

TNE International, LLC

...we bring the world to your doorstep...



FDA Registered Medical Device Initial Importer
(ID # 3008342449)



Overview

- ▶ TNE International is an FDA-registered Initial Importer for Medical Devices.
- ▶ Most Product is FDA Registered and FDA Cleared if required.
- ▶ Product that does not have FDA Registration or Clearance – meet FDA EUA Requirements, including listing if required.
- ▶ 20 Years of Expertise in supplying product from foreign manufactures and managing the reliable quality, delivery, and logistics required.

Overview (Cont.)

- ▶ TNE is a Broker that purchases product and sells to its customer across the US and Europe.
- ▶ Engaged in supply of PPE at this critical time to lend our expertise to help curb critical shortages.
- ▶ All due diligence is completed to verify FDA Registration, 510K approved / cleared (where 510K required), or FDA EUA requirements as applicable.

N95 Respirators

FDA Product Code: MSH, Class II, 510K Exempt

Various Suppliers:

- Supplier 1: FDA Registered, NOISH Certified & 510K Pre-Approval (Head Band Style)
- Supplier 2: FDA Registered (Ear Loop Style)
- Supplier 3: FDA Registered (Ear Loop Style)
- Supplier 4: NOISH Certified, FDA EUA Listed, Head Band Style)

*Picture is for Supplier 1



KN95 Respirators



FDA Product Code: NA
Class NA

Supplier:

- Not FDA Registered, FDA EUA Approved and on EUA List

Ear-Loop Surgical Masks



FDA Product Code: FXX

Class II

510K Required

Various Suppliers:

- Supplier 1: FDA Registered & 510K Pre-Approval (Cleared)
- Supplier 2: FDA Registered & 510K Pre-Approval (Cleared)

* Picture is for Supplier

Vinyl, Patient Examination Gloves



FDA Product Code: LYZ
Class 1
510K Required

Product:

- No Powder
- Clear Color

Supplier:

Supplier: FDA Registered & 510K Pre-Approval (Cleared)

Nitrile, Patient Examination Gloves

FDA Product Code: LZA
Class 1
510K Required

Product:

- No Powder
- Clear Blue



Supplier:

Supplier: FDA Registered & 510K Pre-Approval (Cleared)

Isolation Gown, Coverall



FDA Product Code: OEA
Class 1
510K Exempt

Product:

- Non-Surgical
- White & Blue Color
- Hooded
- Coverall, Full Body

Supplier:

Supplier 1 & 2: FDA Registered

Isolation Gown, 360 Wrap



FDA Product Code: OEA
Class 1
510K Exempt

Product:

- Non-Surgical
- Blue Color
- 360 Wrap
- Coat Style

Supplier:

Supplier: FDA Registered

Face Shield



FDA Product Code: NA
Class NA
CE EN166:2001 Declaration

Product:
- Clear PVC Face Mask

Supplier:
Supplier: Not FDA Approved, Authorized
per FDA EUA

Commercial Terms

- ▶ Payment Terms:

- 70% Deposit/30% before Delivery

- ▶ Various Shipping Terms:

- ▶ FOB China Sea Port / Airport of Export
 - ▶ FOB (DDP) Chicago or other US City.
 - ▶ FOB (DDP) Customer's Door

- ▶ Shipping Lead-times:

- ▶ Air = 11 – 13 days from Port Date
 - ▶ Sea = 31 – 38 days from Port Date

Commercial Terms (Cont.)

- ▶ Manufacturing Lead-times – 3 to 21 days, depending on product and order volumes
- ▶ Price – Refer to Price Sheet Provided
- ▶ **Process:**
 - ▶ Customer Places PO
 - ▶ PO acknowledged with Carrier & Mfr.
 - ▶ 70% Deposit paid to TNE by ACH
 - ▶ Order Placed with Mfr.
 - ▶ Product Lands in the US and clears US CBP & FDA
 - ▶ 30% Paid to TNE by ACH
 - ▶ Product Delivered to Customer per PO Terms

Contact Information

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