Certification & Inspection

Certificate of Compliance

Certificate Number :

This is to certify that

[redacted]

at

ADDRESS: 502, SUNDARAM HEIGHTS, B/H.UMIYA MARKET, SAKAT SANALA, MORBI-363641, GUJARAT, INDIA

has been assessed and found to be conforming the requirements of the

FDA

MANUFACTURING, SUPPLY, IMPORT AND EXPORT OF MEDICAL ANDVETERINARY APPARATUS AND INSTRUMENTS, MASKS AND EQUIPMENT FOR ARTIFICIAL RESPIRATION, MASKS FOR MEDICAL USE FOR ANTI BACTERIAL PROTECTION, MASKS FOR SURGICALS USE FOR TOXIC SUBSTANCE PROTECTION, SANITIZERS FOR HOUSEHOLD USE, ALCOHOL BASED ANTIBACTERIAL SKIN SANITIZER GELS AND THERMAL GUN

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the FDA Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits

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

Date of Certification	30th May 2020
1st Surveillance Audit Due	29th May 2021
2nd Surveillance Audit Due	29th May 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	29th May 2023

Authorised Signatory

UK Certification & Inspection Ltd.

FDA compliant


OPTIMASK
HEALTH CARE

ICL Integral Certification (P) Ltd.
AN ISO 9001: 2015 CERTIFIED LAB
Certificate No : 0913616A

Agmark Approved
by Government of India

envitro™ LABORATORIES
The leading Edge in Science

Celebrating 12 Years of Excellence...
ENVITRO LABORATORIES PVT. LTD.
"Krushna Niwas", 6 Naval Nagar, Mavdi Main Road,
Opp. Fulia Hanuman Temple, Rajkot - 360 004 (Gujarat) INDIA.

TEST REPORT

TEST REPORT No. : EL/O/2006368-A
DATE OF ISSUE: 25/06/2020
SAMPLE COLLECTED BY : Self
SAMPLE DESCRIPTION : N95 Mask

BRAND NAME:NM	DECLARED VALUE : ND		
QUANTITY	BATCH NO.	DOM	DOE
50 Pieces	---	---	---
DATE OF RECEIPT	DATE OF START ANALYSIS	: 23/06/2020	
23/06/2020	DATE OF COMPLETION OF ANALYSIS	: 25/06/2020	

TEST NAME:
Bacterial Filtration Efficiency ASTM F 2101-Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Material, Using a Biological Aerosol of *Staphylococcus aureus*

TEST CONDITION:

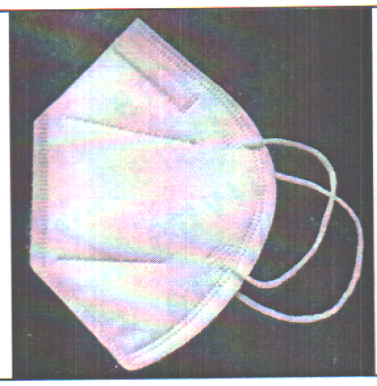
Inoculums size:	Staphylococcus aureus ATCC 6538=5 X 10^5 CFU/ml
Media Used:	Tryptic soya agar
Dilution medium used:	Peptone water
Incubation conditions:	37 ^{0}C for 24h

TEST RESULTS

SI No.	TESTS/PARAMETERS	Described by the customer : Face Mask
1.	Area of test specimen	Facemask
2.	Sample exposure side	Face side
3.	Flow rate of aerosol	28.5 L/min.
4.	Mean particle size of challenging aerosol	3.0 ± 0.3 micron
5.	Average plate count of positive control	3420
6.	Average plate count of negative control	0
7.	BFE of test specification %	98.2
8.	PFE (Particle Filtration Efficiency) of test Specification %	99.4

Result: The sample showed 98.2% bacterial filtration efficiency against *Staphylococcus aureus* ATCC 6538 when tested according to ASTM F 2101 test method.

SAMPLE IMAGE:



REMARKS:

1 This report, in full or in part, shall not be published, advertised, used for any legal action, unless prior permission has been secured from **The Director, ENVITRO LABORATORIES, RAJKOT.**
2 The test report pertains to the sample tested.
3 Sample not drawn by us.
4 All above Parameters are not covered/Not accredited under NABL Scope of Accreditation.

Approved By:

Authorized Signatory

Envitro Laboratories Pvt. Ltd. envitro Laboratories Pvt. Ltd. Rajkot

Tested By:

एन्वीट्रो लेबोरेटरीझ प्रा. ली.
खाद्य-खुराक, जल, मृदु (जमीन) एवं पर्यावरण के परीक्षणो के लीए पृथ्थकरण एवं संशोधन प्रयोगशाला
''कृष्णा निवास'', ६ नवलनगर, मवडी मेइन रोड, फुलीया हनुमान मंदीर के सामने, राजकोट – ३६० ००४ (गुजरात) भारत.

इडरा IEDRA Award Winner Laboratory

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Opp. Fulia Hanuman Temple, Rajkot - 360 004 (Gujarat) INDIA.

TEST REPORT

TEST REPORT No. : EL/O/2006368
DATE OF ISSUE: 25/06/2020
SAMPLE COLLECTED BY : Self
SAMPLE DESCRIPTION : N95 Mask

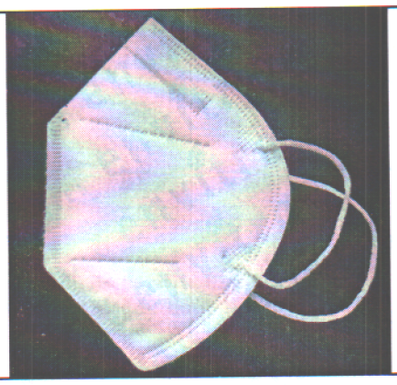
BRAND NAME:NM	DECLARED VALUE : ND		
QUANTITY	BATCH NO.	DOM	DOE
50 Pieces	---	---	---
DATE OF RECEIPT	DATE OF START ANALYSIS	: 23/06/2020	
23/06/2020	DATE OF COMPLETION OF ANALYSIS	: 25/06/2020	

TEST RESULTS

SI No.	TESTS/PARAMETERS	Test Method	UNIT	LIMIT	RESULTS
BREATHING RESISTANCE					
1.	Inhalation permitted resistance @95 1/min	NIOSH IS 9473: 2002	mbar	3.0 max	1.23
2.	Exhalation permitted resistance @160 1/min		mbar	3.0 max	1.08

Filter Efficiency as per NIOSH Standard
Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized and passed through the test article at a concentration not exceeding 200 mg/m^3 the initial airflow resistance and particle penetration for each respirator was determined.

According to 42CFR Part 84,64. Pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.



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2 The test report pertains to the sample tested.
3 Sample not drawn by us.
4 All above Parameters are not covered/Not accredited under NABL Scope of Accreditation.

Approved By:

Authorized Signatory

Tested By:

Envitro Laboratories Pvt. Ltd. envitro Laboratories Pvt. Ltd. Rajkot

एन्वीट्रो लेबोरेटरीझ प्रा. ली.
खाद्य-खुराक, जल, मृदु (जमीन) एवं पर्यावरण के परीक्षणो के लीए पृथ्थकरण एवं संशोधन प्रयोगशाला
''कृष्णा निवास'', ६ नवलनगर, मवडी मेइन रोड, फुलीया हनुमान मंदीर के सामने, राजकोट – ३६० ००४ (गुजरात) भारत.

इडरा IEDRA Award Winner Laboratory

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Certificate of Compliance

CE

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

Certificate No.: CE-4604

Manufacturer

Name [redacted]

Address : **502, Sundaram Heights, B/H. Umiya Market, Sakat Sanala, Morbi-363641, Gujarat, India**

Product Name : **Medical and Veterinary Apparatus and Instruments, Masks and Equipment for Artificial Respiration, Masks for Medical Use for Anti Bacterial Protection, Masks for Surgicals Use for Toxic Substance Protection, Sanitizers for Household Use, Alcohol Based Antibacterial Skin Sanitizer Gels and Thermal Gun**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified 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.

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.

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

Date of Certification	12th May 2020
1st Surveillance Audit Due	11th May 2021
2nd Surveillance Audit Due	11th May 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	11th May 2023

Authorised Signatory

UK Certification & Inspection Ltd.

CERTIFICATE

This is to Certify that the
Quality Management System
of

[redacted]

502, Sundaram Heights, B/H. Umiya Market, Sakat Sanala,
Morbi-363641, Gujarat, India

has been assessed and approved
in accordance with the guidelines of:

ISO 9001: 2015

For the following scope of activities:

Manufacturing, Supply, Import and Export of Medical and Veterinary Apparatus and Instruments, Masks and Equipment for Artificial Respiration, Masks for Medical Use for Anti Bacterial Protection, Masks for Surgical Use For Toxic Substance Protection, Sanitizers for Household Use, Alcohol Based Antibacterial Skin Sanitizer Gels and Thermal Gun

Certificate Number: Q-2050200512001

Date of initial registration:	**12th May 2020**
Date of this Certificate:	**12th May 2020**
Surveillance Audit on or before:	**11th May 2021**
Recertification Due / Certificate Expiry:	**11th May 2023**

This Certificate is property of DBS Certifications and remains valid
subject to satisfactory surveillance audits

Head of Certification

ACCREDITED
Management Systems Certification Body.
MSCB-157

The certificate remains the property of DBS Certifications Private Limited, to whom it must be returned upon request.

DBS CERTIFICATIONS PVT. LTD.
142, IInd Floor, Avtar Enclave, Paschim Vihar, Delhi-110063, (INDIA) info@dbscertification.com, www.dbscertification.com

ACCREDITED BY :
International Accreditation Service (IAS) 3060, Saturn Street Suite 100, Brea, Ca 92821-1732, United States of America