Mask supply & delivery complete solution

FFP2 / KN95 / Surgical Masks

Manufacturing in China, Reserved Airfreight Space, Door to door solution

IDC Innovation Développement Création

Heppner Transport & Logistics

ASI LOGISTICS

KN95

Capacity:
2M/day

Product Description

KN95 without valve
Metal strip for nasal adjustment
Elastic rubber
Origin: China

Standards

FDA
KN95 (GB2626-2006)

Box: 55 x 44 x 38 cm
Box GW: 9.5kg
1000 pcs / box

Sizes subject to change

FDA

FFP2

Capacity:
1.5M/day

Product Description

FFP2 without valve
Metal strip for nasal adjustment
Elastic rubber
Origin: China

Standards

Directive 2016/425
EN149:2001+A1:2009
FDA

Box: 55 x 44 x 38 cm
Box GW: 9.5kg
1000 pcs / box

Sizes subject to change

CE FDA

N95

Capacity:
Consult us

Product Description

N95 without valve
Metal strip for nasal adjustment
Elastic rubber
Origin: China
Niosh

Standards

Niosh

Box: 62 x 29 x 34 cm
Box GW: 5.0 kg
400 pcs / box
20 packs / box
20 units / pack

Sizes subject to change

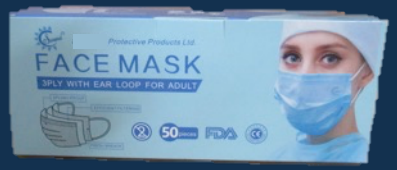
CDC NIOSH

3Ply

Capacity:
4M/day

Product Description

3 ply Medical Face Mask
17.5*9.5cm
Elastic ear loop
Type I & Type II (BFE > 99%)



Standards

Directive 93/42/EEC
EN14683
FDA

Box: 52x38x30 cm
Box GW: 7.6kg
2000 pcs / box

Sizes subject to change

CE FDA

FFP2/KN95 CERTIFICATES

Certificate Of Conformity NPS

Applicant :
Address :

Manufacturer :
Address :

DECLARE ON OUR SOLE RESPONSIBILITY THAT THE PRODUCT
Trade Name : Details
Product : Particulate Respirator KN95
Model : DT002

This EC-Declaration of conformity is following the provisions of Personal Protective Equipment (PPE) Directive (EU)2016/425 (89/686/EEC)
It is confirmed that a sample of the product has been tested and found in conformity with below

Test Standard : EN 149:2001+A1:2009Respiratory protective devices-Filtering half masks to protect against particles-Require-ments,testing,marking

Classifications : FFP2
Date of issue : March 19, 2020

Detailed Soecification of the tested product shown in the followino test Recorti(s)
Certificate No. : NPS020030190-CE

CE

Technical director

NPS Laboratory Company Limited www.nps.gs e.nps@nps.gs www.nps.hk e.nps@nps.hk
UK Phone:+44-20-37342132 USA Phone:+1-213-2895039 HK Phone:+852-53700317
The statement is based on a single evaluation of the sample of above mentioned products. It does not imply an assessment of the whole production.

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10062984

Device Listing#: See Next pager

FDA

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CCT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
Issued: 03/15/2020
Expiration Date:12/31/2020

CCT

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Web: http://www.fda.gov Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D375030	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	Face Mask
D375029	OEA	Non-surgical isolation gown	Protective clothing
D375028	HQY	Sunglasses (non-prescription including photosensitive)	Goggles
D375027	KHA	MASK, SCAVENGING	Mask

Chief engineer
Issued: 03/15/2020
Expiration Date:12/31/2020

CCT

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Web: http://www.fda.gov Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov

CE FDA

3 PLY CERTIFICATES

Nelson Labs.
A Sotera Health company

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

Test Article: Surgical Face Mask
Purchase Order: SHLAB2003160001A
Study Number: 1277685-S01
Study Received Date: 16 Mar 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^5 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: ~40 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions: ~175 mm x ~150 mm
Positive Control Average: 2.0 x 10^5 CFU
Negative Monitor Count: <1 CFU
MPS: 3.2 µm

Study Director James W. Luskin Study Completion Date 23 MAR 2020

1277685-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Page 1 of 2

Nelson Labs.
A Sotera Health company

Synthetic Blood Penetration Resistance Final Report

Test Article: Surgical Face Mask
Purchase Order: SHLAB2003160001A
Study Number: 1277684-S01
Study Received Date: 16 Mar 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s): None

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 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 29
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 22°C and 22% RH

Study Director James W. Luskin Study Completion Date 25 MAR 2020

1277684-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Page 1 of 2

TÜVRheinland

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60111758 0001
Report No.: 15095978 001

Manufacturer:

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Surgical Caps, Sterile Surgical Face Masks, Sterile Surgical Gowns, Sterile Bed Protections, Sterile Surgical Drapes, Sterile Surgical Packs

Expiry Date: 2021-08-11

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2016-08-12
Date: 2016-08-12

TÜV Rheinland LGA Products GmbH · Tillystraße 2 · 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Nelson Labs.
A Sotera Health company

TÜVRheinland
CERTIFIED

OUR SOLUTIONS

- ✓ Sourcing
- ✓ Factory Auditing
- ✓ Presence on Manufacturing site
- ✓ Inspections before shipment

Reserved 66 CBM by Air

~ 800K FFP2/KN95/N95
~ 2M Surgical

Departure every Tuesday

Chartering capacity for important volumes

AUDITING AND QC

THEY TRUST US FOR MASKS SUPPLY

THALES

crit
Travaillons ensemble

BUT

FNAIM

NEUILLY-SUR-SEINE

UMEP
UNION MARITIME ET PORTUAIRE LE HAVRE
United know-how

NEUILLY-SUR-SEINE

CHU
NIMES

Région
Hauts-de-France