

Buyer Beware:

How Do You Know that the PPE You are
Sourcing is Approved for Use in Healthcare Settings?

Presented by:

Mary Govoni, CDA, RDH, MBA

Mary Govoni & Associates



Brought to you by:



1

Thanks to our sponsor!



2

**Can't we just assume that
the PPE we purchase and use
is safe and effective?**



3

**How do we make sure our PPE is safe,
effective and meets standards
for use in healthcare?**

Hint:
You need to be armed with the facts.



This Photo by Unknown Author is licensed under CC BY-SA

4

CNN health Life, But Better Fitness Food Sleep Mindfulness Relationships • LIVE TV CNN+ 🔍 👤 ☰

CNN Investigation: Tens of millions of filthy, used medical gloves imported into the US

By Scott McLean, Florence Davey-Attlee, Kocha Olarn and Tim Lister, CNN
⌚ Updated 2:55 PM ET, Fri October 29, 2021



Source: cnn.com

<https://www.cnn.com/2021/10/24/health/medical-gloves-us-thailand-investigation-cmd-intl/index.html>

5

🇺🇸 An official website of the United States government [Here's how you know](#)

FDA U.S. FOOD & DRUG ADMINISTRATION 🔍 Search ☰ Menu

Home / Medical Devices / Medical Device Safety / Emergency Situations (Medical Devices) / Coronavirus (COVID-19) and Medical Devices / Medical Gloves for COVID-19

Medical Gloves for COVID-19

FDA Investigating Certain Imported Medical Gloves

The FDA recommends that health care facilities and providers **do not** purchase, or use imported medical gloves from companies included on [Import Alert 80-04 Surveillance and Detention Without Physical Examination of Surgeon's and Patient Examination Gloves](#).

Companies are listed on an import alert when the agency has enough evidence to allow for detention without physical examination (DWPE) of their products as they appear to be in violation of the FDA's laws and regulations and thus, create a potential risk to health care professionals, patients and users.

To identify FDA-cleared medical gloves, search the [510\(k\) Premarket Notification database](#) using the product codes for medical gloves.

Report a Problem with Medical Gloves

If you have purchased any medical gloves that are visibly soiled, are a different color, appear to have been used, or otherwise seem to be fraudulent, please report it to the FDA by email to FDA-COVID-19-Fraudulent-Products@fda.hhs.gov.

<https://bit.ly/3qqeE6D>

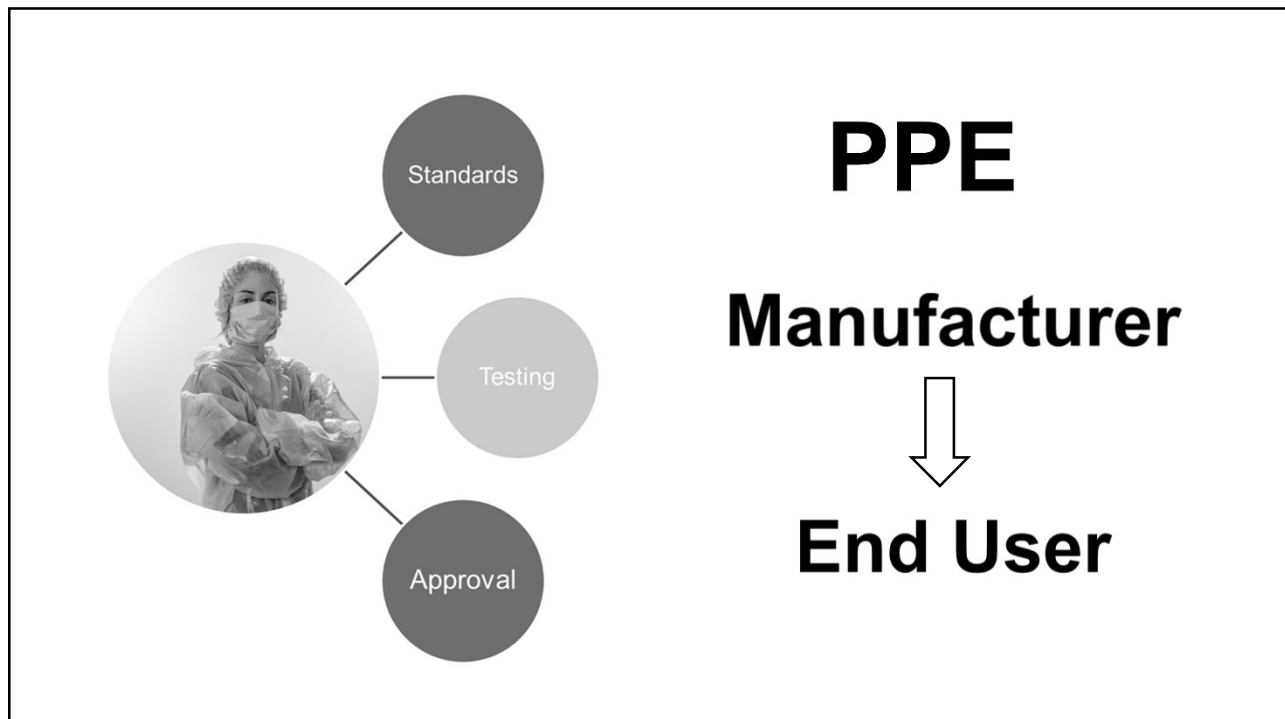
6

Why???



- Response to global shortages due to COVID-19
- Manufacturers that produce gloves for industry trying to expand markets
- Unscrupulous manufacturers or distributors

7



8

Facts You Need to Know About PPE

- ▶ Which certifications, approvals or clearances PPE must have to be appropriate for use in healthcare
- ▶ What OSHA and CDC guidance to follow for appropriate PPE



This Photo by Unknown Author is licensed under CC BY-SA



9

Organizations that Coordinate Standards

- ▶ American National Standards Institute – ANSI
 - ▶ <https://ansi.org/>
 - ▶ Devices marked with number of standard that applies
- ▶ Standards Council of Canada
 - ▶ <https://www.sca.ca>



Source: safetyglassesusa.com

10

Make certain that your PPE is approved for use in healthcare

- ▶ Medical gloves and masks are Class I medical devices (FDA)
- ▶ Not all exam gloves are equal in quality
 - ▶ Acceptable Quality Limits (AQL) established by the FDA
 - ▶ Measured in percentage of defects per 100 units
- ▶ Not all gloves are manufactured using GMP



11

 The image is a screenshot of the FDA website. The top navigation bar includes the FDA logo and links for Home, Medical Devices, Products and Medical Procedures, Device Approvals, Denials and Clearances, and 510(k) Clearances. The main heading is "510(k) Clearances". Below this, there are social media sharing buttons for Facebook, Twitter, LinkedIn, Email, and Print. A URL <https://bit.ly/3N2e9tn> is displayed. Below the URL is a smaller screenshot of the FDA website showing the "CFR - Code of Federal Regulations Title 21" page. This page includes a search bar, a list of regulations, and a section for "PART 800 -- GENERAL" which mentions "Requirements for Specific Medical Devices" and "Sec. 800.20 Patient examination gloves and surgeons' gloves: sample plans and test method for leakage defense: validation." The entire screenshot is framed by a dark border with virus-like icons at the corners.

12

OSHA and PPE

General Industry (29 CFR 1910)		Related Information
1910 Subpart G - Occupational Health and Environmental Control	1910.94, Ventilation.	Related Information
	1910.95, Occupational noise exposure.	Related Information
1910 Subpart H - Hazardous Materials	1910.120, Hazardous waste operations and emergency response.	Related Information
1910 Subpart I - Personal Protective Equipment	1910.132, General requirements.	Related Information
	1910.133, Eye and face protection.	Related Information
	1910.134, Respiratory protection.	Related Information
	1910.135, Head protection.	Related Information
	1910.136, Foot protection.	Related Information
	1910.137, Electrical Protective Equipment.	Related Information
	1910.138, Hand Protection.	Related Information
	1910.140, Personal fall protection systems.	Related Information

Standards

Personal protective equipment is addressed in specific OSHA standards for general industry, maritime, and construction. OSHA requires that many categories of personal protective equipment meet or be equivalent to standards developed by the American National Standards Institute (ANSI).

[More »](#)

<https://www.osha.gov/personal-protective-equipment>

13

Organizations that test PPE

- ▶ National Institute for Occupational Safety and Health – NIOSH – U.S.
 - ▶ <https://cdc.gov/niosh/>
- ▶ American Society for Testing and Materials – ASTM – U.S. and international
 - ▶ <https://www.astm.org/>
- ▶ CSA Group – Canada and international
 - ▶ <https://bit.ly/3ilOaPx>

	ASTM Level 1	ASTM Level 2	ASTM Level 3
Bacterial Filtration Efficiency @ 3 µm	≥ 95%	≥ 98%	≥ 98%
Differential Pressure (mm H ₂ O/cm ²)	< 4.0	< 5.0	< 5.0
Sub-Micron Particulate Filtration @ 0.1 µm	≥ 95%	≥ 98%	≥ 98%
Resistance to Penetration by Synthetic Blood (mmHg)	80	120	160
Flammability	Class 1	Class 1	Class 1

14

Organizations that Certify/Clear/Approve PPE

- ▶ Food and Drug Administration – FDA – U.S.
 - ▶ <https://bit.ly/3iofr3S>
 - ▶ Quality Systems Regulations and Good Manufacturing Practices
 - ▶ <https://bit.ly/3traj5a>
 - ▶ Emergency use authorizations (EUA's)



15

FDA and PPE

**U.S. FOOD & DRUG
ADMINISTRATION**

Search

[Home](#) / [Medical Devices](#) / [Products and Medical Procedures](#) / [General Hospital Devices and Supplies](#) / [Personal Protective Equipment for Infection Control](#) / [Medical Gloves](#)

Medical Gloves

About medical gloves

Medical gloves are examples of personal protective equipment that are used to protect the wearer and/or the patient from the spread of infection or illness during medical procedures and examinations. Medical gloves are one part of an infection-control strategy.

Medical gloves are disposable and include examination gloves, surgical gloves, and medical gloves for handling chemotherapy agents (chemotherapy gloves). These gloves are regulated by the FDA as Class I reserved medical devices that require a 510(k) premarket notification. FDA reviews these devices to ensure that performance criteria such as leak resistance, tear resistance and biocompatibility are met.

<https://bit.ly/3imhSDI>

Personal Protective Equipment EUAs

Personal Protective Equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.


To help address concerns about availability during the COVID-19 pandemic, the FDA has issued Emergency Use Authorizations (EUAs) for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: [Recent Final Medical Device Guidance Documents](#).

<https://bit.ly/3wow7Ac>

16

Organizations that Certify/Clear/Approve PPE

- National Institute for Occupational Safety and Health (NIOSH)
 - <https://www.cdc.gov/niosh/index.htm>


 Centers for Disease Control and Prevention
CDC 24/7 Saving Lives. Protecting People™

The National Institute for Occupational Safety and Health (NIOSH)

Respirator Resources ^

[NIOSH-Approved Particulate Filtering Facepieces Respirators](#)
 This page provides a listing of all NIOSH-approved particulate filtering facepiece respirators by each filter series type (e.g., N95, P100, etc.). The manufacturer's donning procedures are also available from these listings.

[Respirator Approval Information](#)
 This page provides information for manufacturers on applying for NIOSH approval, test procedures, standards, and other technical support.

[NIOSH Federal Respiratory Regulations 42 CFR Part 84](#) external icon 
 42 Code of Federal Regulations Part 84 defines the NIOSH performance requirements. NIOSH-approved respirators conform to this standard.

NIOSH Videos v

OSHA Videos v

<https://bit.ly/3qp3kl9>

17

Respirator Approval Program

Updated July 26, 2021



Approval Support, Test Procedures, Standards, and User Notices

Respirator Approval Information

How to apply, application procedures, fees, logos, testing procedures, other information.

Respirator Standards

Standards for respirators with and without chemical, biological, radiological, and nuclear protection, standards approved and under development.

Respirator User Notices

Inform users of conditions or risks that may exist with NIOSH-approved respirators.

Resources and Technical Support

Additional resources and support contact information.

<https://bit.ly/3D04mPL>

18

CDC Home
Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

A-Z Index for All CDC Topics

The National Personal Protective Technology Laboratory (NPPTL)

Certified Equipment List

Search

Instructions and Tips
General Cautions and Limitations
Definitions of Terms
Prior Manufacturers Names

Program at NIOSH
Respirator Trusted-Source Information
Approved Particulate Filtering Facepiece Respirators
Respirator User Notices
Contact NPPTL

NIOSH > NPPTL > Certified Equipment List

Certified Equipment List Search

Quick Search

To use the quick search feature, simply select the type of respirator you are interested in then click on View Quick Results to see a list of approvals in the selected category. Each selection is a complete search. Multiple selections are not supported.

Respirators Providing CBRN Protection

- ☐ CBRN Self-Contained Breathing Apparatus (SCBA)
- ☐ CBRN Air Purifying Respirators (CBRN/APR)
- ☐ CBRN Air Purifying Respirators (CBRN/APER)
- ☐ CBRN Powered Air Purifying Respirators (CBRN/PAPR)

View: CBRN Quick Results | Reset

Other Respirators of Current Interest

- ☐ Surgical N95 Filtering-Facepiece Respirators (Surgical N95 in compliance with FDA/CDC MOU 225-18-006)
- ☐ N95 Filtering Facepiece Respirators (N95 FFRs)
- ☐ Filtering-Facepiece Respirators - all filtration efficiencies (FFRs)
- ☐ Public Health Emergency, N95 Filtering-Facepiece Respirators (PHE FFRs)
- ☐ Non-Valved, (i.e., no exhalation port) Particulate-Filtering Elastomeric Half Mask Respirators (NV EHMRS)
- ☐ Public Health Emergency, Powered Air-Purifying Respirators (PHE PAPRs)

https://www2a.cdc.gov/drds/cel/cel_form_code.asp

19

**What else can we do to make sure
our PPE is safe, effective, and
meets the standards
for use in healthcare?**

20

What can you do?

- Purchase from reputable manufacturer
 - Research and request samples
- Purchase from reputable supplier
 - Trusted relationships



21

What can you do?



- If purchasing from online or unknown supplier, inquire about ASTM/ANSI certifications, FDA clearance
 - ***Many online sellers do not vet their products***
- If products (gloves) are soiled, discolored or appear to be fraudulent, report to the FDA MedWatch Program
 - <https://bit.ly/3iquCJS>

22

Gloves in Healthcare Settings

- ▶ **Exam/procedure gloves**
 - ▶ Non-sterile
 - ▶ Ambidextrous
- ▶ **Surgical gloves**
 - ▶ Sterile
 - ▶ Hand specific
- ▶ **Utility gloves**
 - ▶ Typically, reusable but some are disposable



23

Gloves are medical devices



← Home / Medical Devices / Products and Medical Procedures / General Hospital Devices and Supplies / Personal Protective Equipment for Infection Control / Medical Gloves

Medical Gloves

[f Share](#)
[t Tweet](#)
[in LinkedIn](#)
[✉ Email](#)
[🖨 Print](#)

About medical gloves

<https://bit.ly/3NduyLp>

Medical gloves are examples of personal protective equipment that are used to protect the wearer and/or the patient from the spread of infection or illness during medical procedures and examinations. Medical gloves are one part of an infection-control strategy.

Medical gloves are disposable and include examination gloves, surgical gloves, and medical gloves for handling chemotherapy agents (chemotherapy gloves). These gloves are regulated by the FDA as Class I reserved medical devices that require a 510(k) premarket notification. FDA reviews these devices to ensure that performance criteria such as leak resistance, tear resistance and biocompatibility are met.

24

Considerations for Glove Selection

- ▶ Latex free and powder free
 - Powdered gloves banned by FDA in 2016
- ▶ Free of irritant chemicals
 - Causes dermatitis in healthcare workers
- ▶ Comfort and fit
- ▶ Tactile sense
- ▶ Manufacturer follows Good Manufacturing Practices
 - Clean factories
 - Humane labor practices
- ▶ Shelf life



25

The screenshot shows the FDA's 510(k) Premarket Notification database search interface. At the top, there's a navigation bar with links to Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main heading is "510(k) Premarket Notification". Below this, there's a "Search Database" section with various input fields: 510K Number, Type, Product Code, Center, Applicant Name, Device Name, Panel, Decision, Decision Date (with a date range selector), and Sort by (set to Decision Date (descending)). There are also checkboxes for Combination Products, Cleared/Approved In Vitro Products, Redacted FOIA 510(k), Third Party Reviewed, and Clinical Trials. A "Search" button is at the bottom right of the search section. To the right of the search section, there's a "Other Databases" list including De Novo, Medical Device Reports (MAUDE), CDRH Export Certificate Validation (CECV), CDRH FOIA Electronic Reading Room, CFR Title 21, CLIA, Device Classification, FDA Guidance Documents, Humanitarian Device Exemption, Medsun Reports, Premarket Approvals (PMAs), Post-Approval Studies, Postmarket Surveillance Studies, Radiation-Emitting Products, Radiation-Emitting Electronic Products Corrective Actions, Recalls, Registration & Listing, Standards, Total Product Life Cycle, and X-Ray Assembler. At the bottom, there's a footer with the page last updated date (03/14/2022) and a note about language assistance in multiple languages.

<https://bit.ly/3ilw7c4>

26



Strategies for Optimizing the Supply of Disposable Medical Gloves

Updated Dec. 23, 2020 Print

<https://bit.ly/369OiiD>

Once PPE supplies and availability return to normal, healthcare facilities should promptly resume conventional practices.

Optimization NEVER means reusing gloves.

27

<https://bit.ly/3qmzMuN>

Surge capacity refers to the ability to manage a sudden increase in patient volume that would severely challenge or exceed the present capacity of a facility. While there are no widely accepted measurements or triggers to distinguish surge capacity from daily patient care capacity, surge capacity is a useful framework to approach a decreased supply of gloves during the COVID-19 response. To help healthcare facilities plan and optimize the use of gloves in response to COVID-19, CDC has developed a [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#). Three general strata have been used to describe surge capacity and can be used to prioritize measures to conserve glove supplies along the continuum of care.

- **Conventional capacity:** measures consisting of engineering, administrative, and personal protective equipment (PPE) controls that should already be implemented in general infection prevention and control plans in healthcare settings.
- **Contingency capacity:** measure that may be used temporarily during periods of expected glove shortages. Contingency capacity strategies should only be implemented after considering and implementing conventional capacity strategies. While current supply may meet the facility's current or anticipated [utilization rate](#), there may be uncertainty if future supply will be adequate and, therefore, contingency capacity strategies may be needed.
- **Crisis capacity:** strategies that are not commensurate with U.S. standards of care but may need to be considered during periods of known gloves shortages. Crisis capacity strategies should only be implemented after considering and implementing conventional and contingency capacity strategies. Facilities can consider crisis capacity strategies when the supply is not able to meet the facility's current or anticipated [utilization rate](#).

CDC's optimization strategies for glove supply offer a continuum of options for use when glove supplies are stressed, running low, or exhausted. Contingency and then crisis capacity measures augment conventional capacity measures and are meant to be considered and **implemented sequentially**. Once glove availability returns to normal, healthcare facilities should promptly resume standard practices.

28

Current issues affecting dental practices and the sourcing of gloves

- COST
- Access to preferred types/brands
- Limited supply in some areas



This Photo by Unknown Author is licensed under CC BY



This Photo by Unknown Author is licensed under CC BY-SA

29

Unfortunately, cost should not be the main consideration for supply management in issues related to safety.



IT'S
NOT
FAIR !!

30

**Buyer Beware – Make Safe/Smart
Purchasing Decisions and Follow
Guidance
for Healthcare Settings**

31

Thanks again to our sponsor



Mary Govoni, CDA, RDH, MBA
mary@marygovoni.com
www.marygovoni.com
www.thecompliancedivas.com
www.superstardentalassistants.com

32