

# BIWEIKANG MASK

## FFP2



**Test Report**                      **SL52035274456801TX**                      **Date: August 10, 2020**                      **Page 1 of 6**  
 YIWUBIWEIKANG LABOR PROTECTION PRODUCTS CO., LTD.  
 1ST FLOOR. NO.162, CHOUYI WEST ROAD, HUANGLINSHAN INDUSTRIAL ZONE, YITING TOWN, YIWU CITY, ZHEJIANG PROVINCE.

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description                      :    (A)Half Mask

Style No.                                    :    9600

Sample Color                             :    (A)white

Manufacturer                            :    YIWUBIWEIKANG LABOR PROTECTION PRODUCTS CO., LTD.

Previous No.                              :    SL52035261874201TX

Country of Destination                :    European countries

Test Performed                         :    Selected test(s) as requested by applicant

Sample Receiving Date                :    Jul 29, 2020

Testing Period                            :    Jul 29, 2020 - Aug 10, 2020

Test Result(s)                            :    Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Based on the results of the tests reported and the previous report SL52035261874201TX issued on Jul 17, 2020, our Lab concluded that the recommendation level can be as below.

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 7.7 Practical Performance**

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

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

**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 sharp edges or burrs.	No sharp edges or burrs	Pass

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**Clause 7.9.1 Total Inward Leakage**

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

Test Requirement	Results	Comment
<p>The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. 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</p> <p>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</p>	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

**Appendix 1: Summarization of Test Data**

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	5.55	5.28	6.51	6.62	6.18	6.03
Luo	2	A.R.	6.23	8.05	7.02	7.15	6.84	7.06
Lu	3	A.R.	5.51	6.10	6.01	6.38	7.01	6.20
Wang	4	A.R.	6.33	4.90	6.26	4.80	4.38	5.33
Bao	5	A.R.	7.84	6.77	6.08	6.23	8.75	7.13
Ding	6	T.C.	6.36	4.72	4.81	5.31	6.59	5.56
Li	7	T.C.	6.96	7.07	8.44	8.32	7.37	7.63
Chen	8	T.C.	5.89	6.39	4.84	5.89	5.01	5.60
Song	9	T.C.	7.39	6.63	5.23	6.06	6.25	6.31
Ye	10	T.C.	7.48	7.36	7.58	7.79	6.93	7.43

Facial Dimension(mm)

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

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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	Pass
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.	Comply	

**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 7.18 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

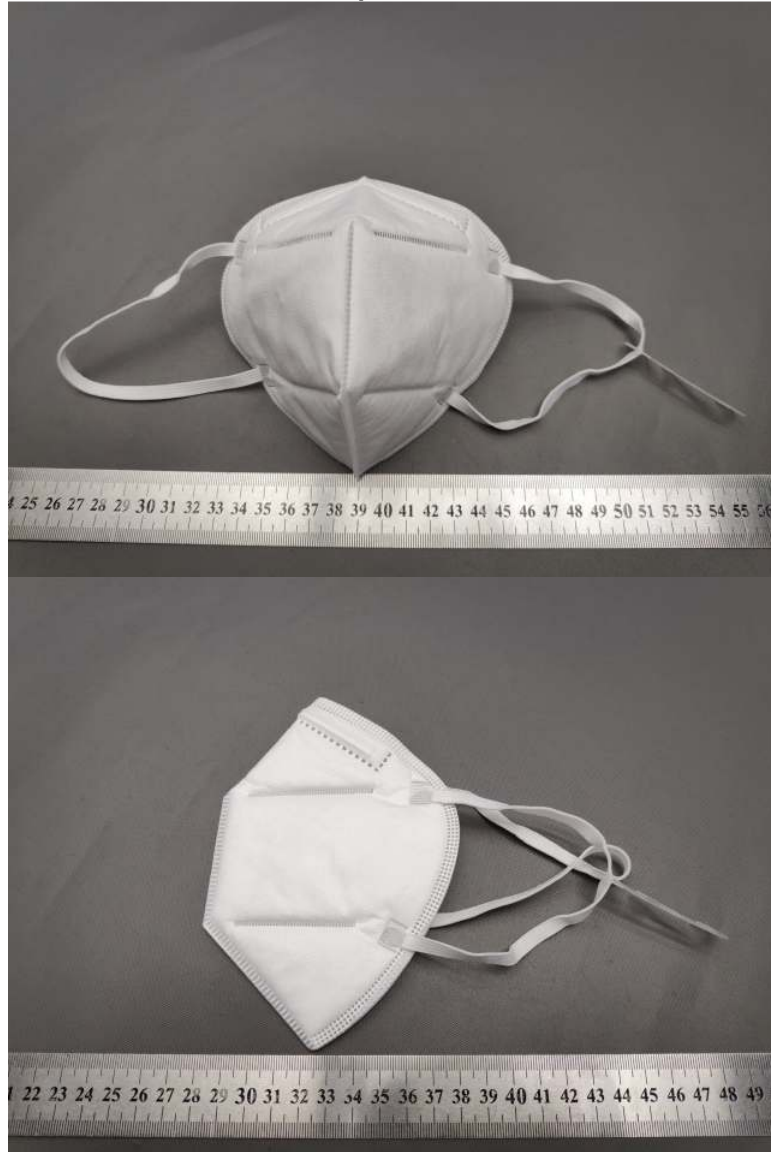
Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

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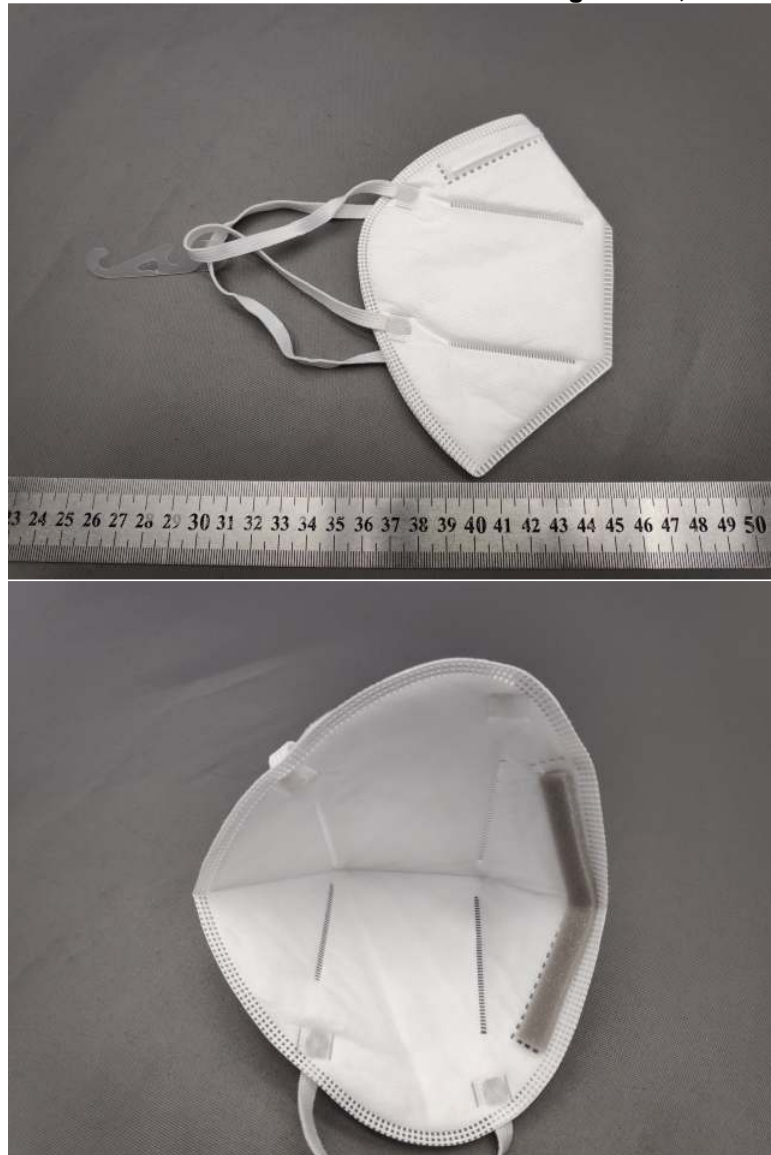
### Sample Photo



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\*\*\*End of Report\*\*\*



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Documentation No.: *Half mask / 9600*

Creation Date: *2020-09-09*

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



Section 1

Section	Contents
1	<u>Contents</u>
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4	<u>Manufacture Information</u> <u>(Sequence of Manufacture &amp; Quality Control Procedure)</u>
5	<u>Essential Health and Safety Requirements</u>
6	<u>Manufacturer's Instructions and Information</u>
7	<u>Markings</u>
8	<u>Test Reports</u>
9	<u>Declaration of Conformity</u>
10	<u>Declaration of Material Innocuousness</u>

**Section 2**

**Applicant/Manufacture & Product General Information**

1. Manufacturer General Information

Manufacturer Name	Yiwu Biweikang Labor Protection Products Co., Ltd.
Manufacturer Address	1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000
Supplier/Factory Name	Yiwu Biweikang Labor Protection Products Co., Ltd.
Supplier/Factory Address	1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000
Brand name (if any)	<b>BI WEI KANG</b>
Destination Country	European countries

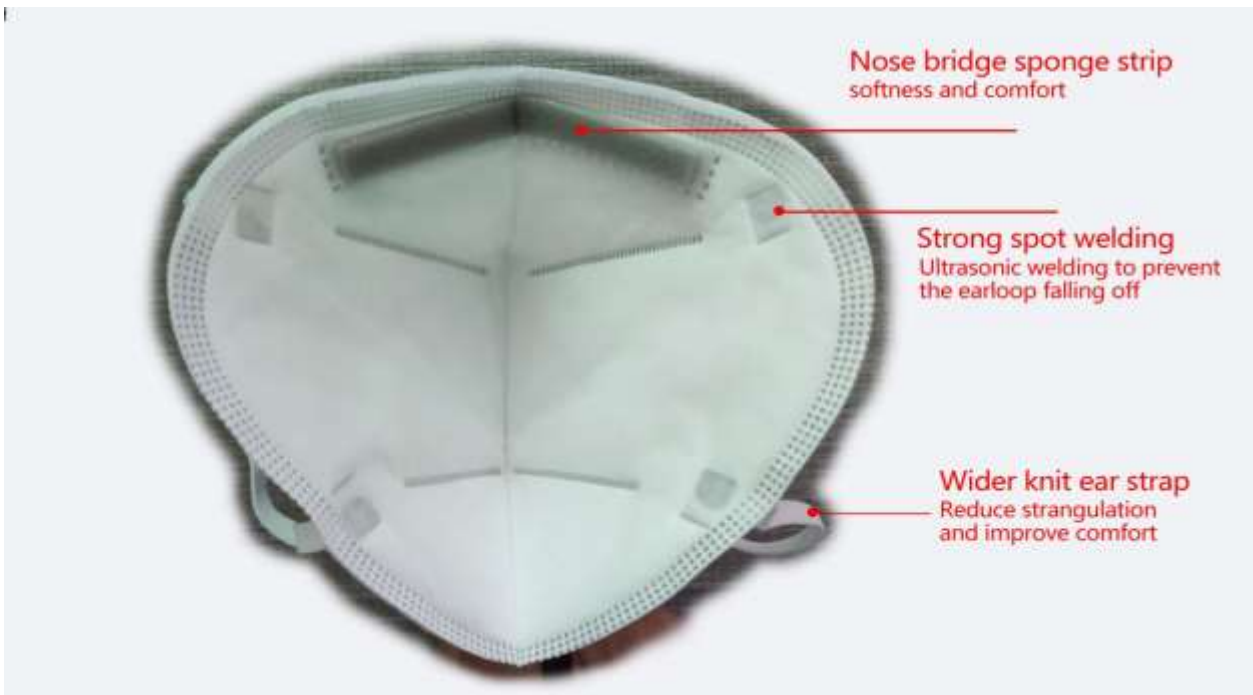
**Section 3**

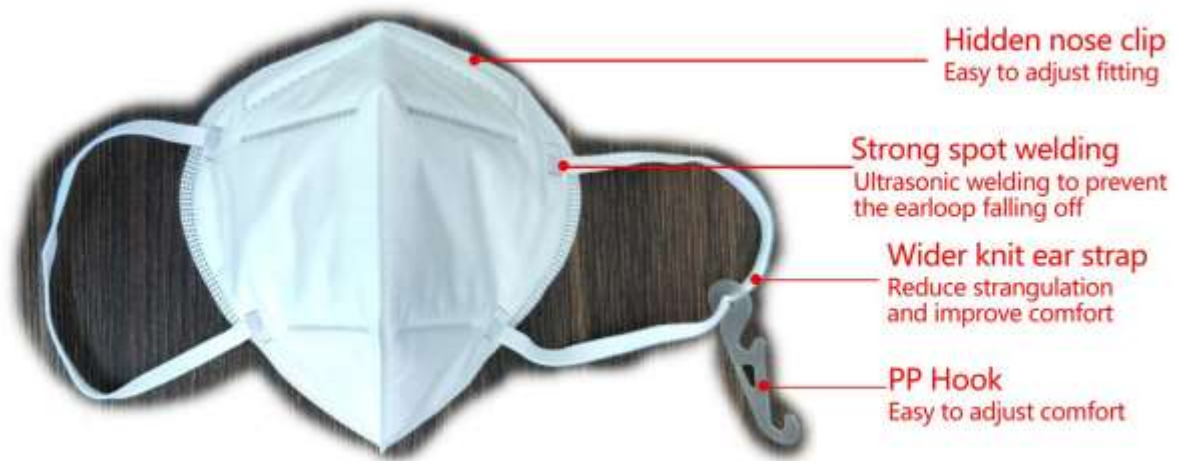
**Product Specifications**

1. Product General Information

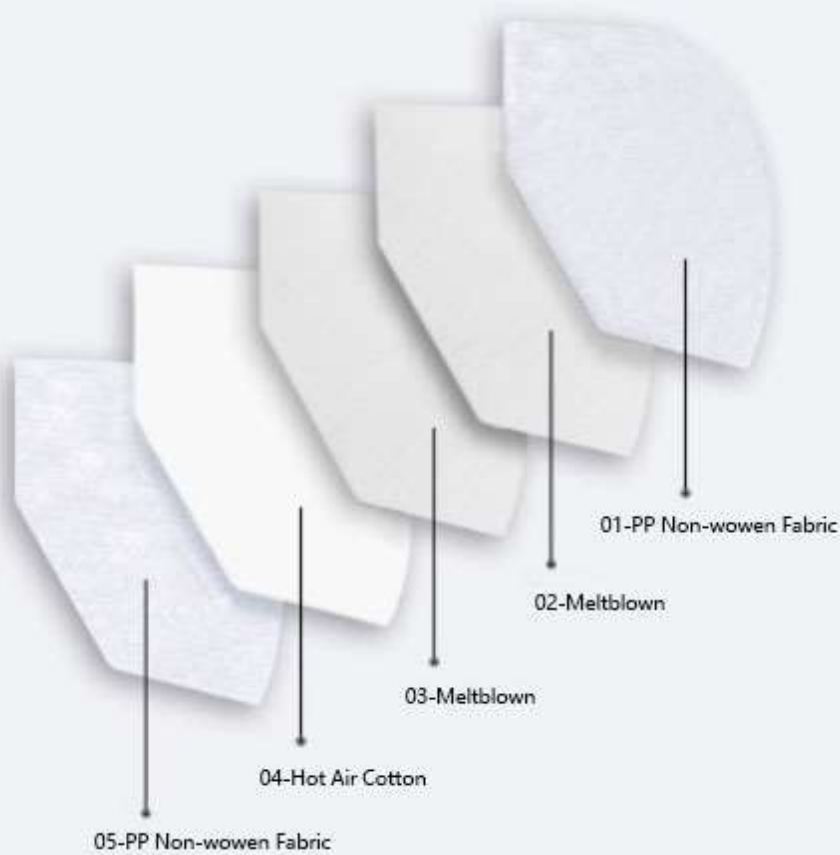
Description of products	Half mask
Products Colour	White
Product style/order No	9600
Product Type	Non-reusable, Folding mask, Particle filtering half mask
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

2. Product Photograph(s)





### 5-Ply Protection System

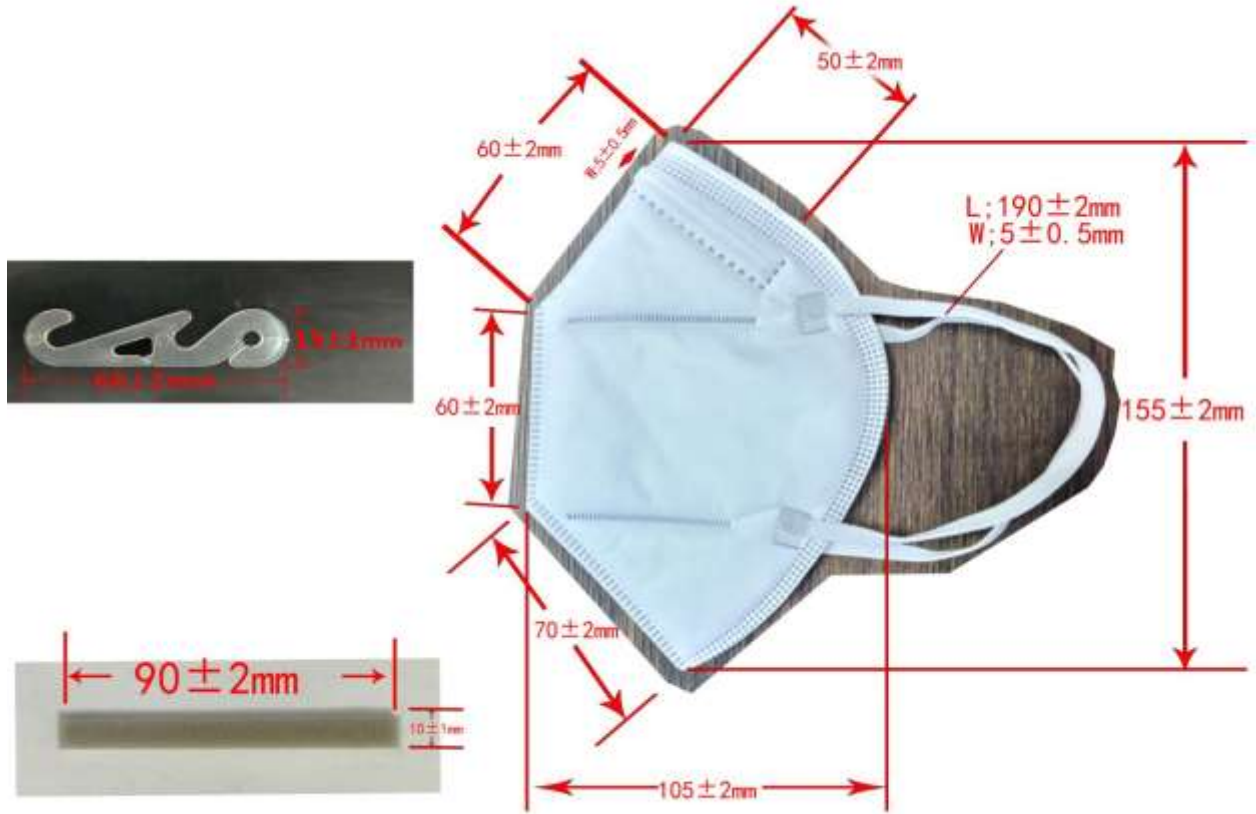


3. Parts List

Parts	Components	Supplier name and address
Filtering facepiece	Outer Layer 1: 100% polypropylene non-woven fabric, white, 50gsm	Zhejiang Yuanfan Nonwoven Co., Ltd. No. 19 Xiangyun Road, Lingjiang Park, Longzhou Street, Longyou County, Quzhou City, Zhejiang Province, China
	Middle Layer 2: 100% polypropylene melt-blown fabric, white, 25gsm	Jiangsu Bangmei New Materials Co., Ltd. Huaihe West Road, Sihong County, Suqian City, Jiangsu Province
	Middle Layer 3: 100% polypropylene melt-blown fabric, white, 25gsm	Jiangsu Bangmei New Materials Co., Ltd. Huaihe West Road, Sihong County, Suqian City, Jiangsu Province
	Middle Layer 4: 100% polypropylene melt-blown fabric, white, 60gsm	Hangzhou Lin'an Huahong Nonwoven Products Co., Ltd. No. 32, Shangyang Road, Yangdai Village, Jinnan Street, Lin'an District, Hangzhou City, Zhejiang Province
	Inner Layer 5: 100% polypropylene non-woven fabric, white, 25gsm	Zhejiang Yuanfan Nonwoven Co., Ltd. No. 19 Xiangyun Road, Lingjiang Park, Longzhou Street, Longyou County, Quzhou City, Zhejiang Province, China
Ear strap	85 polyester and 15% Spandex, white	Guangzhou Weibin Ribbon Co.,Ltd No. 3, Road 5, Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou City, Guangdong Province, China
Nose clip	58% iron and 42% Polypropylene, white	Dongguan Niufa Plastic Hardware Co., Ltd. Fuma Industrial Zone, Humen Automobile Port, Dongguan City, Guangdong Province, China
Nose bridge sponge strip	100% Polyurethane Sponge, gray	Dongguan Baolonghua Adhesive Products Co.,Ltd No.8, Alley 1, Zhangwu Street, Changli Town, Changping Town, Dongguan City, Guangdong Province, China
Adjustable hook	100% Polypropylene, transparent	Dongguan Niufa Plastic Hardware Co., Ltd. Fuma Industrial Zone, Humen Automobile Port, Dongguan City, Guangdong Province, China



4. Product(s) Dimension



**Section 4**

**Manufacture Information**

1. Sequence of Manufacture

1	Incoming materials inspection
2	Shaping and trimming
3	Welding ear straps
4	Fixture of nose clip
5	Performance Test
6	Pressing mask marking
7	Fixture the nose bridge sponge strip and hook
8	In-process inspection
9	Packaging: ten pieces in each bag package; 25 pieces in each box package. User information on each bag package, DOC are packed in each bag package; User information and DOC are packed in each box package.
10	Finished product inspection
11	Storage before shipment

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, strength of Exhalation valve (if any) 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	Nose clip set up	Set up the nose clip and check the strength of the attachment. Adjust the procedure if any failure.
5	Seal the ear strap	The ear strap should be sealed with durability.  For tensile test of the samples, each ear strap of the folding mask must conform to the requirements. No slippage or fracture shall occur when each ear strap 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 batch/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 rapidly	N/A
2.8. PPE for intervention in very dangerous situations	10

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
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
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



Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
3.9.2. 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**

**Manufacturer’s Instructions and Information**

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:**

Risk	Standard Clause	Assessment method
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
<b>BI WEI KANG</b> 9600 FFP2 NR EN149:2001+A1:2009 CE 0598	BI WEI KANG	Brand name
	9600	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification Filter Efficiency 94%, non reusable
	CE0598	CE marking & notified body number

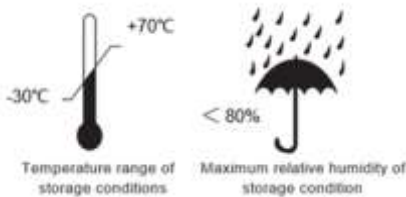
**Easy to Use/Donning and fitting**

	<p>1. Take the mask out of the bag</p>		<p>3. Position the mask under the chin covering mouth and nose. Use an adjustable hook to tighten the mask.</p>
	<p>2. Unfold the mask</p>		<p>4. Put your fingers in the middle of the nose wire, and move your fingertips along the side of your nose until the nose wire is completely pressed into the shape of the nose.</p>

**5. Fit Check**

- ◆ To test fit of the particle filtering half mask, cup both hands over mask and inhale sharply.
- ◆ If air flow felt in the nose area, re-adjust/tighten the nose clip.
- ◆ If air flows is felt around the edges of the respirator, re-position the particle half mask/ear straps to achieve a better fit.

**Temperature and humidity range of Storage Condition**



**End of shelf life**



**Date of manufacture: 2020/09**

**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:** Yiwu Biweikang Labor Protection Products Co., Ltd.

Address: 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China

Tel: 0579-85380610

EU declaration of conformity can be accessed with the product

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

**BI WEI KANG**  
**9600 FFP2 NR**  
**EN149:2001+A1:2009**  
**CE 0598**

Height of CE is 5.5 mm

Marking	Description on label	Explanation
<p style="text-align: center;"><b>BI WEI KANG</b>                      9600 FFP2 NR                      EN149:2001+A1:2009                      CE 0598</p>	BI WEI KANG	Brand name
	9600	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification Filter Efficiency 94%, non reusable
	CE0598	CE marking & notified body number



2. Package Marking

See Appendix A Bag Package

See Appendix B Box Package

Height of "CE" is 8 mm

**Section 8**

**Test reports**

	<b>Test Report No.</b>
EN 149:2001+A1:2009	SL52035286856801TX SL52035286858501TX
pH and AZO	SL52035287024901TX

**Section 9**

**EU DECLARATION OF CONFORMITY**

**Manufacturer**

Name: Yiwu Biweikang Labor Protection Products Co., Ltd.

Address: 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000

declares that the new PPE described hereafter

Description of products	half mask
Product style/order No	9600
Product colour and type	White and Non-reusable, Folding mask, 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: Li Qiming

Position: Assistant General Manager

Signature: *Li Qiming*

Date: *2020.8.27*



**Section 10**

**DECLARATION OF MATERIAL INNOCUOUSNESS**

The manufacturer or his authorized representative established in the Community:

Manufacturer: Yiwu Biweikang Labor Protection Products Co., Ltd.

Address: 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000

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	half mask
Product style/order No	9600
Product colour and type	White and Non-reusable, Folding mask, 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 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000

Signed for on behalf of Company

Name: Li Qiming

Position: Assistant General Manager

Signature: *Li Qiming*

Date: 2020.8.27



# Yiwu Biweikang Labor Protection Products Co., Ltd.

1<sup>st</sup> Floor, No.162, West Chouyl Road,  
Yiting Town, Yiwu City,  
Zhejiang Province,  
China 322000

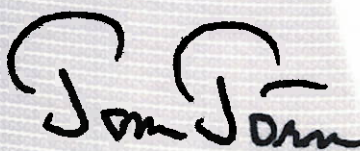
It is certified that the manufacturer's technical file and the PPE product detailed on  
page 2 have been assessed and found to be in accordance with

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

This certificate is valid from 04 November 2020 until 04 November 2025

1. Certified since 04 November 2020

Authorised by

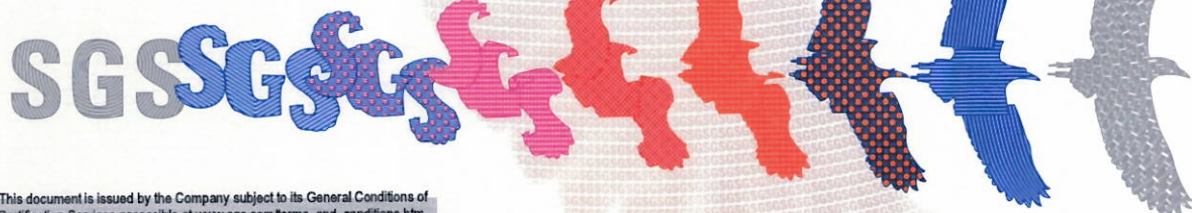


  
**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)

SGS FIMKO OY, Notified Body 0598

Takomotie 8, FI-00380, Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 2





# Yiwu Biweikang Labor Protection Products Co., Ltd.

## Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

BI WEI KANG (logo) 9600 particle filtering half mask, consisting of a five layer (Polypropylene) disposable face mask, with Polypropylene covered iron nose clip, Polyurethane sponge nose strip, Polypropylene adjustable hook and Polyester/Spandex Ear strap.

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.

The logo for FINAS, featuring a stylized triangle above the word 'FINAS' in a bold, sans-serif font. Below it, the text 'Finnish Accreditation Service' and 'S003 (EN ISO/IEC 17065)' is displayed.

**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)

This certificate is issued on 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:

Half mask /9600, Dated 09.09.2020

SGS Reference Number UK/CRS 242168

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



Certificate CN20/42531

The management system of

# Yiwu Biweikang Labor Protection Products Co., Ltd.

1<sup>st</sup> Floor, No.162, West Chouyi Road,  
Yiting Town, Yiwu City,  
Zhejiang Province,  
China 322000

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425

Module C2

For the following activities

**Manufacture of Biweikang (logo) 8228, 8228V and 9600 particle filtering half mask.**

**(Note: All products marked CE0598 must have a valid EU type-examination 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 14 November 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 14 November 2020

Authorised by

SGS FIMKO OY, Notified Body 0598

Takomotie 8, FI-00380 Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 1

**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)



**Section 9**

**EU DECLARATION OF CONFORMITY**

**Manufacturer**

Name: Yiwu Biweikang Labor Protection Products Co., Ltd.

Address: 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000

declares that the new PPE described hereafter

Description of products	half mask
Product style/order No	9600
Product colour and type	White and Non-reusable, Folding mask, 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 20/967131

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: Li Qiming

Position: Assistant General Manager

Signature: *Li Qiming*

Date: *2020.8.27*



**Section 10**

**DECLARATION OF MATERIAL INNOCUOUSNESS**

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Manufacturer: Yiwu Biweikang Labor Protection Products Co., Ltd.

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

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Done at 1st Floor, No.162, West Chouyi Road, Yiting Town, Yiwu City, Zhejiang Province, China 322000

Signed for on behalf of Company

Name: Li Qiming

Position: Assistant General Manager

Signature: *Li Qiming*

Date: 2020.8.27

