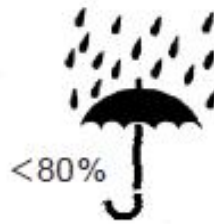
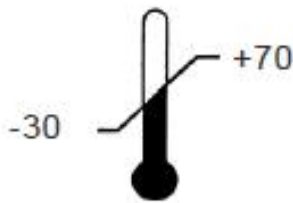
Close to the face, and stretch the mask until it fully covers the nose mouth and chin.



Adjust the nosepiece and press it, and keep it closely to nose and face.

To check fit, cup both hands over the mask and exhale vigorously. If air flows around nose, tighten the nosepiece. If air leaks around the edge, reposition the ear band for better fit. Re-check the seal and repeat the procedure until the mask is sealed properly.

**TEMPERATURE AND HUMIDITY RANGE OF STORAGE CONDITION**



**END OF SHELF LIFE**



2022/06

**Date of manufacture: 2020/07/28**

**WARNINGS**

1. Failure to follow all instructions and limitations on the use of this product, or failure to achieve proper fit, may result in damage to your health or death or will not provide the expected level of protection
2. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when the oxygen concentration is less than 19.5%.
3. Do not use when concentrations of contaminants are immediately dangerous to health or life. Do not use this product in an explosive atmosphere.
4. Facial hair, beards and certain facial characteristics may reduce the effectiveness of this respirator.
5. "NR" means non reusable, this particle filtering half mask shall not be used for more than one shift.

The length of time this respirator can be used depends on contaminants present but should not exceed one shift. The respirator should be replaced sooner if breathing becomes difficult.

6. Respirator should be discarded after use or when it becomes damaged or deformed in any way; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult.
7. The respirators must be stored and transported in their original package and protected by the storage temperature and humidity as suggested by the manufacturer.

**Manufacturer:** Cangnan County Jiawei Bag Making Factory

Address: No. 39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China.

EU declaration of conformity can be accessed at: <http://www.cnxjwzdc.com/>

Detailed content of the Instructions and information notice is the responsibility for manufacture

**Made in China**

EU type-examination for Regulation (EU) 2016/425 by Notified Body Number: 0598

SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.

## **Section 7**

### **Markings**

1. Product Marking



Remark: The height of the CE marking is 6.0mm.

2. Package Marking

See Appendix A bag package.

See Appendix B giftbox package.

Height of CE marking in bag package is 10.0mm.

Height of CE marking in giftbox package is 16.0mm.

## **Section 8**

### **Test reports**

<b>Clause and Tests in EN 149</b>	<b>Test Report No.</b>
EN 149:2001+A1:2009	SL52035297133901TX

**Section 9**

**EU DECLARATION OF CONFORMITY**

Manufacturer

Name: Cangnan County Jiawei Bag Making Factory

Address: No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

declares that the new PPE described hereafter

Description of products	Face mask
Product style/order No	CNJW-2020
Product colour and type	White, Non-reusable, folded, particle filtering half mask

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate FI????

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598.

Signed for on behalf of Company

Name: Yankun Xiang

Position: General manager

Signature:

yankunxiang

Date: 10/20/2020





**Section 10**

**DECLARATION OF MATERIAL INNOCUOUSNESS**

The manufacturer or his authorized representative established in the Community:

Manufacturer: Cangnan County Jiawei Bag Making Factory

Address: No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

declares that the materials which are coming into contact with the human skin and body used on the new PPE described hereafter

Product description:

Description of products	Face mask
Product style/order No	CNJW-2020
Product colour and type	White, Non-reusable, folded, particle filtering half mask

are known not to undergo appreciable alteration from contact with sweat or with substances likely to be found in toiletries and are known not to cause any harm to human skin and body.

Done at No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

Signed for on behalf of Company

Name: Yankun Xiang

Position: General manager

Signature:

*yankunxiang*

Date: 10/20/2020

