



NOSIHTAM
INC
GLOBAL SOURCING SOLUTIONS

Product: Personal Protective Supplies

Supplier: China manufacturer for professional healthcare products

Updated: April 16, 2020

Contact: Jeremy Mathison | 204-803-9242 | jeremy.m@nosihtam.com



Disposable Masks (Adult)

A quality non-woven and filter fabric made with folding, hot pressing, cut and welded with ear bands. Easy pop out ear looks ideal reminders the mask has been used and not to reuse.



Product Application

Mainly used for respiratory protection. Filters air particles, blocks droplets, and various micro-organisms. For medical and health care use.

Specification: 180mm x 95mm (3 Layers)

Validity: 2 Years

Execution Standard: Q/GDYY 03

Hygiene Standard: GB15979

International Standard: FDA and CE Approved. ISO Certified

Origin: Dongguan, China

Manufacturer production capacity: 1 million pieces per day, 21 production lines

Storage: Should be protected from light and stored in a well-ventilated room where the humidity is less than 80%, without corrosive substances.

Packaging Information:

50 pcs per box

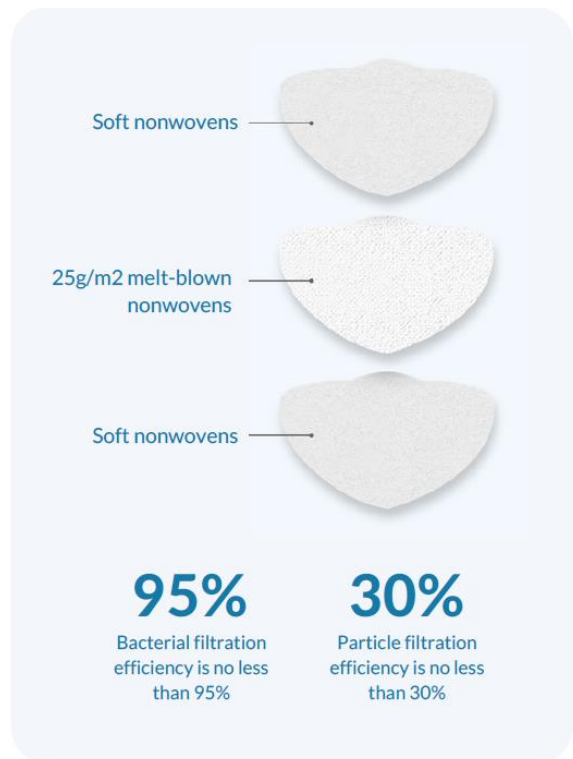
50 Boxes per carton

2500 per carton

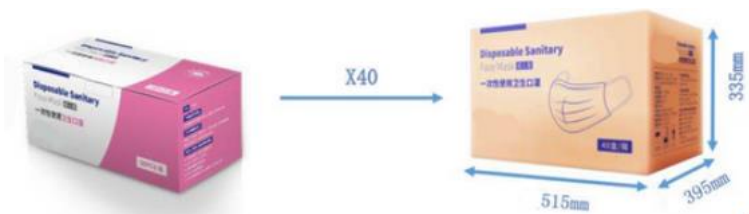
Unit Price orders >1M Pcs \$1.77 CAD per piece*

Unit Price orders <1M Pcs \$1.84 CAD per piece*

**Excluding Freight, Duty and taxes*



Freight: TBD based on order size and time of shipment



N95 Mask (Adult)

Filter efficient 95% protection N95 mask made with non woven fabrics. FFP2 rating.



Product Application

Mainly used for respiratory protection. Filters air particles, blocks droplets, and various micro-organisms. For medical and health care use.

Validity: 2 Years

Execution Standard: EN149:2001

Hygiene Standard: GB15979

International Standard: FDA and CE Approved.

Origin: Dongguan, China

Manufacturer production capacity: 100,000 per day

Storage: Should be protected from light and stored in a well-ventilated room where the humidity is less than 80%, without corrosive substances.

Packaging Information:

20 pcs per box

40 Boxes per carton

800 per carton

Unit Price orders >1M pcs: \$4.47 CAD per piece*

Unit Price orders <1M Pcs \$5.34 CAD per piece*

**Excluding Freight, Duty and taxes*

Freight: TBD based on order size and time of shipment



Disposable



Healthy



Soft and skin friendly



Folding design



Stop droplets



Soft nose clip

Protective Clothing

Medical grade polypropylene non-woven materials with PE breathable film. Sterile and non sterile types.

Materials

Polypropylene non-woven (PE Breathable film). Medical Grade, soft and comfortable, antibacterial and durable, wear-resistant and tear-resistant.

Gram weight: 85gsm

Grade: Highest Medical grade

Manufacturing Process

Standard dust free workshop/needle car (flat car)/Side car/Gluepress/packer/Laser machine/Disinfection cabinet (ethylene oxide)/Pure water equipment/Synthetic blood penetration tester/ Moisture permeability tester/Tensile elongation tester/Flame retardant Tester

Sizes: 165 (s), 170 (m), 175 (L), 180 (XL), 185 (2XL)

Service life: Use within 12 months from the date of sterilization

Execution standard: GB19082-2009

International Standard: FCE Approved

Origin: Guandong, China

Manufacturer production capacity: 1500-2000 per day



PACKAGING SPECIFICATION	OUTER BOX SPECIFICATION	PACKING NUMBER OF 20GP CABINET	PACKING NUMBER OF 40GP CABINET	PACKING QUANTITY OF 40HQ CABINET	PACKING QUANTITY OF 45HQ CABINET
50 PIECES / BOXES	64 X 50 X 44CM	9000 PIECES /180 BOXES	18000 PIECES /360 BOXES	21600 PIECES / 432 BOXES	25000 PIECES / 500 BOXES

Packaging Information:

Pack size: 49.5 x 35 cm per suit. 0.3kg
Carton Size: 64 x 50 x 44 cm. 50 pcs per carton



Unit Price*

Upon request

*Excluding Freight, Duty and taxes

Freight: TBD based on order size and time of shipment

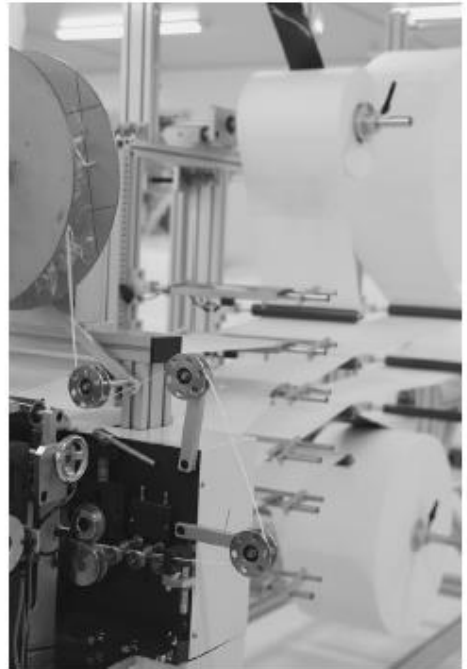


Market conditions are unstable due to extremely high demand and material prices are continuing to escalate. Therefore, the validity of this offer is limited to 48 hours. Supplier will not refuse orders after 48 hours but we may need to re-confirm lead-times and costs.

Our trusted supplier for personal protective supplies has direct access to 8 manufacturers spanning the Guangdong province providing a variety of goods including

protective masks, clothing and various medical items.

Nosihtam Inc. has a team on the ground to provide quality inspection and export assistance to ensure all parts of the process meet the criteria for international standards.



Sample Pictures



Manufacturer provided certificates

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

CE Documentation Review



No. 0P200324S.GYC0T24

Holder:

[Redacted]
China

Review goal:

Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product:

Medical masks (Not Sterile)

Model(s):

18 cm x 9.5cm, 14cm x 9.5cm, 14cm x 18cm, 11.5cm x 14cm

Classification:

Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output:

This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.

Technical documentation identified with the no. TMGD20032023092 dated 24 march.

The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. 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

Date of issue 24 March 2020

Approver
ECM Service Director
Luca Badanni

Expiry date 23 March 2025

Technical Expert
Amanda Payne

Ente Certificazione Macchine

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Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation




Fiscal Year 2020
CERTIFICATE OF FDA REGISTRATION
This certifies that:
[REDACTED] GUANGDONG,
523000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.
Owner/Operator Number: 10064336

Listing No.	Product Code:	Device Name:
D378855	LYU	ACCESSORY, SURGICAL APPAREL - Disposable Diapers

UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

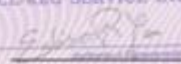
Pursuant to 21 CFR 807.39: "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration 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. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.



UCL-REGSERVICE INC.
662 ROCKWOOD ROAD, WILMINGTON,
NEW CASTLE, DE 19802 USA

Not and to behalf of
UCL-REG SERVICE INC.



Authorized Signature

Cert No. M20672
Issued Date: 25 March 2020
Expiration Date: 31 December 2020



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: [REDACTED]

Listing No.	Code	Device Name	Proprietary Names	Activities
D377441	MSH	Respirator, surgical	Disposable Protective mask Face mask (filter) N95 Protective mask Folding mask	Manufacturer

END OF THE ANNEX

A handwritten signature in black ink, appearing to read "John Flor".

Chief engineer

Issued: March 23, 2020

Expiration Date: December 31, 2020