

Documentation No.: *Particle Filtering Half Mask / 20001*

Creation Date: *2020-07-09*

Revision No.: *Version 2*

Revision Date: *2020-08-05*

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>
2	<u>Applicant/Manufacture & Product General Information</u>
3	<u>Product Specifications</u>
4	<u>Manufacture Information</u> <u>(Sequence of Manufacture & 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	ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD
Manufacturer Address	NO.3 Yue Feng Rd., Provincial Economic Development Zone,Zhangjiagang City, Jiangsu Province, China
Supplier/Factory Name	ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD
Supplier/Factory Address	NO.3 Yue Feng Rd., Provincial Economic Development Zone,Zhangjiagang City, Jiangsu Province, China
Brand name (if any)	ESLH
Destination Country	European countries
EU declaration of conformity can be accessed at	http:// www.eslhchina.com

Section 3

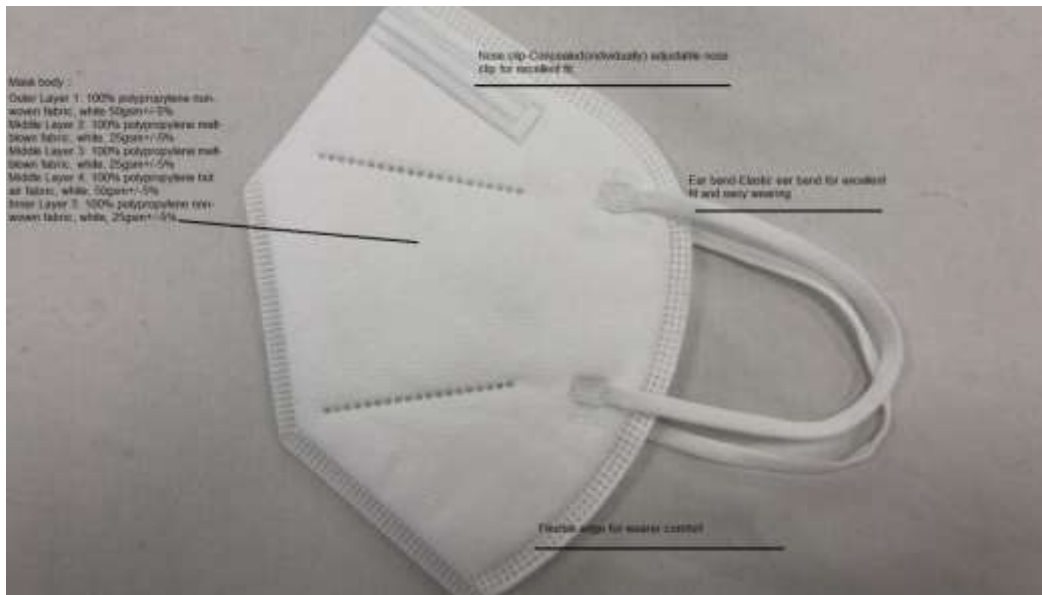
Product Specifications

1. Product General Information

Description of products	Particle Filtering Half Mask
Products Colour	White
Product style/order No	20001
Product Type	Particle Filtering Half Mask, Non-reusable, folded
Standard	EN 149:2001+A1:2009
Classification	FFP2 NR

2. Product Photograph(s)



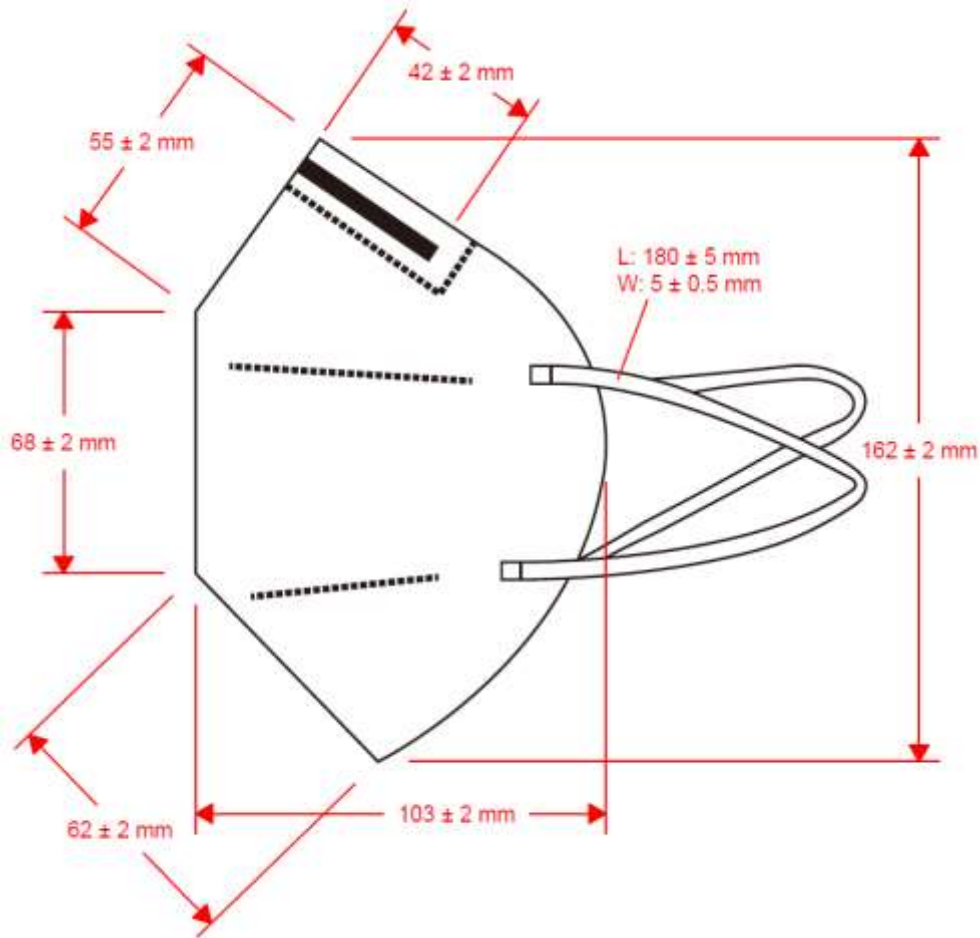


3. Parts List

Parts	Components	Supplier name and address
Mask body	Outer Layer 1: 100% polypropylene non-woven fabric, white 50gsm+/-5%	Zhangjiagang Junma Non-woven Fabrics CO., LTD. Junma Industrial Garden, Jiangqiao, Yangshe Town, ZHANGJIAGANG, - 215617, China
	Middle Layer 2: 100% polypropylene melt-blown fabric, white, 25gsm+/-5%	Zhangjiagang Junma Non-woven Fabrics CO., LTD. Junma Industrial Garden, Jiangqiao, Yangshe Town, ZHANGJIAGANG, - 215617, China
	Middle Layer 3: 100% polypropylene melt-blown fabric, white, 25gsm+/-5%	Zhangjiagang Junma Non-woven Fabrics CO., LTD. Junma Industrial Garden, Jiangqiao, Yangshe Town, ZHANGJIAGANG, - 215617, China
	Middle Layer 4: 100% polypropylene hot air fabric, white, 50gsm+/-5%	Jiangsu Yingrui Industries CO.,LTD. No.1689 ChenFeng Road ,Jingang,Zhangjiagang 215631 Jiangsu,China

	Inner Layer 5: 100% polypropylene non-woven fabric, white, 25gsm+/- 5%	Zhangjiagang Junma Non-woven Fabrics CO., LTD. Junma Industrial Garden, Jiangqiao, Yangshe Town, ZHANGJIAGANG, - 215617, China
Ear band	85% polyester, 15% spandex, white	Zhangjiagang Baihong Textile Co., Ltd. Nanzhuang Industrial Park, Tangshi, Yangse Town, Zhangjiagang City, Jiangsu Province, China
Nose clip	Aluminium metal, silver, rolled with White plastic	Dongguan Lanfeng Technology Electronics Co.,Ltd Building 4, no. 28, Shangyong Road, Santun Management District, Houjie Town, Dongguan City, Guangdong Province

4. Product(s) Dimension



Section 4**Manufacture Information**

1. Sequence of Manufacture

1	Incoming material inspection
2	Shaping and trimming
3	Fixture of nose clip
4	Welding ear band
5	Performance test
6	Printing mask marking
7	In-process inspection
8	Packaging: 20 pcs by one Polybag, then put in one box, the user information is given to each individual package.
9	Finished product inspection
10	Storage before shipment

2. Quality Control Procedure

No	Procedure	Quality control
1	Raw material control	Quality inspector chooses suppliers according to qualification selection, ask supplier to supply 3 rd party test report, such as Penetration of filter material test for melt-blow fabric, eco testing for non-woven fabric, ear band and nose clip. Quality inspector will accept the material only when all are in good quality.
2	In house lab testing	The basic testing e.g. Penetration of filter material, breathing resistance will be checked by in-house lab under the test method EN 149. The raw material will be rejected if they cannot meet the minimum requirement.
3	Mould, cut	Mould and cut as per the specification, make sure the working side is clear to avoid pollution.
4	Nose clip set up	Set up the concealed nose clip and check the appearance. Adjust the procedure if any rupture.
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@10S.
6	Breathing resistance, filtration efficiency	Bulk production products will be sent to 3 rd party lab to test EN 149 with Breathing resistance, filtration efficiency from batch to batch/year to year to ensure performance. Rework the problem goods. Make sure all the goods are in good quality
7	Appearance check	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	Quality inspector will pick up the final product to check the fitting. The mask must be designed and manufactured so 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 level possible.
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	Quality inspector must be conducted according to the requirements and the finished product inspection report should be filled in and kept.

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

Manufacturer's Instructions and Information

Please read this manual carefully before use to avoid misuse of this product. This product complies with the requirements of Regulation(EU) 2016/425 for personal Protective Equipment and meets the requirements of European standard EN 149:2001+A1:2009.

Failure to follow all instructions and limitations of use could seriously reduce the effectiveness of this particle filtering half mask and could lead to illness, injury or death.

1. Intended use of the particle filtering half-mask

The Particle filtering half-mask is a complete respiratory protection equipment and is intended to protect the user against the harmful effects of air pollution in the form of solid and/or liquid particles forming aerosols (dusts, fumes and mists). This particle filtering half mask does not eliminate exposure to other contaminants, misuse may result in sickness or death.

The product is designed to protective against the risks:

Risk	Standard clause	Assessment method
Penetration of particle	EN149:2001 +A1:2009 clause 7.9.1	Total inward leakage test
	EN149:2001 +A1:2009 clause 7.9.2	Penetration of filter material test

2. Limitations of use

Do not use the particle filtering half mask and enter or stay in a contaminated are if:

- ◆The user has ear injuries that prevent the proper donning of the mask.
- ◆Atmosphere contains less than 19.5% oxygen.
- ◆The user smell or taste contaminant.
- ◆The environment contains hazardous gases or vapors.
- ◆Contaminants or their concentrations are unknown or immediately dangerous to life or health.
- ◆In sandblasting, Paint-spray operations and environment with asbestos.
- ◆In explosive atmospheres.
- ◆After expiry date of the particle filtering half mask.
- ◆Checks prior to use has not been performed.
- ◆Substitute, modify, add, or omit parts.

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 this particle filtering half mask shall not be used for more than one shift.

3. Checks 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 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.

4. Easy to use/Donning and fitting

HOW TO WEAR



1. Stretch the mask to check whether the front of the mask intact.
2. Put the mask against your chin.
3. Cover the nose and mouth with mask, hang the ear band on both ears respectively, and adjust the ear band to a more comfortable state.
4. Use the index and middle fingers of both hands to press the nose clip from the top to the mask center to both sides until it is close to the bridge of the nose.
5. Cover the mask with both hands as much as possible, and perform positive and negative pressure tests to ensure the tightness of the mask.

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 filtering half mask /ear band to achieve a better fit.

6. Single shift use only (NR)

- ◆This particle filtering half mask shall not be used for more than one shift.

7. Warning

- ◆The user must be trained to properly select and correctly use the particle filtering half mask in accordance with applicable health and safety regulations.
- ◆Do not make modifications to the particle filtering half mask
- ◆Check fit of particle filtering half mask before each use.
- ◆Using particle filtering half mask with facial hair passing under the face seal may prevent good fit, and requirements for leakage is unlikely to be achieved under this circumstance.
- ◆The particle filtering half mask does not provide oxygen, please use in environment with sufficient oxygen level and good ventilation.
- ◆Leave the contaminated area if dizziness, irritation or other distress occurs.
- ◆Discard the particle filtering half mask and replace with a new one if:

- a. Breathing difficulty is noticed as a result of increased breathing resistance.
- b. The particle filtering half mask becomes damaged or distorted.
- c. Proper facial fit cannot be achieved.

8. Storage condition

- ◆Store the product in -30-+70°C ambient temperature and maximum humidity of 80%.
- ◆Prevent mechanical extrusion, excess temperature or humidity, sunlight exposure, and contact with chemicals.

9. Shelf life: 2 years

End of shelf life: 2022/06 is shown on the product package.



See instruction provided by manufacture

Manufacture: ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Address: NO.3 Yue Feng Rd., Provincial Economic Development Zone, Zhangjiagang City, Jiangsu Province, China

Marking	Description on label	Explanation
ESLH CE 0598 20001 EN 149:2001+A1:2009 FFP2 NR ESLH (Suzhou) Protective Equipment Co., Ltd.	ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD	Manufacture name
	ESLH	Trademark
	20001	Type-identifying marking, style No
	EN 149:2001+A1:2009	Number of European standards
	FFP2 NR	Classification FFP2, Non-reusable
	CE 0598	CE mark and notified body number

EU type-examination for Regulation(EU) 2016/425 by

Notified body Number: 0598

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

Made in China

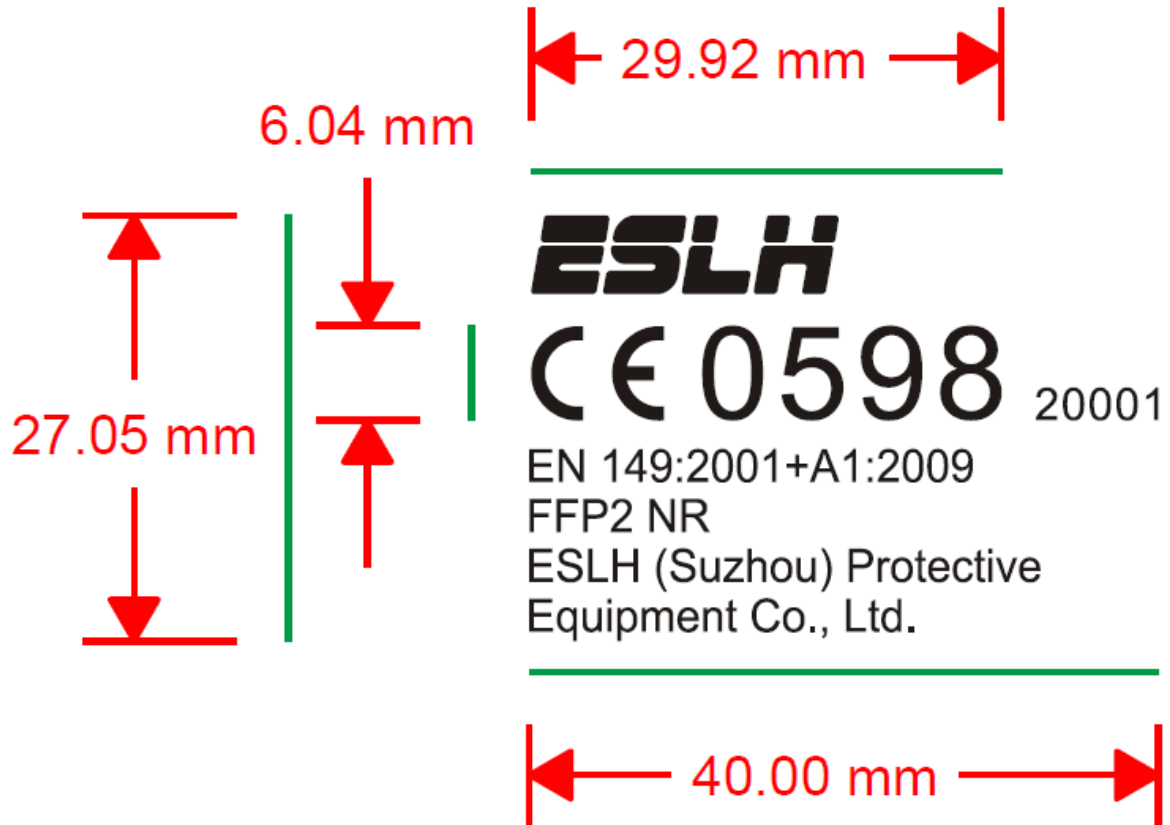
Declaration:

1. EU Declaration of Conformity can be accessed at: [http://
www.eslhchina.com](http://www.eslhchina.com)
2. Each Manufacturer's Use Instructions and Information can be found attach to the each product package.
3. All the information in the instruction will be at least in the official language(s) of the destination country when the product be put into the market.
4. Detailed content of the Instructions and information notice is the responsibility for manufacture

Section 7

Markings

1. Product Marking



2. Package Marking

Details:

Cover and Face side:




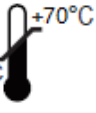


back side:

⚠ WARNING


- The user must be trained to properly select and correctly use the particle filtering half mask in accordance with applicable health and safety regulations.
- Do not make modifications to the particle filtering half mask
- Check fit of particle filtering half mask before each use.
- Using particle filtering half mask with facial hair passing under the face seal may prevent good fit, and requirements for leakage is unlikely to be achieved under this circumstance.
- The particle filtering half mask does not provide oxygen, please use in environment with sufficient oxygen level and good ventilation.
- Leave the contaminated area if dizziness, irritation or other distress occurs.
- Discard the particle filtering half mask and replace with a new one if:
 - a. Breathing difficulty is noticed as a result of increased breathing resistance.
 - b. The particle filtering half mask becomes damaged or distorted.
 - c. Proper facial fit cannot be achieved.

Storage condition

- Store the product in -30 to 70°C ambient temperature and maximum humidity of 80%.
- Prevent mechanical extrusion, excess temperature or humidity, sunlight exposure, and contact with chemicals.

-30°C+70°C<80%

Model No.: 20001



2 816190 521045

Made in China

End of shelf life: 2022/06

Manufacturer: ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Address: NO.3 Yue Feng Rd., Provincial Economic Development Zone, Zhangjiagang City, Jiangsu Province, China

Left& Right side

HOW TO WEAR



1. Stretch the mask to check whether the front of the mask intact.
2. Put the mask against your chin.
3. Cover the nose and mouth with mask, hang the ear belt on both ears respectively, and adjust the ear belt to a more comfortable state.
4. Use the index and middle fingers of both hands to press the nose clip from the top to the mask center to both sides until it is close to the bridge of the nose.
5. Cover the mask with both hands as much as possible, and perform positive and negative oressure tests to ensure the tightness of the mask.

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 are flows is felt around the edges of the respirator, re-position the particle half mask/head harness to achieve a better fit.

SINGLE SHIFT USE ONLY (NR)

This particle filtering half mask shall not be used for more than one shift.

⚠ WARNING

This respirator helps protect against certain particles.
Misuse may result in sickness or death.
For proper use, see use instructions.

Limitations of use

Do not use the particle filtering half mask and enter or stay in a contaminated area if:

- The user has ear injuries that prevent the proper donning of the mask.
- Atmosphere contains less than 19.5% oxygen.
- The user smell or taste contaminant.
- The environment contains hazardous gases or vapors.
- Contaminants or their concentrations are unknown or immediately dangerous to life or health.
- In sandblasting, Paint-spray operations and environment with asbestos.
- In explosive atmospheres.
- After expiry date of the particle filtering half mask.
- Checks prior to use has not been performed.
- Substitute, modify, add, or omit parts.

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 this particle filtering half mask shall not be used for more than one shift.

Checks 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 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.

Section 8

Test reports

Clause and Tests in EN 149	Test Report No.
EN 149:2001+A1:2009	SL52025246242001TX

Section 9

EU DECLARATION OF CONFORMITY

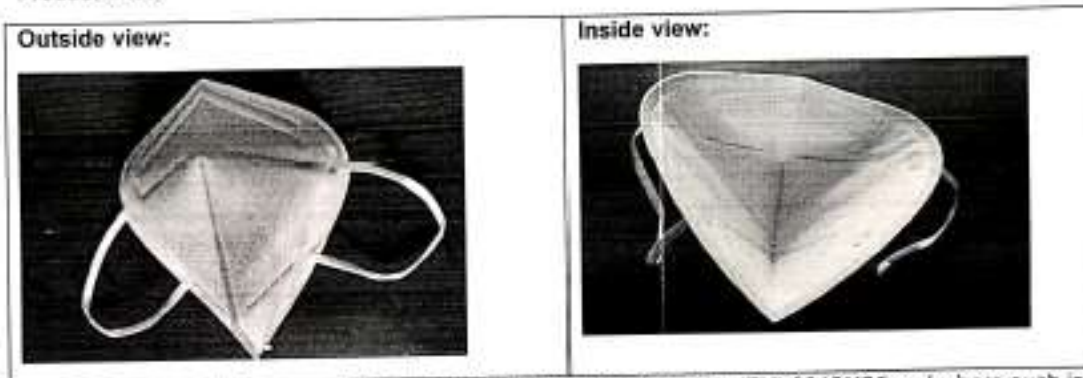
Manufacture: ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Address: NO.3 Yue Feng Rd., Provincial Economic Development Zone, Zhangjiagang City, Jiangsu Province, China

Declare under our sole responsibility that the following product

Description of products	Particle Filtering Half Mask
Trademark	ESLH
Type designation/classification	20001 / FFP2 NR
Products Colour/type	White, Particle Filtering Half Mask, Non-reusable, folded

Product Photo



Is in conformity with the essential requirements of the PPE regulation(EU) 2016/425 and where such is the case, with the international harmonized standard EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles-Requirements, Testing, Marking.

The notified body SGS Fimko Oy, Takomatie 8, FI-00380 Helsinki, Finland.

Notified Body Number 0598

performed the EU type-examination (Module B) class III PPE category and issue 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 and on behalf of ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Name: 任绍群

Position: 业务员

Place and Date: 2020.07.10

Signature:



Declaration: EU Declaration of Conformity can be accessed at: [http:// www.eslhchina.com](http://www.eslhchina.com)

Section 10

DECLARATION OF MATERIAL INNOCUOUSNESS

The manufacturer or his authorized representative established in the community:

Manufacture: ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Address: NO.3 Yue Feng Rd., Provincial Economic Development Zone, Zhangjiagang City, Jiangsu Province, China

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

Description of products	Particle Filtering Half Mask
Trademark	ESLH
Type designation/classification	20001 / FFP2 NR
Products Colour/type	White, Particle Filtering Half Mask, Non-reusable, folded

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.3 Yue Feng Rd., Provincial Economic Development Zone, Zhangjiagang City, Jiangsu Province, China

Signed for and on behalf of ESLH (SUZHOU) PROTECTIVE EQUIPMENT CO.,LTD

Name: ... 任超群

Position: ... 业务员

Place and Date: ... 2020.07.10

Signature:

