

INTEGRUM PROTECTION MASKS



PERFORMANCE: LEVEL 1 | LEVEL 2 | LEVEL 3

CHOOSE YOUR LEVEL OF PROTECTION

Available in three performance levels, Integrum Protection Masks are the new diamond standard. Whether you choose level 1—perfect for everyday use—or level 2 or 3—suitable for medical & dental use—Integrum Masks provide high-quality protection without sacrificing comfort and wearability.



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Integrum Level 1 Protection Masks are the easy, convenient way to make everyday safety a priority, while still maintaining maximum comfort and breathability. Score additional style points by rocking these black disposable masks!

MASK PROTECTION LEVEL 1 4 PLY





PRODUCT NAME: INTEGRUM LEVEL 1 PROTECTION MASKS **TYPE:** FLAT EAR BAND, ANTIBACTERIAL PAPER **DIMENSIONS:** 17.5CM X 9.5CM PER MASK, 50 MASKS PER BOX



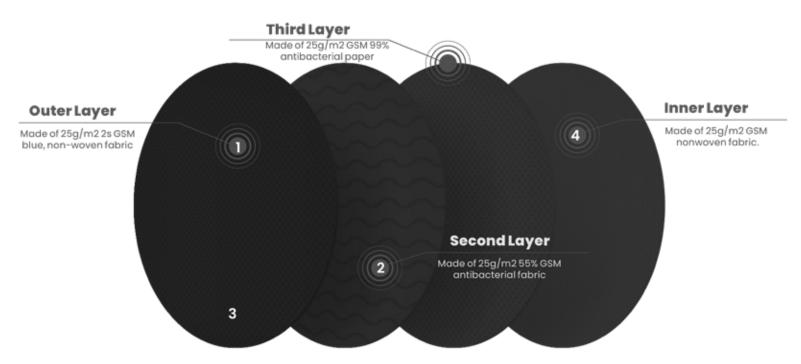








4 LAYERS OF PROTECTION



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Choose Integrum Level 2 masks for medical/dental purposes or for situations where you want enhanced protection. Level 2 masks offer 4 layers of higher bacterial filtration and fluid resistance in accordance to ASTM testing standards.

MASK PROTECTION LEVEL 2 4 PLY

ASTM STANDARDS IN PERFORMACE FOR MEDICAL GRADE MASKS			
TEST TYPE	LEVEL 2	LEVEL 3	
BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101	≥ 98%	≥ 98%	
PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299	≥ 98%	≥ 98%	
Delta P (Differential Pressure) MIL-M-36954C, mm H2O/cm2	< 6.0	< 6.0	
Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg	120	160	
Flame Spread 16 CFR part 1610	Class 1	Class 1	



PRODUCT NAME: INTEGRUM LEVEL 2 PROTECTION MASKS

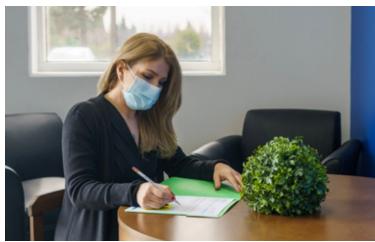
TYPE: FLAT EAR BAND, ANTIBACTERIAL PAPER

DIMENSIONS: 17.5CM X 9.5CM PER MASK, 50 MASKS PER BOX











4 LAYERS OF PROTECTION





Quality matters when the risk is high or unknown. Integrum Level 3 masks provide the highest protection level in accordance to ASTM testing standards. Designed for a close fit that protects against fluid transmission, these 4-Layer medical masks offer premium protection suitable for medical & dental settings.

MASK PROTECTION LEVEL 3 4 PLY

ASTM STANDARDS IN PERFORMACE FOR MEDICAL GRADE MASKS			
TEST TYPE	LEVEL 2	LEVEL 3	
BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101	≥ 98%	≥ 98%	
PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299	≥ 98%	≥ 98%	
Delta P (Differential Pressure) MIL-M-36954C, mm H2O/cm2	< 6.0	< 6.0	
Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg	120	160	
Flame Spread 16 CFR part 1610	Class 1	Class 1	



PRODUCT NAME: INTEGRUM LEVEL 3 PROTECTION MASKS

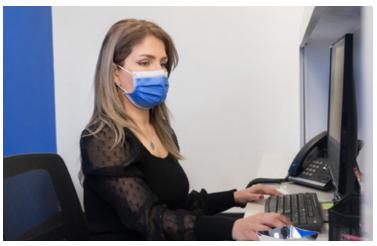
TYPE: FLAT EAR BAND, ANTIBACTERIAL PAPER

DIMENSIONS: 17.5CM X 9.5CM PER MASK, 50 MASKS PER BOX











4 LAYERS OF PROTECTION





Factory 1: Tien Son Industrial Park, Noi Due Commune, Tien Du District, Bac Ninh, VIETNAM

Factory 2: Dong Xep Street, Hoan Son Commune, Tien Du District, Bac Ninh Province. VIETNAM

Da Nang Branch: Hoa Khanh Industrial Park, Hoa Khanh Bac Ward, Lien Chieu District, Da Nang City. VIETNAM









CERTIFICATES OCUMENTATIO INTEGRUM INTEGRUN INTEGRUM

Certificate of Registration

This certificate of Registration certifies that:

AN PHU MINING INVESTMENT JOINT STOCK COMPANY

SO 102 LACH TRAY PHUONG LACH TRAY QUAN NGO QUYEN THANH PHO, HAI PHONG, 18000, VIETNAM

has registered with the US Food and Drug Administration pursuant to Title 21 of the United States Code of Federal Regulations.

Owner Operator Number: 10073255

Listed Device

MSH D400365 Respirator, Surgical OKR D400368 Face Mask (except N95)

FXO D400370 Suit, Surgical

OEA D400371 Non-surgical Isolation Gown

US Agent: Willow Glen Consultancy LLC Willow Glen Number: WG2071137 Expiration Date: December 31, 2020

This certificate affirms that the above-named facility is registered with the US FDA pursuant to the regulations required by the US laws. This registration has been verified as effective by Willow Glen Consultancy as of the date below, unless such registration has been terminated after issuance of this Certificate. Willow Glen Consultancy makes no additional representations or warranties, nor does this certificate carry any to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Willow Glen Consultancy assumes no liability to any person or entity in connection with the foregoing, nor does the U.S. FDA recognize a certificate of registration issued by Willow Glen Consultancy.

Willow Glen Consultancy is a private agent not affiliated with the U.S. Food and Drug Administration.

Amanda Ou, Operation Director Willow Glen Consultancy LLC

Imanda Or

+1-619-869-0249 Date: May 7, 2020 Willow Glen

WillowGlenFDA.com Info@WillowGlenFDA.com 3755 Avocado Blvd, Suite 208 La Mesa, CA 91941, USA



Certificate of Compliance

Application for Medical Device Directive (MDD) 93/42/EEC.

This is to certify that the product(s):

Manufacturing and Trading: Medical Face Masks; Non-sterile Gloves; KN95 Masks; Medical Protective Clothing.

Manufactured by

AN PHU MINING INVESTMENT JOINT STOCK COMPANY

Head Office: No. 102 Lach Tray Street, Ngo Quyen District, Hai Phong City, Vietnam

Manufactory Address: Lot E, Street 7 Hoa Khanh Industrial Park, Hoa Khanh Bac Ward, Lien Chieu District, Da Nang City, Vietnam

Complies with the requirement of the "Test Standard: EN 14683:2019 & EN 149:2001+A1:2009"

has been assessed & found in accordance with the requirements of MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile).

QCC is non-notified certification body, issue this
'compliance certificate' after audit of manufacturer product(s) & technical file(s).
This certificate applies to the tested sample only not for whole production.
It's manufacturer sole responsibility to meet all the necessary conformity
assessment activities according to MDD 93/42/EEC and related standards
before placing them on the market & CE mark on the product(s).

Certificate No. : CE/016273/0320

Original Certificate Date: 12 - May - 2020

Issue Date : 12 - May - 2020

Expiry Date : 11 - May - 2021

To check this certificate status visit: "http://uasl.uk.com/certifiedorganization.html"



For Quality Control Certification

UK Office: 1929, Chynoweth House, Trevissome Park, Truro-TR48UN, Cornwall, UK









Quality Control Certification accredited by UASL, UK
This certificate doesn't provide the certified organisation with immunity from its legal obligations
This certificate remains the property of QC Certification to whom it must be returned on request.



Certificate

This is to Certify that

AN PHU MINING INVESTMENT JOINT STOCK COMPANY

Head Office: No.102 Lach Tray Street, Ngo Quyen District, Hai Phong City, Vietnam

Manufactory Address: Lot E, Street 7 Hoa Khanh Industrial Park, Hoa Khanh Bac Ward, Lien Chieu District, Da Nang City, Vietnam

has been found in Compliance with requirements of

Medical Devices - Quality Management System

ISO 13485:2016

for the following scope:

Manufacturing and Trading: Medical Face Masks; KN95 Masks; Medical Protective Clothing.

Certificate No. : MDQM/016272/0320

Original Certificate Date: 12 - May - 2020

Issue Date : 12 - May - 2020

Expiry Date : 11 - May - 2021

To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature

Quality Control Certification

UK Office: 1929, Chynoweth House, Trevissome Park, Truro-TR48UN, Cornwall, UK India Office: 2nd Floor, Aman Market,

India Office: 2nd Floor, Aman Market Narela Mandi, Delhi - 110 040, India











"Quality Control Certification (QCC)" accredited by "UASL, England, UK". This certificate remains the property of "QCC" to whom it must be returned on request.



Test Report No. VNT/MHS/20/000029R1 Dated 21/09/2020



Add value. Inspire trust.

Applicant : AN PHU MINING INVESTMENT JOINT STOCK COMPANY

TS 10 Road, Tien Son Industrial Zone, Noi Due Commune, Tien

Du District, Bac Ninh Province, Viet Nam

Attention : Nguyen Thi Thu Trang

Mail Box : -

Test Sample : Received on 13/07/2020

Test Period : From 13/07/2020 to 13/09/2020

Sample Description : Medical face mask (water resistant, breathable and non allergic

fabric, mask layers include: filler layers and bacterial filtration

layer)

Color : Blue

Mfg./Exp. Date : Mfg. Date: 05.2020 / Exp. Date: 05.2023

Lot No./ Batch No. : TN/01/05/20

Brand : ·

Manufacturer :

Sample Quantity : 150pcs

Country of Origin : Vietnam

Country of Destination : USA

Note: the submitted samples are Not Drawn by the Laboratory

Note: (1) General Terms & Conditions as mentioned overleaf, (2) the test report shall not be reproduced except in full without the written approval of the laboratory.

Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production. For further details, please see testing and certification regulation, chapter A-3.4.

Disclaimer Measurement Uncertainty.
Unless otherwise agreed upon, Pass or Fall verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laberatory according to ISO/IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as PASS nor as FAIL

Laboratory: TÜV SÜD Vietnam Co. Ltd. Lot III-26, 19/5A Street, Industry Group III, Tan Binh I.P, Tay Thanh Ward, Tan Phu District, Ho Chi Minh City, Vietnam

Phone :084-28-62678506 Fax :084-28-62678511 E-Mail : enquiries@tuv-sud.vn Url : www.tuv-sud.vn



Test Report No. VNT/MHS/20/000029R1 Dated 21/09/2020

Vietnam

Result summary/ Conclusion:

Test parameters	Test Standard	Conclusion	
Bacterial Filtration Efficiency (BFE) *	ASTM F2101-19	Level 3 (According to ASTM F2100-19)	
Differential Pressure *	EN 14683:2019 + AC:2019 (E) Annex C		
Synthetic Blood Penetration Resistance Test *	ASTM F1862/F1862M-17		
Sub-Micron Particle Filtration Efficiency (PFE) *	ASTM F2299/F2299M-03 (reapproved 2017)		
Flammability *	16CFR Part 1610		

Remark:

- This product achieved Level 3 according to ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks (ASTM F2100-19 TABLE 1 – MEDICAL FACE MASK MATERIAL REQUIREMENTS BY PERFORMANCE LEVEL)
- 2. (*) This test is subcontracted to other accredited laboratory (TÜV SÜD South Asia Pvt. Ltd.)
- R1: The report no. VNT/MHS/20/000029 dated 17/09/2020 has been superseded. The test report is revised in terms of to
 update company address as per customer's request.
- 4. This test report is for intended use such as internal scientific research, education, quality control, product, R&D.

TÜV SÜD Vietnam

Authorized by

Nguyen Manh Duc MHS Auditor

Laboratory: TÜV SÜD Vietnam Co. Ltd. Lot III-26, 19/5A Street, Industry Group III, Tan Binh I.P, Tay Thanh Ward, Tan Phu District, Ho Chi Minh City, Vietnam

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