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Face Mask 3PLY Civil - JV

Item no: PPLYJV01



Disposable 3-layer face mask in high quality with elastic ear loops. Adjustable nose-bridge for good fit and skin friendly fabric. Bacterial filtration efficiency above 95%.

Protection Class: 3PLY

BFE: ≥95%

CE Certificates: EN149:2001+A1:2009

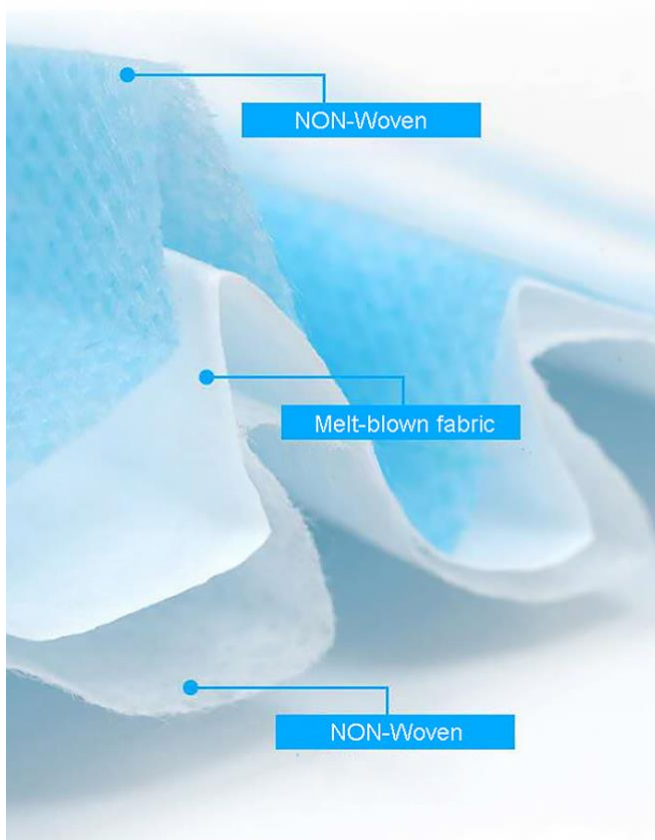
FDA Certificate: GTS22391

Material: Non-woven, Melt-blown fabric

Colors: Blue

HS Code: 6307909810

Packaging: 60 pcs/box, 3000 pcs/carton • Carton size 52x42x47 cm (weight 13.5kg)



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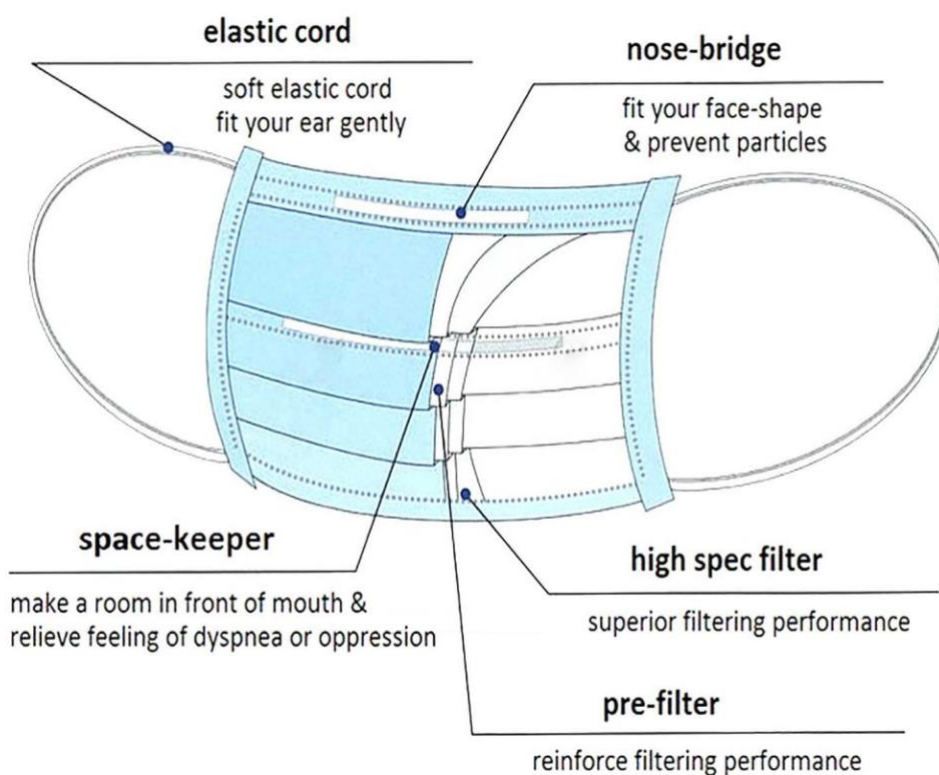
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3Layers Protection
making your breathing safer and fresher



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Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance



No. OP200318T.FFO0038

Technical Construction File no. TPFJ20031322390

Certificate's
Holder:

Certification ECM
Mark:



Product: Disposable protective mask
Model(s): HX001, HX002, HX003, HX004, HX005

Verification to: Standard:
EN 149: 2001+A1:2009
related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 18 March 2020

Expiry date: 17 March 2025

Reviewer
Technical expert
Amanda Payne



Approver
ECM Service Director
Luca Bedonni



Ente Certificazione Macchine Srl

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شهادة – Certificat – 증명서 – Certificate – Сертификат




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Report No. TPFJ20031322390

TECHNICAL CONSTRUCTION FILE	
Report Reference No.....	TPFJ20031322390
Tested by (+ signature).....	Jessica Meng
Approved by (+ signature).....	Kevin Shi
Date of issue.....	Mar. 20, 2020
	
Testing Laboratory.....	Shanghai Global Testing Services Co., Ltd.
Address.....	Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Testing procedure	TL [X] TMP[] WMT[]
Applicant's name.....	FLUKE FURUO OUTDOOR ARTICLES CO., LTD.
Address.....	NO. 288 CHANGSHAN ROAD, HULU INDUSTRIAL AREA, TIANJIN ROAD, LICHENG, GUANGDONG, PLENN, CHINA
Test specification:	
Standard.....	EN 149:2001+A1:2009
Type of Test	PST[] Registration (type test) [X]
Non-standard test method.....	N/A
Manufacturer.....	FLUKE FURUO OUTDOOR ARTICLES CO., LTD.
Adress.....	NO. 288 CHANGSHAN ROAD, HULU INDUSTRIAL AREA, TIANJIN ROAD, LICHENG, GUANGDONG, PLENN, CHINA
Product name.....	Disposable protective mask
Model No.	HX001, HX002, HX003, HX004, HX005

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Possible test case verdicts:	
- test case does not apply to the test object.....	N/A
- test object does meet the requirement.....	P(Pass)
- test object does not meet the requirement.....	F(Fail)
Testing	
Date of receipt of test item.....	Mar. 13, 2020
Date (s) of performance of tests.....	Mar. 13, 2020 to Mar. 20, 2020
General remarks:	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma (point) is used as the decimal separator.	

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TEST CONDUCTED:

**Respiratory protective devices — Filtering half masks to protect against particles —
Requirements, testing, marking
(EN 149:2001 +A1:2009)**

Test Property	Test Method	Test Principle / Requirements	The Result
7. Requirements			
General	EN149 Clause 7.1	In all tests all test samples shall meet the requirements.	-
Nominal values and tolerances	EN149 Clause 7.2	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$. Unless otherwise specified, the ambient temperature for testing shall be $(16 - 32)^\circ\text{C}$, and the temperature limits shall be subject to an accuracy of $\pm 1^\circ\text{C}$.	Pass
Visual inspection	EN149 Clause 7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass
Packaging	EN149 Clause 7.4	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.	Pass
Material	EN149 Clause 7.5	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have	Pass

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Test Property	Test Method	Test Principle / Requirements	The Result
		suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	
Cleaning and disinfecting	EN149 Clause 7.5	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer	Pass
Practical performance	EN149 Clause 7.7	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.	Pass
Finish of parts	EN149 Clause 7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass
7.9 Leakage			
Total inward leakage	EN149 Clause 7.9.1	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.	Pass

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Test Property	Test Method	Test Principle / Requirements	The Result
Penetration of filter material	EN149 Clause 7.9.2	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	Pass
Compatibility with skin	EN149 Clause 7.10	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass
Flammability	EN149 Clause 7.11	The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	<5s Pass
Carbon dioxide content of the inhalation air	EN149 Clause 7.12	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
Head harness	EN149 Clause 7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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.	Pass
Field of vision	EN149 Clause 7.14	The field of vision is acceptable if determined so in practical performance tests.	Pass
Exhalation valve(s)	EN149 Clause 7.15	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in	N/A

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Test Property	Test Method	Test Principle / Requirements	The Result
		all orientations.	
Breathing resistance	EN149 Clause 7.16	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	Pass
7.17 Clogging			
General	EN149 Clause 7.17.1	For re-usable devices the test is mandatory.	N/A

Sample Photo:



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

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The 3rd Party Certificate of FDA Medical Device Registration

Note:

This file is Not being issued by GTS. We, SFT, as the 3rd party, produce it, intended to facilitate customer display & transmit information. The following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

Registration Number / FEI Number*:

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Status: **Active**

Date of Registration Status: **2020**

Owner/Operator

Owner/Operator Number: **10063132**

Official Correspondent

Contact Name: Ivy Huang General assistance
CHANGXING ROAD, HUOJU INDUSTRIAL AREA, NANHUAN ROAD, LICHENG,
QUANZHOU, FUJIAN, CHINA 362000
Tel: +86- 595-22462299 E-mail: 13305073377@163.com

U.S. Agent

Contact Name: Grace Liu
Address: 839 FM 1489 Road, Brookshire, Texas 77423 U.S.A
Phone: (281) 600-8227 E-mail: grace.liu@ltlqa.com

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable protective mask	LYU	1	D37****	Manufacturer
Protective mask for medical use	LYU	1	D37****	Manufacturer
Disposable protective suit for medical use	OEA	1	D37****	Manufacturer
protective clothing	OEA	1	D37****	Manufacturer

⚠ Please careful protect your Listing Number.

Professional FDA Registration Services, by Shanghai Global Testing Services Co., Ltd.

More details on the website: <http://www.gts-lab.com>

Need help? Contact us, GTS, at +86(021) 33637866 & info@gts-lab.com FDA

CERTIFICATE NUM: **GTS22391**