

Documentation No.: *Protective Mask/ FP8888*

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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

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Section 2**Applicant/Manufacture & Product General Information**

1. Manufacturer General Information

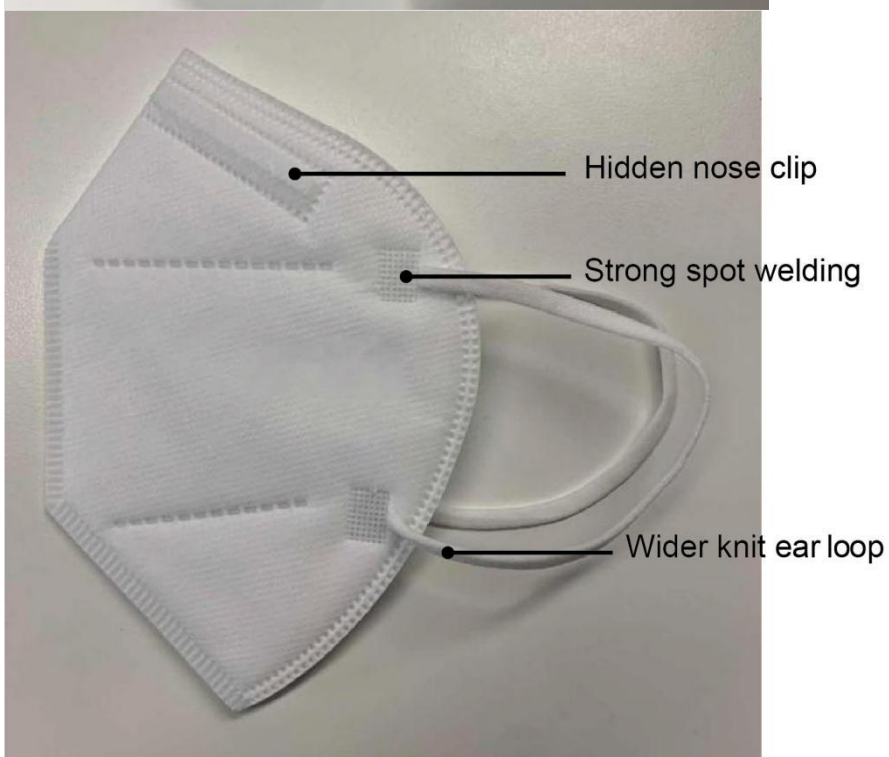
Manufacturer Name	WENZHOU FUPING BAGS CO., LTD
Manufacturer Address	36 TH,BUILDING,XINYA INDUSTRAILA ZONE, LONGGANG CITY,ZHEJIANG PROVINCE,CHINA
Supplier/Factory Name	WENZHOU FUPING BAGS CO., LTD
Supplier/Factory Address	36 TH,BUILDING,XINYA INDUSTRAILA ZONE, LONGGANG CITY,ZHEJIANG PROVINCE,CHINA
Trademark	 “FUPING”
Brand name	FUPING
Destination Country	European countries

Section 3**Product Specifications**

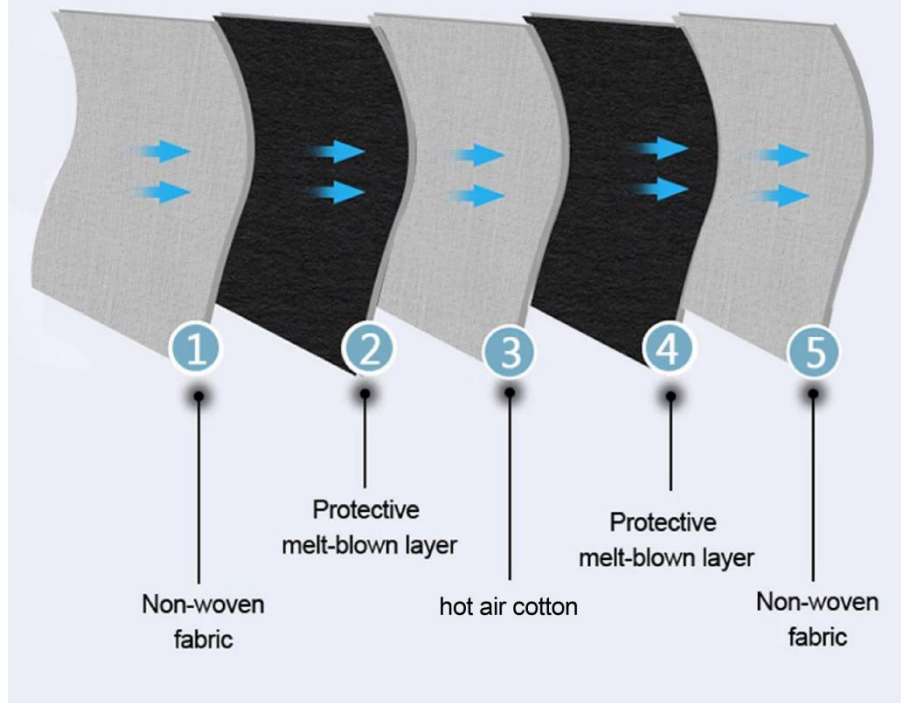
1. Product General Information

Description of products	Protective Mask
Products Colour	White
Product style/order No	FP8888
Product Type	Folded, non-reusable, filtering half mask
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

2. Product Photograph(s)



Five Layers of Protection

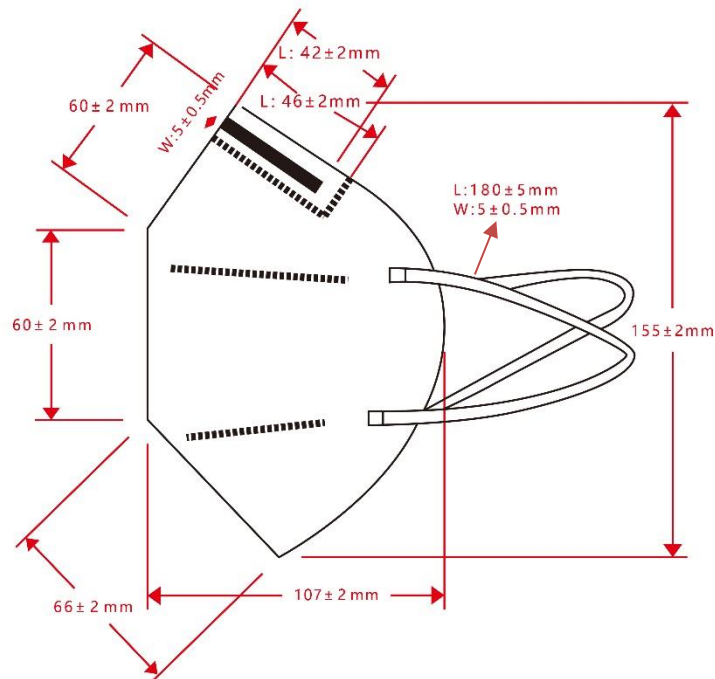


3. Parts List

Parts	Components	Supplier name and address
Filtering facepiece	Out Layer1:100% polypropylene non woven fabric White, 50gsm	Chengbai Nonwoven co., ltd 10 TH BUILDING,NENGKE INDUSTRY ZONE,NO.588 SHIDAI AVENUE, LONGGANG CITY,WENZHOU CITY, ZHEJIANG,CHINA
	Middle Layer 2:100% Polypropylene melt-blown fabric, white, 25gsm	Crown Name Disposable Hygiene Products Fty.ltd CHENGBEI VILLAGE,QICHENG STREET,XINZHOU AREA,WUHAN CITY,HUBEI PROVINCE,CHINA
	Middle Layer 3:100% polypropylene hot air cotton, White,45gsm	Hengmei(Fujian) Sanitary Materials Co. , Ltd. ZHAOYANG INDUSTRIAL, SHUANGYANG STREET, LUOJIANG AREA,QUANZHOU CITY, FUJIANG PROVINCE,CHINA
	Middle Layer 4:100% polypropylene melt-blown fabric, white, 25gsm	Crown Name Disposable Hygiene Products Fty.ltd CHENGBEI VILLAGE,QICHENG STREET,XINZHOU AREA,WUHAN CITY,HUBEI PROVINCE,CHINA
	Inner Layer 5:100% polypropylene non woven fabric , White, 25gsm	Chengbai Nonwoven co., ltd 10 TH BUILDING,NENGKE INDUSTRY ZONE,NO.588 SHIDAI AVENUE, LONGGANG CITY,WENZHOU CITY, ZHEJIANG,CHINA
Ear loop	76.3%Nylon and 23.7% spandex white	Longgang Weihao Bags Co.,LTD NO.523 SHAGNNAN VILLAGE, LONGGANG CITY, ZHEJIANG PROVINCE,CHINA

Nose clip	100% white polypropylene plastic	Zhejiang Yuanbao Packaging Technology Co.,LTD 4F, NO.11TH BUILDING, KANGWEIERJING INDUSTRIAL ,NO. 571SONGYANG ROAD, LONGGANG CITY, ZHEJIANG PROVINCE, CHINA
Nose bridge pad	100% grey Polyurethane sponge,	DONGGUAN RAYAN POLYMER CO.,LTD XIAOBIAN 2ND INDUSTRIAL AREA, CHANGAN, DONGGUAN, GUANGDONG, CHINA

4. Product(s) Dimension



Nose bridge pad: L:90+/-5mm, W: 10+/-1mm

Section 4

1. Sequence of Manufacture

1	Incoming materials inspection
2	Full automatic production: Shaping、Welding ear loop、Fixture of nose clip、Pressing mask
3	Install nose bridge pad
4	Performance Test
5	In-process inspection
6	Packaging: each one by transparent polybag, 20 bags in one box as the minimum sale package. User information in each box.
7	Finished product inspection
8	Storage before shipment

2. Quality Control Procedure

No.	Procedure	Quality Control
1	Raw material control	The testing under EN 149 report should be submitted for the filter materials. Supplier should also submit the “test report” of raw materials. Bulk production products will be 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	Seal the ear loop	The ear loop should be sealed with durability. For tensile test of the samples, each ear loop of the folding mask must conform to the requirements. No slippage or fracture shall occur when each ear loop bear the tension of 10N and 10S. And take notes.
5	Nose clip set up	Set up the nose clip and check the strength of the attachment. Adjust the procedure if any failure.
6	Nose bridge pad fixture	Fix nose bridge pad as required to ensure correct installation position of sponge nose bridge pad.
7	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.
8	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.
9	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.
10	Ergonomics	The QC will carry out the fitting test for the final products. Make sure the fitting is correct.
11	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.
12	Identification	check whether the name, trademark, model, production date and other information is complete and correct.
13	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
2.9. PPE incorporating components which can be adjusted or	7.13; 7.18

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
removed by the user	
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
3.9.2. 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
3.9.2.1. 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
FUPING FP8888 EN 149:2001+A1:2009 FFP2 NR CE 0598	FUPING	Manufacturer name, brand name
	FP8888	Type-identifying marking, style No
	EN149 :2001+A1 :2009	Number of European standards
	FFR 2 NR	Classification Filter Efficiency 94%, non reusable
	CE 0598	CE marking & notified body number

Easy to Use/Donning and fitting



- ① Hold the mask in hand with the nose clip up. Allow ear loop to hang freely.
- ② Position the mask under the chin covering mouth and nose.
- ③ Pull the ear loop to the ear and adjust the ear loop to feel as comfortable as possible.
- ④ Put your fingers in the middle of the nose clip and move your fingertips along the side of your nose until the nose clip is completely pressed into the shape of the nose.

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 are felt around the edges of the respirator, re-position the particle half mask/ear loop to achieve a better fit.

Temperature and humidity range of Storage Condition

Environmental temperature ranging from -30°C to 70°C and humidity lower than 80 %.

End of shelf life: TWO YEARS

Date of manufacture: 2020/05/02

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: WENZHOU FUPING BAGS CO., LTD

Address: 36 TH,BUILDING,XINYA INDUSTRAILA ZONE, LONGGANG CITY,ZHEJIANG PROVINCE,CHINA

EU declaration of conformity can be accessed at: <https://www.fupinghealthcare.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

FUPING
 FP8888
 EN 149:2001+A1:2009
 FFP2 NR
 CE 0598

Height of CE marking: 7mm

Description on label	Explanation
FUPING	Manufacturer name, brand name
FP8888	Type-identifying marking, style No
EN149 :2001+A1 :2009	Number of European standards
FFR 2 NR	Classification Filter Efficiency 94%, non reusable
CE 0598	CE marking & notified body number

2. Package Marking

See Appendix A box package

Height of CE marking: 10mm

Section 8

Test reports

	Test Report No.
EN 149:2001+A1:2009	SL52025257872301TX SL52035272971501TX
Nose bridge pad	SL52035286433801TX

Section 9

EU DECLARATION OF CONFORMITY

Manufacturer

Name: WENZHOU FUPING BAGS CO., LTD

Address: 36 TH, BUILDING,XINYA INDUSTRAILA ZONE, LONGGANG CITY,ZHEJIANG PROVINCE,CHINA

declares that the new PPE described hereafter

Description of products	Protective Mask
Product style/order No	FP8888
Product colour and type	White, Folded, non-reusable, filtering half mask

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

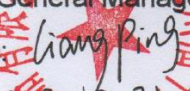

SGS Fimko Oy


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: LIANG PING
Position: General Manager
Signature: 
Date: 



Section 10

DECLARATION OF MATERIAL INNOCUOUSNESS

The manufacturer or his authorized representative established in the Community:

Manufacturer: WENZHOUPING BAGS CO., LTD

Address: 36 TH,BUILDING,XINYA INDUSTRIAL ZONE, LONGGANG 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	Protective Mask
Product style/order No	FP8888
Product colour and type	White, Folded, non-reusable, filtering half mask

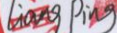
are known not to undergo appreciable alteration from contact with sweat or with substances likely to be found in toiletries and are known not to cause any harm to human skin and body.

Done at 36 TH,BUILDING,XINYA INDUSTRIAL ZONE, LONGGANG CITY,ZHEJIANG PROVINCE,CHINA

Signed for on behalf of Company

Name: LIANG PING

Position: General Manager

Signature: 

Date: 2020.8.21

