

PRODUCTS CATALOG 2020

NANOFIBERS MEDICAL FACE MASK



SEATRACK INTERNATIONAL

PHARMACEUTICALS | MEDICAL DEVICES
— MANUFACTURER & SUPPLIER —

Manufacturing & International Supply:

SEATRACK INTERNATIONAL GROUP

info@seatrackinternational.com

Seatrackinternational.com

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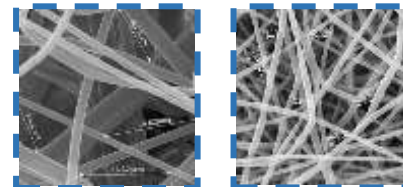
* Nanofibers Medical Face Mask

FDA Cleared 510K,
FDA listed medical device
FFP2 CE certified

* Comparison Charts

* Tests & Analysis

* Certifications



The Vital Shield for You and Your Loved Ones

Powerful Filtering,
Excellent permeability,



Breathing New Technology,

Nanofiber Filter

Medical Face Mask

- ✓ FDA Registered,
- ✓ FDA Cleared 510K,
- ✓ CE Certified

PERMEABILITY BLOCKABILITY DURABILITY



Long-lasting freshness from morning to evening!

- ✓ Nanofiber Filter has great permeability,
So you can feel fresh even after a long term use
- ✓ Blocks pollutants and enables easier breathing
- ✓ Lighter than a sheet of paper
Because we need to wear it all day, we made it lighter

If you care about the skin,
permeability is even more important.

Wearing mask all day causes skin trouble (C Newspaper)

Must wear permeable masks (M Newspaper)

Pimple breaks out due to wearing masks
(National Health Insurance Service blog)

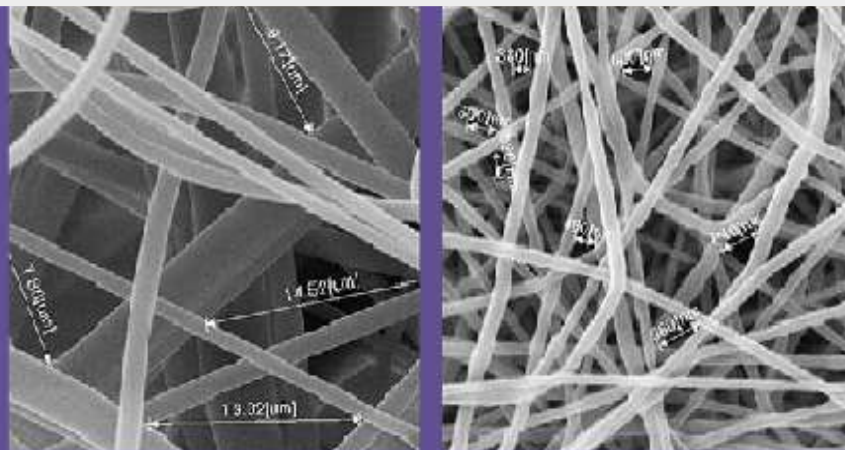
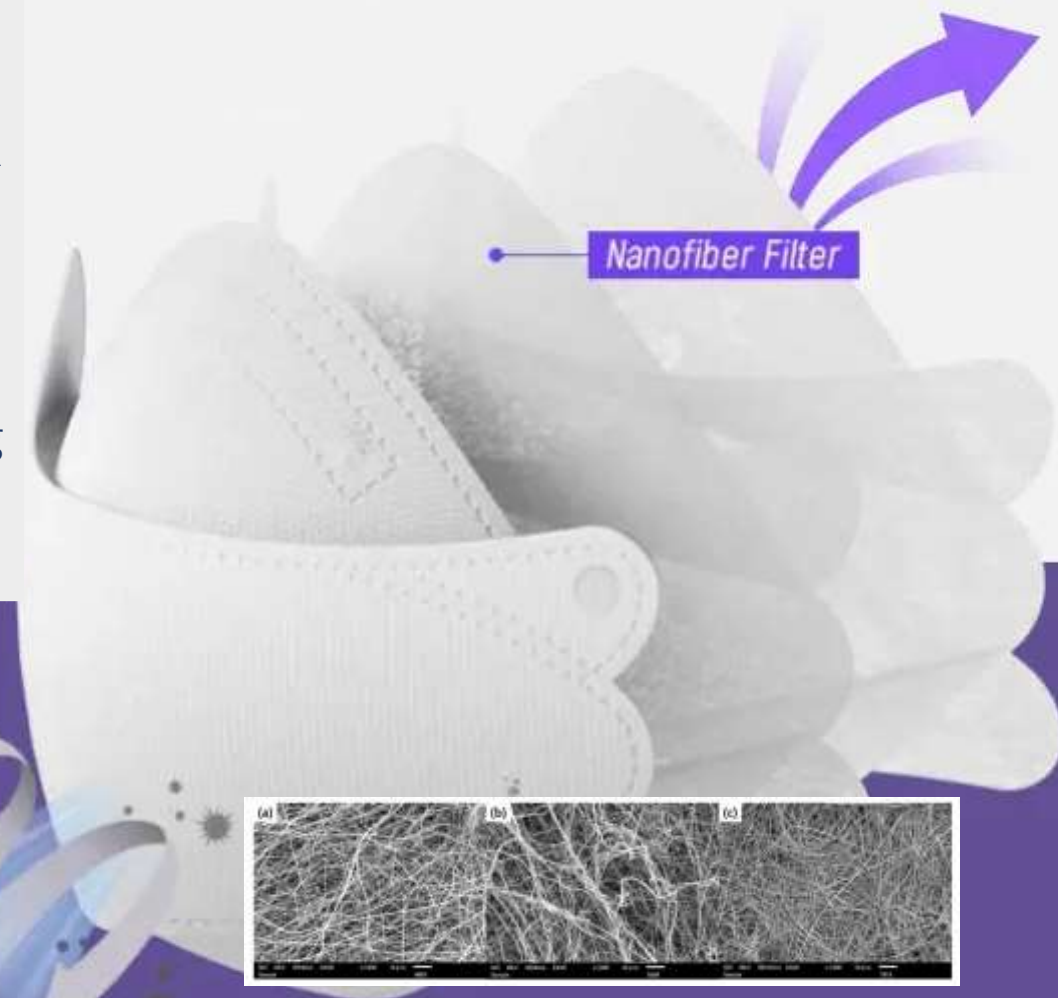
There is moisture in our respiratory system
If a mask has bad permeability, the moisture from within
cannot escape, which causes eczema

If you wear a mask for a long time,
you really need a permeable mask

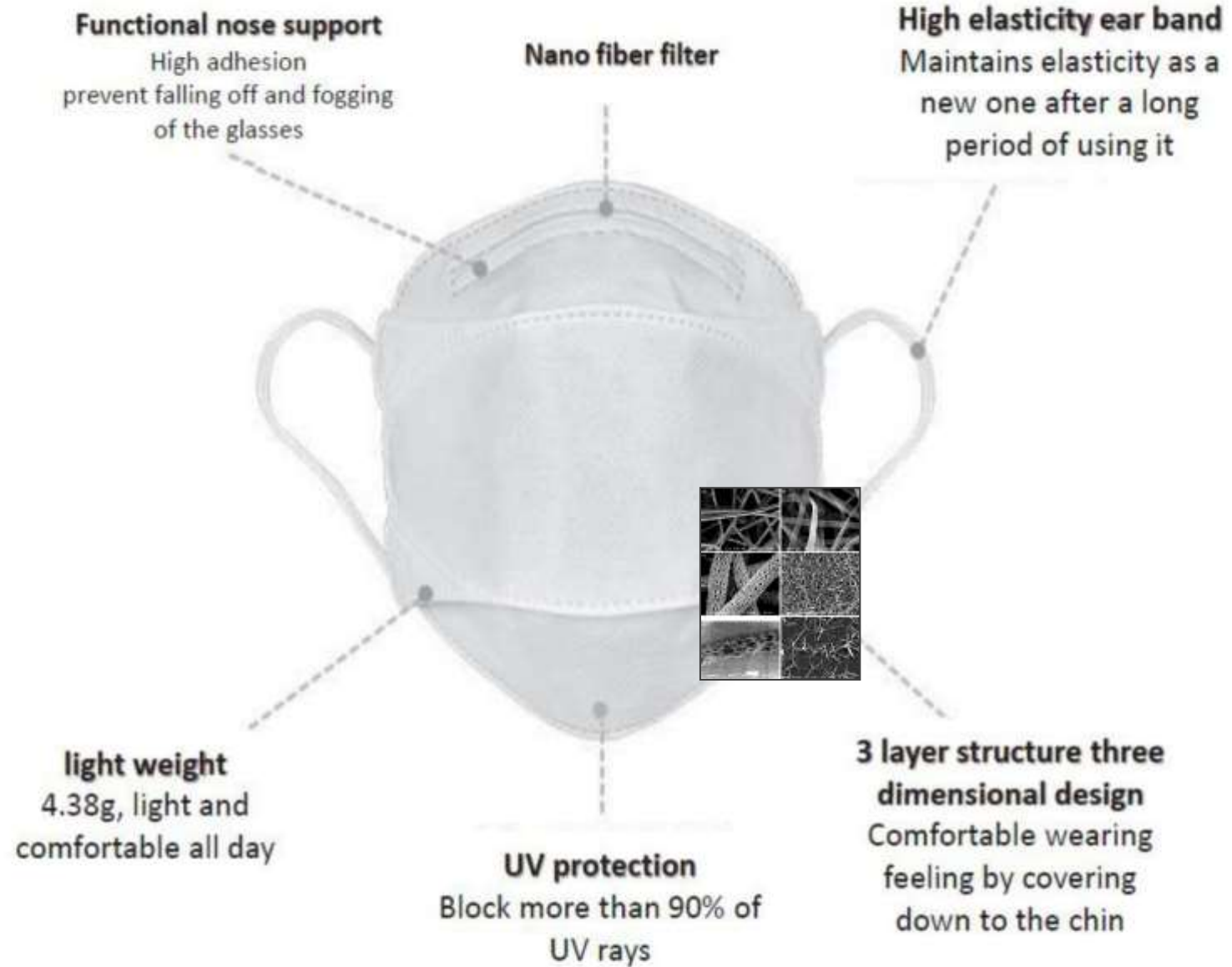
THE DIFFERENCE BETWEEN NANO FILTER AND NORMAL FILTER



- ✓ Nanofibers are only 1 nanometer, 1 billionth of a meter in thickness. Nanofiber is a new material made by building these fibers sterically for fishnet structure that has better permeability, blockability and durability than any fiber ever invented.
- ✓ Nanofiber completely Blocks particles as small as $1 \mu\text{m}$ while most Bacteria are $3-10 \mu\text{m}$
- ✓ Electrospinning is a fiber production method which uses electric force to draw charges threads of polymer solution. There are several millions of pores per 1 inch^2 , protecting against Dust, Virus & Bacteria



NANO FILTER TECHNOLOGY

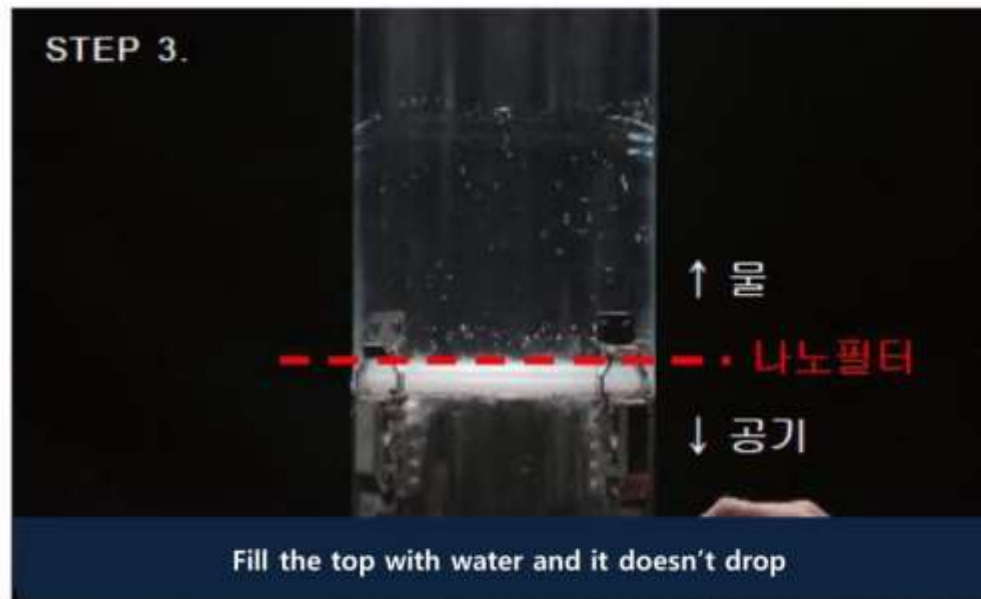


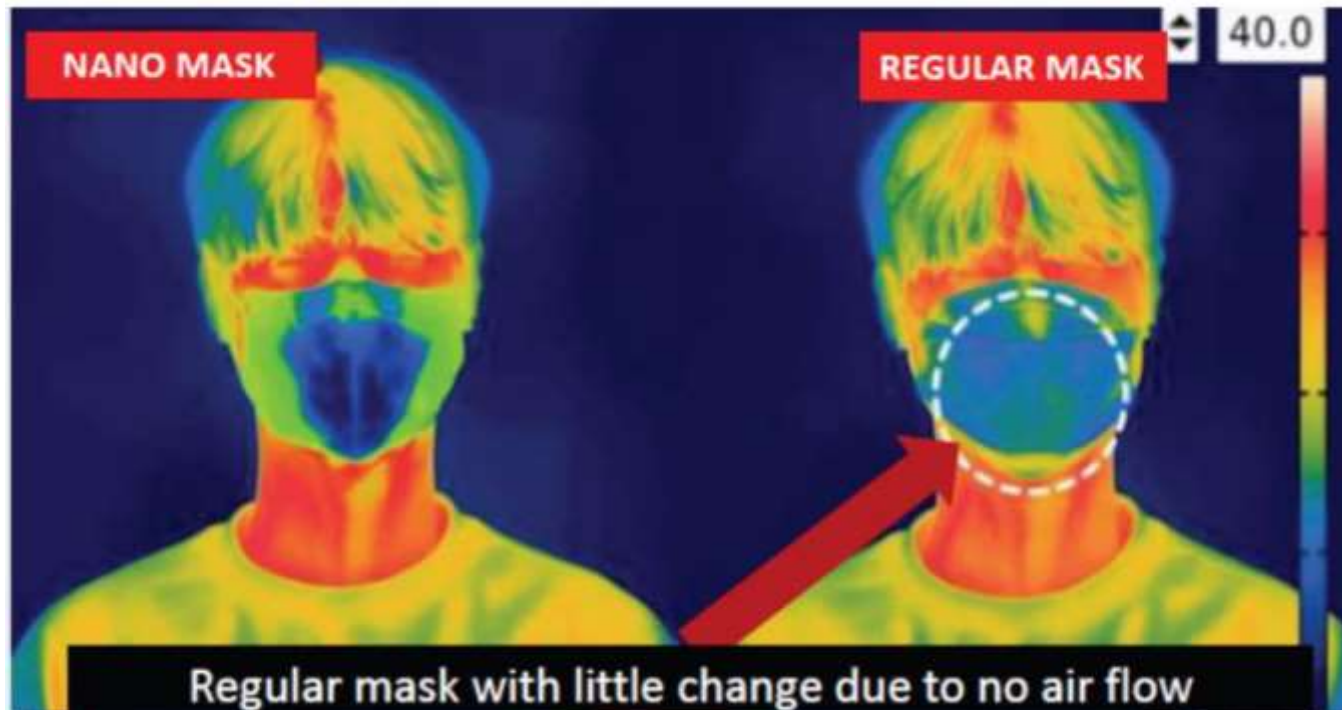
Filtering Performance Comparison

Comparative standard	<u>N95</u>	<u>KF94</u>	<u>Nano Filter Mask</u>
Country	USA	KOREA	KOREA
Filter performance - (must be \geq X% efficient)	$\geq 95\%$	$\geq 94\%$	$\geq 99\%$
Test agent	NaCL	NaCL and paraffin oil	NaCL and paraffin oil
Flow rate	85 L/min	95 L/min	95 L/min
Total inward leakage (TIL)* - tested on	N/A	$\leq 8\%$ leakage (arithmetic mean)	$\leq 5.2\%$ leakage (arithmetic mean)



AIR VENTILATION TEST





BREATHING FIBER

'Nano Membrane'

NANO-membrane is 0.1 μm larger than air particles and smaller than harmful particles, and is filtered by the nanofiber structure itself, allowing for long wear and breathability, blocking, and durability.

Most existing masks are less efficient due to moisture generated when breathing in an electrostatic manner.



Material: Polypropylene Spun-Bond Non-woven Fabrics, plastic coated wire, Polypropylene loop, nylon string

Certification: FDA Registration, FDA Cleared 510(K), FDA Medical Listed Device, FFP2 CE Certified

Product: Nanofibers Face Mask

- Product Type: Surgical Face Mask
- Manufactured in: Korea (Certificate of Origin by Korean Authorities)
- Weight: 4.38g

Feature: Breathable, BFE=>95% ASTM F2101-14, ASTM F1862

Type: Ear-loop, Ultra-Sonic Weld/strongest constructed mask

Expiry date: 3 years

Application: Used in clinic, hospital, pharmacy, restaurant, food processing, beauty salon, electronics industry, etc.





Sponsor:
Kim May
WeDoCare Co., Ltd.
Rm 101, 13, Bokjeong-ro 42 Rd.
Sujeong-gu
Seongnam City, Gyeonggi-do, 13118
KOREA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article: FS-160601
Lot: 20160601
Study Number: 906436-S01
Study Received Date: 25 Jul 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 13

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) at $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met.

Test Side: Inside
BFE Area Tested: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours.
Test Article Dimensions: $\sim 155 \text{ mm} \times \sim 170 \text{ mm}$
Positive Control Average: 2.4×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $2.9 \mu\text{m}$



89-S01
Sponsor:
Kim May
WeDoCare Co., Ltd.
Rm 101, 13, Bokjeong-ro 42 Rd.
Sujeong-gu
Seongnam City, Gyeonggi-do, 13118
KOREA

Synthetic Blood Penetration Resistance GLP Report

Test Article: FS-160601
LOT: 20160601
Study Number: 906437-S01
Study Received Date: 25 Jul 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 08

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception. ISO 22609 requires testing to be performed in an environment with a temperature of $21 \pm 5^\circ\text{C}$ and a relative humidity of $85 \pm 10\%$. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 31
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 20.1°C and 23% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Article Number	Synthetic Blood Penetration
1-17, 19-32	None Seen
18	Yes

Test Method Acceptance Criteria: The output of synthetic blood through the targeting hole before and after every 16 test articles must be within 2% ($\pm 0.04 \text{ g}$) of the theoretical output of 2 mL.

TESTS & ANALYSIS

CERTIFICATIONS



Certificate of Registration

This is to certify that the
Quality Management System
of
**SEATRACK INTERNATIONAL TRADEX
PRIVATE LIMITED**
at
712 B, 7th Floor, Modi Tower 9B, Nehru Place, New Delhi - 110019, India

has been independently assessed and
is compliant with the requirements of:

ISO 9001:2015

For the following scope of activities:

Manufacturer and supplier of Hygienic Products, Face Mask, Sanitizer, Coverall, Hospital Gowns, cover sheet, ventilators, hospital equipments, Medicines, Medicinal Herbs, Saffron, Yarsagumba, Shilajeet

Certificate Number: UQ-20200331001

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	31st March 2020
1 st Surveillance Audit Due	30th March 2021
2 nd Surveillance Audit Due	30th March 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	30th March 2023

Daniel..
Authorised Signatory




This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website - www.ukcertifications.org.uk, email - info@ukcertifications.org.uk
Company No. 11847851



Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC Class I.

Certificate No.: CE-10195

Manufacturer / Applicant
Name : SEATRACK INTERNATIONAL TRADEX PRIVATE LIMITED
Address : Regd. 712B, 7th Floor, Modi Tower 9B, Nehru Place, New Delhi - 110019, India
Products : Hygienic Products, Face Mask, Sanitizer, Coverall, Hospital Gowns, cover sheet, ventilators, hospital equipments.

Complies with the requirements applicable to it
The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the notified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC (class I).

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration	31st March 2020
Date of this certificate	31st March 2020
Certificate Expiry	30th March 2021
Recertification due (subject to the company maintaining its system to the required standard)	30th March 2023

Daniel..
Authorised Signatory



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Certificate of Compliance

Certificate Number: UQ-20200331002

This is to certify that
**SEATRACK INTERNATIONAL TRADEX
PRIVATE LIMITED**
at
712 B, 7th Floor, Modi Tower 9B, Nehru Place, New Delhi - 110019, India

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of "Good Manufacturing Practice" as laid down by "World Health Organisation" which has been in conformance to the requirements of

WHO-GMP

Manufacturer and supplier of Hygienic Products, Face Mask, Sanitizer, Coverall, Hospital Gowns, cover sheet, ventilators, hospital equipments, Medicines, Medicinal Herbs, Saffron, Yarsagumba, Shilajeet

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Company No. 11847851

ADMINISTRATIVES:

712 B, 7th Floor, Modi Tower 98,
Nehru Place, New Delhi 110019, India

Phone: +91 11 46063427, +91 11 49384601,
Fax : +91 11 41063429, +91 11 41582010,

14-4, Itaewon-Ro 15-Gil, Yongsan-Gu,
Seoul, 04351, Republic of Korea

Phone: +82 2797 5800
Fax : +82 2797 5855

Seatrackinternational.com
info@seatrackinternational.com

General Enquiries: +91 790 4257 195
Nationwide (India): +91 999 9765 911
Worldwide (International): +1 929 5232 998

