

Vetting Potential Sources of PPE

The COVID-19 pandemic has driven a high demand for PPE (Personal Protective Equipment) such as masks, gloves, gowns, and other medical devices. In response there are many new manufacturers and distributors that are offering PPE for sale with varying degrees of quality and authenticity. This guide provides some best practices in terms of how to verify if some of these new sources of PPE can be an effective source of supply.

Watch for the following Red Flags:

When reviewing potential offers or sources of PPE be cautious if you come across any of the following potential red flags:

- Suppliers who require 100% payment upfront, or who require an order before they will produce the PPE.
- Offers for PPE where the inventory is not located within the U.S.
- Suppliers who do not have any U.S. representation or points of contact.
- Suppliers who have difficulty or are not timely in answering questions about their product.
- Offers with an unreasonable or vague delivery timeline.
- Prices significantly below current prevailing prices.
- No web presence or website does not reference offered PPE.
- Unsolicited offers for PPE from previously unknown contacts.
- Complaints registered with the [Better Business Bureau](#).

Verification Questions to Ask:

The following is a list of questions you can ask of potential suppliers of PPE to help you validate if they are a legitimate supplier with a quality product:

- Has your product been tested, if so by who and against which standard?
- Is their product certified for use within the U.S. by the FDA or through an FDA EUA (Emergency Use Authorization)?
- How many units are immediately available? Where is this inventory physically located?
- What material is your product made from? What are the specific blends (e.g. if a cotton blend what are the other materials)?
- Who is the original equipment manufacturer (OEM) and at what plant (location) was it manufactured? If the product is FDA Regulated, what is the Registration or FEI number for the producer?
- What quality certifications does the factory hold, and who is the registrar?
- Can you send a sample to test?
- Can you provide references for other entities who have purchased their product in your industry or region?

KEY STANDARDS FOR PPE

N95 Respirators: [42 CFR Part 84 List of approved products](#)

Surgical Masks: [21 CFR 878.4040](#),
ASTM F210

Fabric Face Coverings:
[CDC Recommendations](#)

Face Shields: [Current EUA](#)

Gowns: ASTM F2407,
ANSI/AAMI PB70:2003

Gloves: ASTM D6319

Sanitizing Wipes: [EPA List N](#)

Hand Sanitizer:
[Temporary Standards](#)
[FDA Do not use list](#)

Quality Certifications:
ISO 9001:2015 (General)
ISO 13485 (Medical)
ISO 17025 (Testing Labs)

International Sourcing Details:

Unless you are an experienced importer it is recommended to purchase your PPE from established domestic providers and distributors who already have experience and resources to conduct international sourcing. When sourcing from overseas be sure to consider the following complexities of importing goods:

- Does the proposed transaction seem valid and sound? Is the company an established supplier or if a distributor, do they have pre-existing relationships with U.S. businesses?
- Can the product leave the country of origin? If in China do they have approval from China's National Medical Products Administration (NMPA) to export that specific product and model?
- Is the product authorized for use in the USA (does it need FDA approval and if so does it have such approval)?
- Is the contract balanced between parties or one-sided?
- How will you make payment? Usually Letters of Credit are used for transactions between a new buyer and seller internationally and payment is only made once the seller provides proof of shipment.
- Understand how the goods will be transported from origin to final destination and which party is responsible for which export and import transactions and transportation.
- How are the goods insured while in transit.
- Who will pay the import duties and taxes in the USA? Some local entities (e.g. local health care entities) don't have the capability to do this implying the seller will need to have a legal entity presence in the USA to be the importer of record (or another middleman is involved).

Additional information: www.ciras.iastate.edu/COVID-19

For help responding to the COVID-19 emergency or implementing a response plan, contact: Marc Schneider (563-221-1596, maschn@iastate.edu) or Mike O'Donnell (515-509-4379, modonnll@iastate.edu).