

Documentation No.: *Filtering half mask/GX3307*

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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	YiWu GuangXuan Commodity Co., Ltd
Manufacturer Address	5th floor, No. 67 SiHai Avenue, ChouJiang Street, YiWu City, ZheJiang Prvince , China(mainland)
Supplier/Factory Name	YiWu GuangXuan Commodity Co., Ltd
Supplier/Factory Address	5th floor, No. 67 SiHai Avenue, ChouJiang Street, YiWu City, ZheJiang Province , China(mainland)
Destination Country	European countries

Section 3

Product Specifications

1. Product General Information

Description of products	Filtering half mask
Products Colour	white
Product style/order No	GX3307
Product Type	Non-reusable, folded type, particle filtering half mask
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

2. Product Photograph(s)

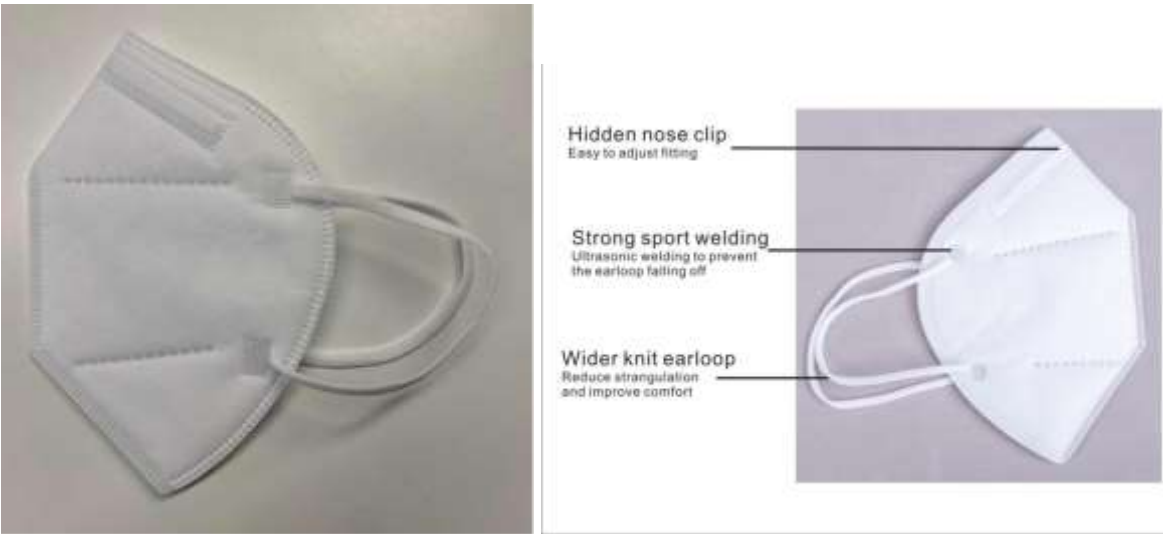
Back side



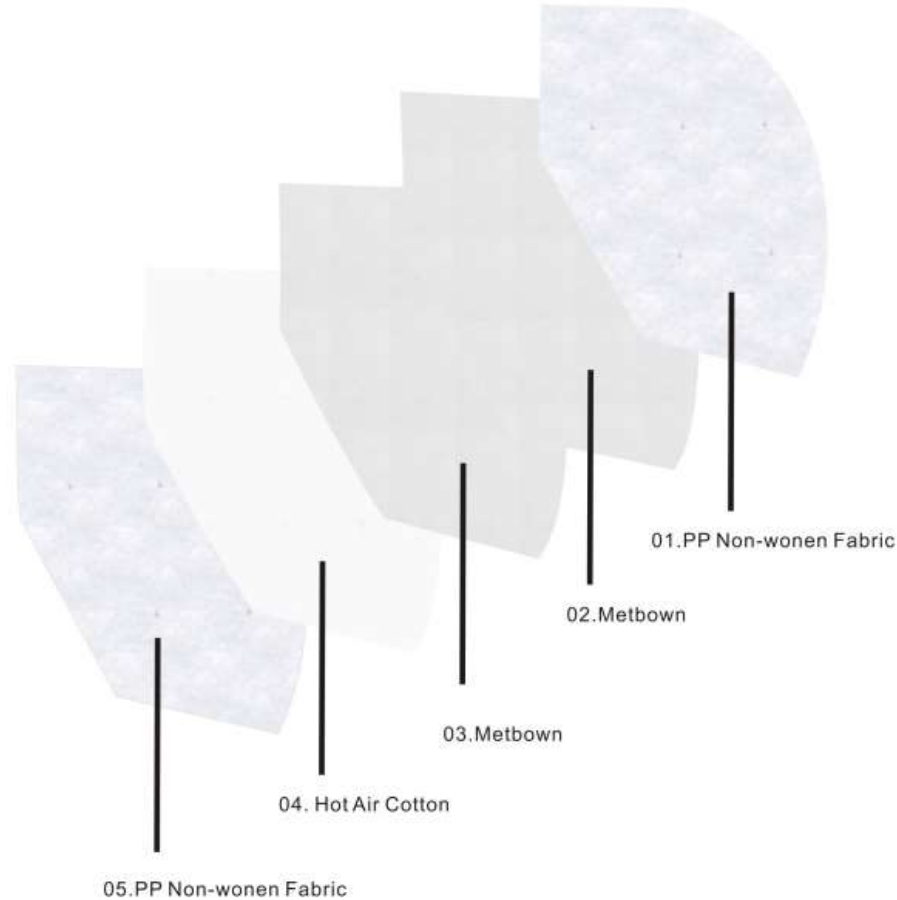
Face side



Folded view



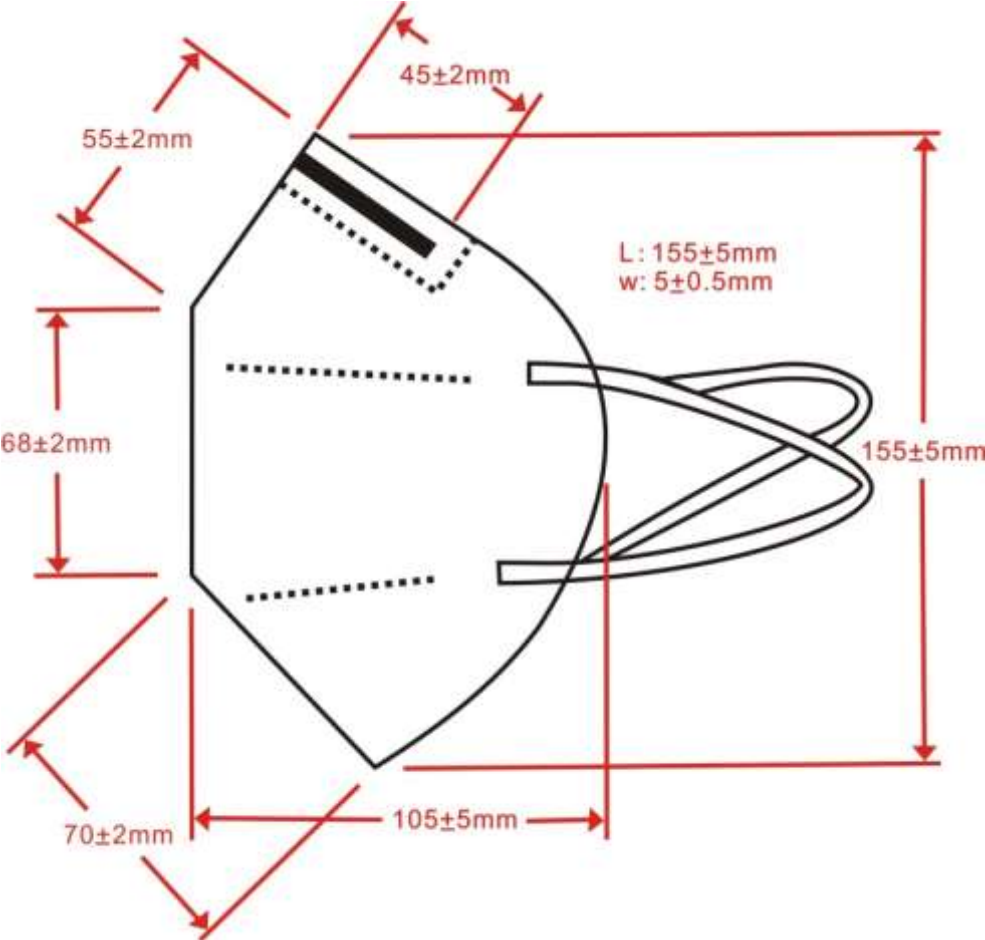
5-Ply Protection System



3. Parts List

Parts	Components	Supplier name and address
Filtering Facepiece	Outer Layer 1: 100% polypropylene non-woven fabric, white, 50gsm	Yiwu Longcheng contraception products Co., Ltd No.2 Ganchuan Road, Yiting Town, Yiwu City, Zhejiang Province
	Middle Layer 2: 100% polypropylene melt-blown fabric, white, 50gsm	Yiwu Longcheng contraception products Co., Ltd No.2 Ganchuan Road, Yiting Town, Yiwu City, Zhejiang Province
	Middle Layer 3:100% polypropylene melt-blown fabric, white, 50gsm	Yiwu Longcheng contraception products Co., Ltd No.2 Ganchuan Road, Yiting Town, Yiwu City, Zhejiang Province
	Middle Layer 4: 100% polypropylene hot air cotton, white, 50gsm	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, 50gsm	Yiwu Longcheng contraception products Co., Ltd No.2 Ganchuan Road, Yiting Town, Yiwu City, Zhejiang Province
Ear loop	85% polyester and 15% spandex, white	Lanxi qiangrui ribbon Co., Ltd No.19 qingshengtang Road, Lanxi Economic Development Zone, Zhejiang Province
Nose clip	aluminum, metal silver	Lin'an qinde Cable Co., Ltd Yayuan village, Linglong street, Lin'an City

4. Product(s) Dimension



Width of Nose clip is $4 \text{ mm} \pm 0.5 \text{ mm}$

Section 4**Manufacture Information**

1. Sequence of Manufacture

1	Incoming materials inspection
2	Shaping and trimming
3	Welding head ear loop
4	Fixture of nose clip
5	Performance Test
6	Pressing mask marking
7	In-process inspection
8	Packaging: each one by polybag, 10 bags in one box. User information in each package
9	Finished product inspection
10	Storage before shipment

2. Quality Control Procedure

No.	Procedure	Quality Control
1	Raw material control	The 3 rd party testing under EN149 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 3 rd party lab to retest EN149, 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 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 bears the tension of 10N and 10S. And take notes.
6	Breath 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	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.

8	Ergonomics	The QC will carry out the fitting test for the final products. Make sure the fitting is correct.
9	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.
10	Identification	Check whether the name, trademark, model, production date and other information is complete and correct.
11	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 batch to batch/year to year will be carried out by an external independent ISO17025 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

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
1.3.2. 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 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

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009 And Section of this Technical File
3.3. 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
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 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.

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

These devices are designed to protect against both solid and liquid aerosols.

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 suitable for use in protection against the non-toxic solid and liquid aerosols. Do not use out of the scope of use defined in 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. 'NR' means non-reusable and should only be used for one shift.

Explanation of product/package marking

Product marking	Description on label	Explanation
YiWu GuangXuan Commodity Co., Ltd GX3307 EN 149:2001+A1:2009 FFP2 NR CE 0598	YiWu GuangXuan Commodity Co., Ltd	Manufacture name
	GX3307	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification and non-reusable
	CE0598	CE marking and notified body number

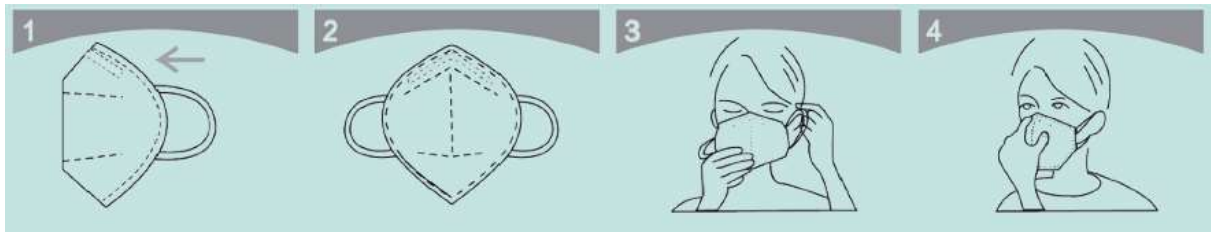


See information supplied by the manufacturer

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 NT/ 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.

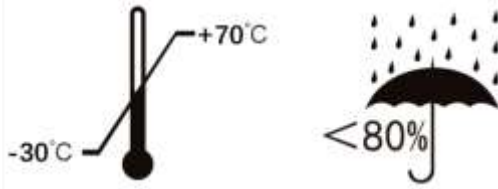
Easy to Use/Donning and fitting



1. Open the packaging pouch and take out the mask.
2. Place the side of nose clip upward. Secure the two sides of the mask straps to the right head position.
3. Press the nose piece to fit the bridge of the nose, then press the nose piece and pull the lower end of the mask to the lower jaw.
4. Adjust the mask so that it covers the bridge of the nose to the lower jaw in order to get the best protection effect.
5. To check fit, cup both hands over the mask and exhale vigorously. If air flows around nose, tighten the nose clip. If air leaks around the edge, reposition for better fit. Re-check the seal and repeat the procedure until mask is sealed properly.

Storage

Recommended temperature range and maximum relative humidity of storage condition



Shelf life: 2 years

Date of manufacture: 2020/06

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.
8. A properly selected respirator is essential to protect your health. Before using this respirator consult a suitably qualified safety professional to determine the suitability of the product for your intended use.

Manufacturer: YiWu GuangXuan Commodity Co., Ltd

Address: 5th floor, No. 67 SiHai Avenue, ChouJiang Street, YiWu City, ZheJiang Province ,
China(mainland)

EU declaration of conformity can be accessed at: www.ywguangxuan.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



Height of CE is 5.6mm

Product marking	Description on label	Explanation
YiWu GuangXuan Commodity Co., Ltd GX3307 EN 149:2001+A1:2009 FFP2 NR CE 0598	YiWu GuangXuan Commodity Co., Ltd	Manufacture name
	GX3307	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification and non-reusable
	CE0598	CE marking and notified body number

2. Package Marking

See Appendix A Bag Package

See Appendix B Box Package

Section 8**Test reports**

Clause and Tests in EN 149	Test Report No.
EN 149:2001 + A1:2009	SL52025269717701TX

Section 9

EU DECLARATION OF CONFORMITY

Manufacturer

Name: YiWu GuangXuan Commodity Co., Ltd

Address: 5th floor, No. 67 SiHai Avenue, ChouJiang Street, YiWu City, ZheJiang Pvince, China(mainland)

declares that the new PPE described hereafter

Description of products	Filtering half mask
Product style/order No	GX3307
Product Type	Non-reusable, folded type, 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: Wang Hua

Position: Manager

Signature: Wang Hua

Date: 2020.7.29



Section 10

DECLARATION OF MATERIAL INNOCUOUSNESS

The manufacturer or his authorized representative established in the Community:

Manufacturer: YiWu GuangXuan Commodity Co., Ltd

Address: 5th floor, No. 67 SiHai Avenue, ChouJiang Street, YiWu City, ZheJiang Prvince, China(mainland)

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	Filtering half mask
Product style/order No	GX3307
Product Type	Non-reusable, folded type, 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 5th floor, No. 67 SiHai Avenue, ChouJiang Street , YiWu City , ZheJiang Prvince , China(mainland)

Signed for on behalf of Company

Name: Wang hua

Position: Manager

Signature: Wang hua

Date: 2020.07.28

