Buyer Beware:

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

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

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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.

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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

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An official website of the United States government Here's how you know

FDA U.S. FOOD & DRUG ADMINISTRATION Search Menu

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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

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Why???

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

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PPE

Manufacturer

⇩

End User

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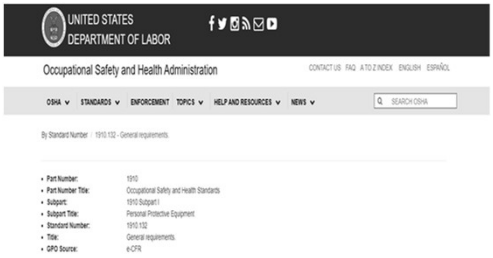
Facts You Need to Know About PPE

- 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



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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

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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

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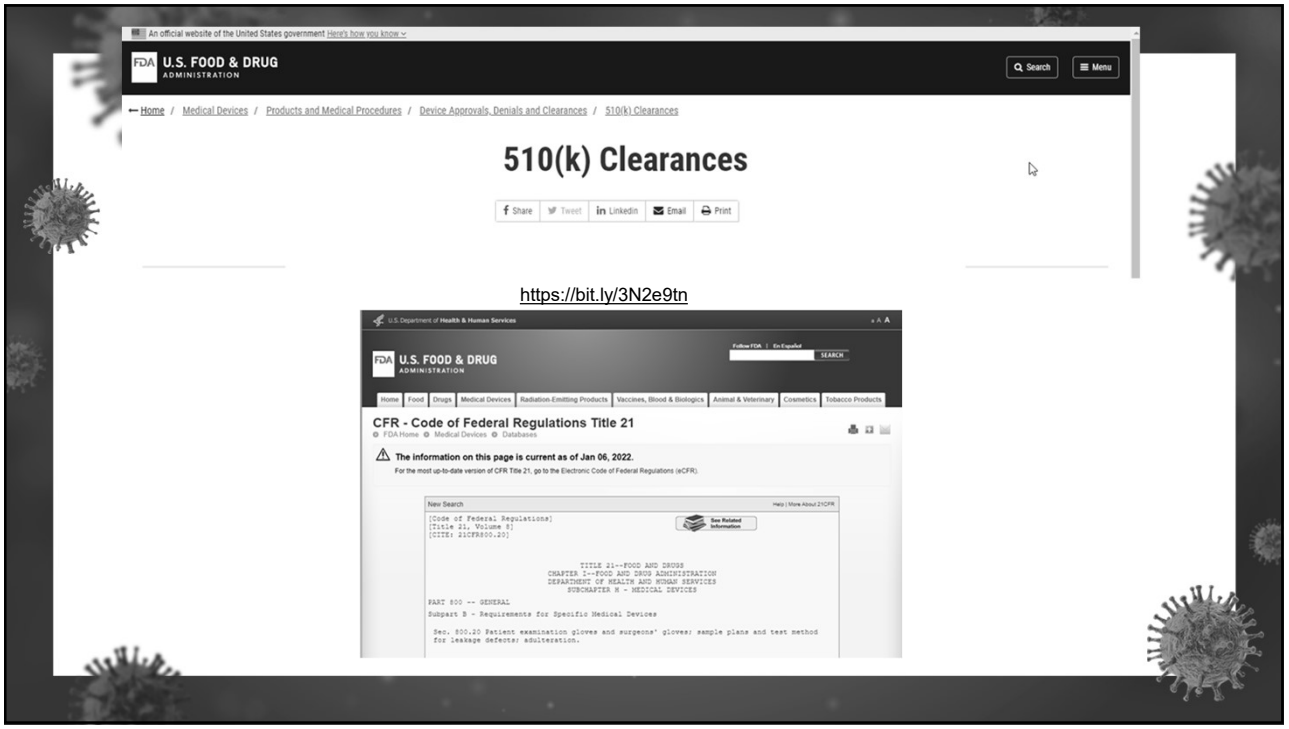

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OSHA and PPE

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

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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_2O/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

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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)

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FDA and PPE

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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.

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Personal Protective Equipment EUAs

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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.

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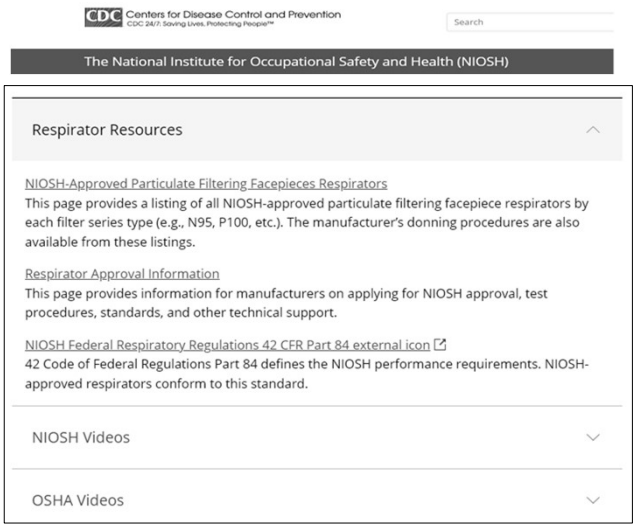
Organizations that Certify/Clear/Approve PPE

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



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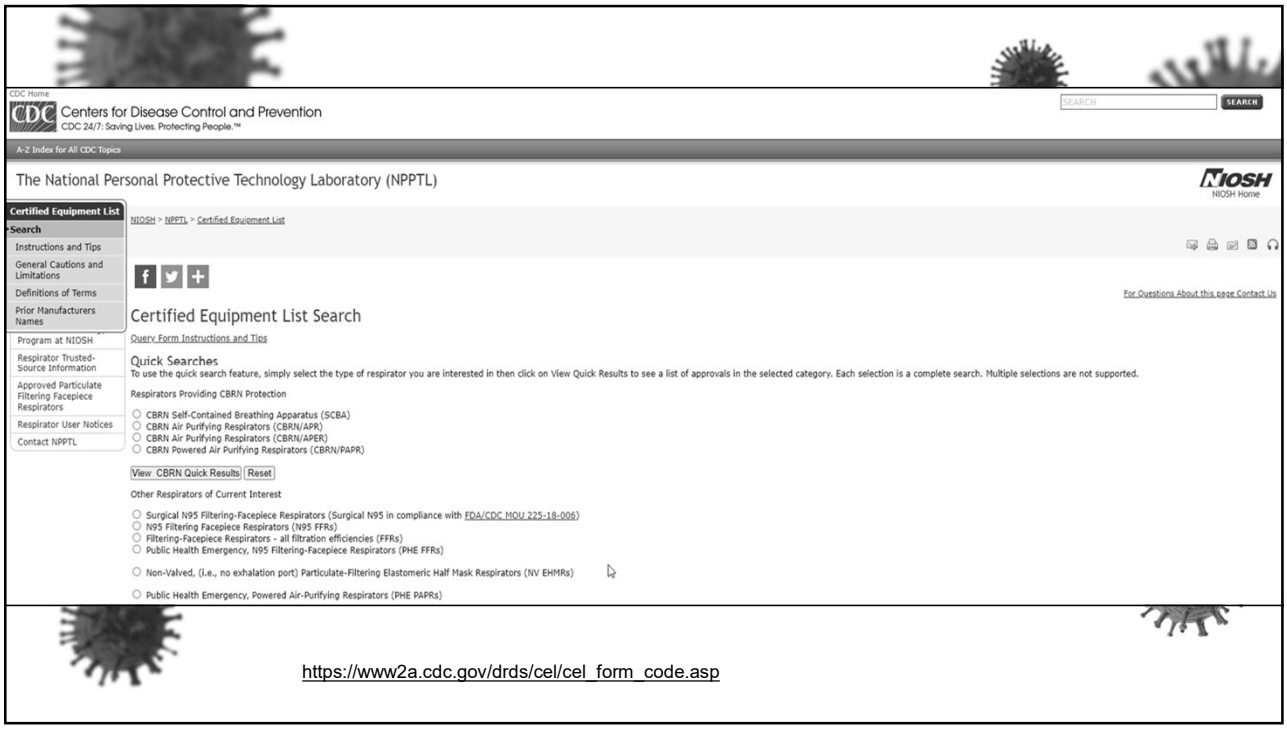

https://www2a.cdc.gov/drds/cel/cel_form_code.asp

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

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What can you do?

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

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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

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Gloves in Healthcare Settings

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

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Gloves are medical devices

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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

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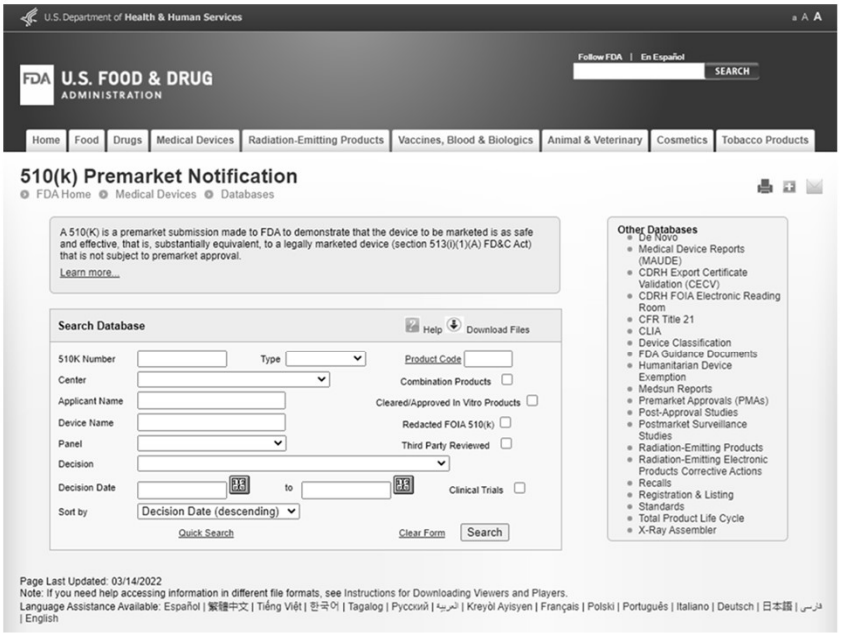

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Optimization NEVER means reusing gloves.

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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.

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Current issues affecting dental practices and the sourcing of gloves

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

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

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

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