

PERSONAL PROTECTIVE EQUIPMENT (PPE) IMPORT FAQs

1) WHAT ARE PPE PRODUCTS (FACE MASKS, GOGGLES, GLOVES, SURGICAL GOWNS, FACE SHIELD)

Personal Protective Equipment (PPE) are designed to create a non-disease specific barrier to penetration of substances, solid, liquid or airborne particles. In general, neither the FDA or the manufacture can provide assurances that PPE will protect against a specific disease. The data that FDA uses for the evaluation and clearance of PPE rarely includes performance evaluation or testing against specific viruses, such as Ebola or the flu. If performance data has met FDA requirements and demonstrate protection against a specific disease, the product labeling will state the claim for protection against a specific virus or bacteria.

ADDITIONAL GUIDANCE ON FACE SHIELDS AND GOWNS

FACE SHIELDS INTENDED FOR MEDICAL USE

- Product includes labeling that accurately describes the product as a face shield
- Includes a list of the body contacting materials
- Does not include any drugs or biologics
- Does not contain any materials that will cause flammability or meets Class I or Class II flammability requirement
- Product is not intended for any use that would create an undue risk in light of the public health emergency

Examples:

- Labeling does not include used for antimicrobial or antiviral protection or related uses
- Labeling does not include uses for infection prevention or reduction or related uses
- Labeling does not include uses for radiation protection

MODERATE-TO-HIGH BARRIER PROTECTION SURGICAL GOWNS

FDA will evaluate the classification of a gown whether:

- It is labeled as such
- It is described as such in its labeling
- It has statements relating to moderate or high-level barrier protection
- It has a statement that is intended for use during sterile procedures
- The product meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70 for the critic
- Meets the Class I or Class II flammability standard
- Has been demonstrated to be sterile if intended for use in surgical settings

NON-SURGICAL GOWNS AND MINIMAL-TO-LOW BARRIER PROTECTION SURGICAL APPAREL

FDA will evaluate whether a gown is not a “surgical gown” whether:

- It is labeled as a gown other than a surgical gown
- It is not described in its labeling as a surgical gown
- It includes statement relating to barrier protection and such statements are for only minimal or low barrier protection
- Product includes labeling that accurately describes the product as a “gown” or “toga”, or other apparel
- Includes labeling that makes recommendations that would reduce sufficiently the risk of use

Examples:

- Recommendations against use in a surgical setting
- Recommendations against use where significant exposure to liquid bodily or other hazardous fluids may be expected
- Recommendations against use in a clinical setting where Level 3 or 4 protection is warranted
- Recommendations against use in the presence of high intensity heat source of flammable gas

The product is not intended for any use that would create an undue risk in light of the public health emergency.

Examples:

- Labeling does not include used for antimicrobial or antiviral protection or related uses
- Labeling does not include uses for infection prevention or reduction or related uses
- Labeling does not include uses for radiation protection

2) WHAT IS REQUIRED TO IMPORT PPE ITEMS DURING THE COVID-19 EMERGENCY?

The FDA has published guidelines tailored on requirements and guidance on importing these items, more information can be found on the FDA website. In addition importers and manufactures that are currently not registered with the FDA are allowed to import PPE items during this time.

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3) WHAT AFFIRMATION OF COMPLIANCE CODES ARE REQUIRED FOR MEDICAL DEVICES (EX: FACE MASKS, GOWNS, GOGGLES, FACE Shields) IMPORTATIONS?

During the COVID-19 Emergency **ONLY**, the FDA has waived the requirements for these codes. The following information is required for clearance by CBP and FDA.

- HTS #
- FDA Product Code
- Program Code
- Processing Code
- Intended Use Code
- Country of Origin
- Parties
- DEQ – Shipper with full name and address

Should be able to pull off the documents

- MFG – Manufacture with full name and address
- FD1 – Importer with full name and address
- DP – Deliver to party with full name and address
- DII – Device Initial Importer with full name and address
- Name of U.S. Company on file with FDA for the Device importation Device Listing number

4) IS HAND SANITIZER CONSIDERED A PPE AND WHAT IS REQUIRED TO IMPORT?

The FDA has stated that hand sanitizer is an FDA regulated over the counter (OTC) drug requiring transmission of the registration of the manufacturer and the drug listing number. We have verified with the FDA at this time they have not made any exceptions to the import reporting requirements.

- HTS#
- C/O
- DRL #
- FDA Program Code
- FDA Processing Code
- Intended Use Code

Should be able to pull off the documents

- DEQ – Shipper with full name and address
- MFG – Manufacturer with full name and address
- FD1 – Importer with full name and address
- DP – Deliver to party with full name and address

REFERENCES

FDA COVID-19-RELATED GUIDANCE DOCUMENTS FOR INDUSTRY, FDA STAFF AND OTHER STAKEHOLDERS

ENFORCEMENT POLICY FOR GOWNS, OTHER APPAREL, AND GLOVES DURING THE CORONAVIRUS DISEASE
PUBLIC HEALTH EMERGENCY

ENFORCEMENT POLICY FOR FACE MASKS AND RESPIRATORS DURING THE CORONAVIRUS DISEASE
PUBLIC HEALTH EMERGENCY

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