

# Personal Protective Equipment (PPE)

Presented By  
Susan DeRagon, QIMA



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# Agenda

## Types of PPE

- > Face masks
- > Face shields/Goggles
- > Gowns
- > Gloves

## Requirements & Recommendations

- > Medical grade
- > Non-medical grade
- > Labeling
- > Proposition 65
- > Children's Products

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# Types of Masks



Uses	Cloth Mask	Surgical Mask	N95 Respirator
CDC recommended for general public	X		
Necessary for medical facilities & first responders		X	X
Protects against droplets	X	X	X
Protects against aerosol			X
Custom fit			X
Loose fit	X	X	

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# Face Masks – N95

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS  
EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH <sub>2</sub> O/cm <sup>2</sup>	<6.0 mmH <sub>2</sub> O/cm <sup>2</sup>		<40 Pa/cm <sup>2</sup>		<60 Pa/cm <sup>2</sup>
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		<ul style="list-style-type: none"><li>• AQL 4% for BFE, PFE, Delta P</li><li>• 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)</li><li>• 14 masks for Flammability</li></ul>			<ul style="list-style-type: none"><li>• Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness</li><li>• 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)</li></ul>		



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# Face Masks – Surgical

	 <b>Surgical Mask</b>	 <b>N95 Respirator</b>
<b>Testing and Approval</b>	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
<b>Intended Use and Purpose</b>	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
<b>Face Seal Fit</b>	Loose-fitting	Tight-fitting
<b>Fit Testing Requirement</b>	No	Yes
<b>User Seal Check Requirement</b>	No	Yes. Required each time the respirator is donned (put on)
<b>Filtration</b>	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
<b>Leakage</b>	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales



Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

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# Face Masks – Cloth



In addition, CDC also recommends that everyone wear cloth face coverings when leaving their homes, regardless of whether they have fever or symptoms of COVID-19. This is because of evidence that people with COVID-19 can spread the disease, even when they don't have any symptoms. Cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.



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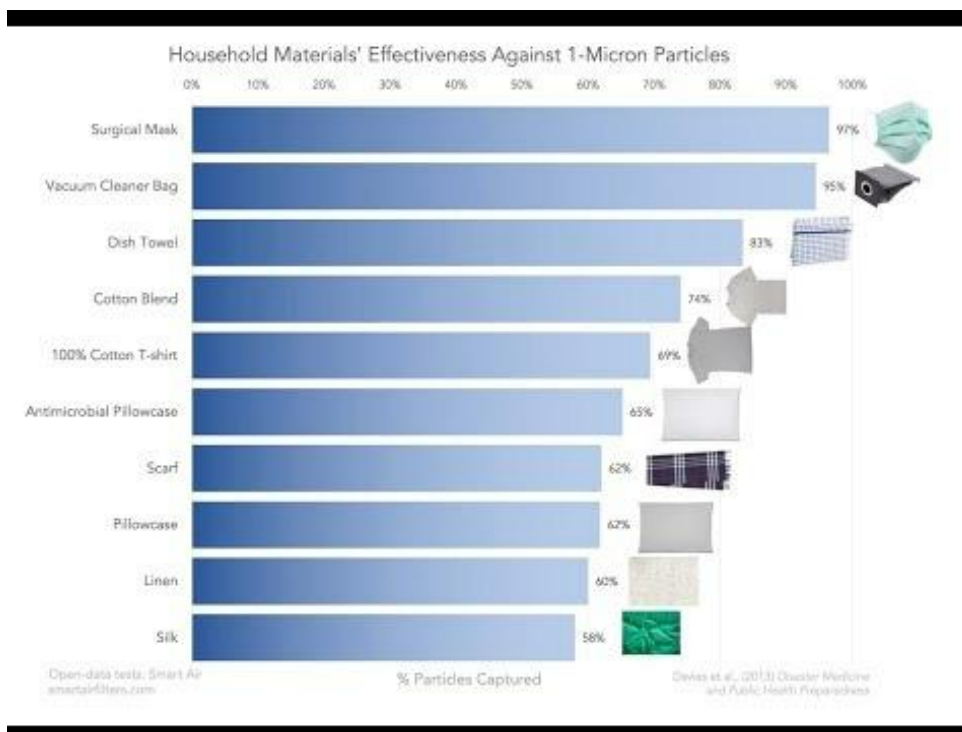
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# Cloth Masks – Materials



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# Cloth Masks – Construction Recommendations

## Recommendations

- Use tightly constructed fabrics;
- Assemble in two or three layers (same fabrics or different fabrics);
- Use fabrics allowing air to pass through when breathing;
- Use fabrics that are sufficiently soft and supple to apply around the face to ensure sealing;
- Use fabrics that are not too warm;
- Use smooth, non-irritating fabrics;
- Do not use light and loosely constructed fabrics;
- Do not make a mask with a single thickness of fabric;
- Do not use staples when designing or assembling the barrier mask;
- Do not use fabrics blocking the passage of air when breathing;
- Do not use fabrics that are too stiff that would not be appropriate for sealing;
- Do not use warm fabrics that would make masks difficult to wear;
- Do not use irritating fabrics that would make masks difficult to wear;
- Do not make vertical seams, along the nose, mouth and chin;

afnor

AFNOR SPEC S76-001

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# Cloth Masks – Testing (US)

Labeling	Testing (Safety)	Quality/Performance Tests
Country of Origin	Flammability	CF to Crocking
Producer Markings/UPLR	CPSIA/Prop 65 - Lead	CF to Laundering
Textile Fiber Identification	Prop 65 - Phthalates	CF to Perspiration
Care Instructions	Prop 65 - Cadmium	Appearance after Laundering
Emergency Use Authorization	Fiber Content Analysis	Dimensional Stability
Tracking Label (if CP)	Mechanical (if CP)	Dimensions
	pH value	Workmanship
	Formaldehyde	Attachment Strength
	ASTM F2100-19-Surgical Face Mask-Differential Pressure (Delta P)	Abnormal Odor

CF = Colorfastness

CP = Children's Product



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# Cloth Masks – Testing (EU)

Labeling	Testing (Safety)	Quality/Performance Tests
Country of Origin	PAH - REACH	CF to Crocking
Producer Markings	SVHC - REACH	CF to Laundering
Textile Fiber Identification	Phthalates - REACH	CF to Perspiration
Care Instructions	Total Cadmium - REACH	Appearance after Laundering
	Fiber Content Analysis	Dimensional Stability
	Azo Dyes - REACH	Dimensions
	pH value	Workmanship
	Formaldehyde	Attachment Strength
	Organotin –REACH	Abnormal Odor

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# FDA's Emergency Use Authorization

## A) Authorized face masks (including cloth face masks) labeling

- Labeled accurately to describe the product and include a list of the body contacting materials;
- Not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
- Not recommend for use in clinical setting;
- Not labeled in a manner that would misrepresent the product's intended use
- Not labeled as a respiratory protective device and not labeled to be used for particulate filtration;
- Not labeled for use in high risk aerosol generating procedures

## B) Conditions related to advertising and promotion

- All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in part A above;
- No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.
- All advertising/promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that
  - The product has not been FDA cleared or approved
  - The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.

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# Face Shields/Goggles

Mandatory US Regulation:

- ANSI Z87.1:2015 American National Standard – Occupational and Educational Personal Eye and Face Protection Devices

Scope of this standard:

- Requirements to address hazards such as impact, non-ionizing radiation and liquid splash exposures
- Certain hazardous exposures are not covered: bloodborne pathogens, X-rays, high-energy particulate radiation, microwaves, radio-frequency radiation, lasers, sports and recreation

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# Face Shield/Goggle Requirements

## Optical Requirements

- > Optical quality
- > Luminous transmittance
- > Haze
- > Refractive powers

## Physical Requirements

- > Drop ball
- > Ignition (flammability)
- > Corrosion or metal parts
- > Minimum coverage area

## Other Requirements

- > Googles ventilation

## Chemical/Prop 65

- > Lead
- > Cadmium
- > Phthalates
- > BPA



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# Face Shield/Goggle Claims and Optional Tests

## Impact-Rated Marking – Z87+

- > Lateral protection
- > High mass impact
- > High velocity impact

## Other Optional Tests

- > Droplet and Splash protection – D3
- > Dust protection – D4 or D5



Ball Drop Test Mechanism



High Mass Impact Test



High Velocity Test

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# FDA's Emergency Use Authorization

## A) Authorized face shields labeling

- Labeled accurately to describe the product as a face shield for medical purposes and include a list of the body contacting materials;
- Not integrated with any other article of PPE such as face mask but rather is for use as a standalone face shield;
- Intended for either a single user, single use, or for multiple uses by the same user;
- Includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable;
- Must not contain any materials that will cause flammability;
- Not intended for any use that would create an undue risk in light of the public health emergency

## B) Conditions related to advertising and promotion

- All printed matter, including advertising and promotional materials, relating to the use of the authorized face shield shall be consistent with the labeling elements listed in part A above;
- No printed matter, including advertising or promotional materials, relating to the use of the authorized face shield may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.
- All advertising/promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that
  - The product has not been FDA cleared or approved
  - The product has been authorized by FDA under an EUA for use by healthcare providers as personal protective equipment

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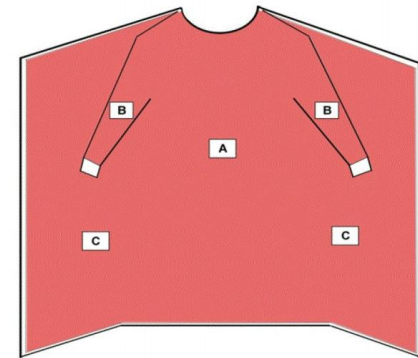
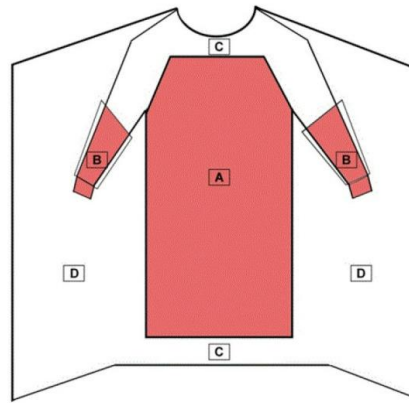
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# Types of Gowns

- > Surgical gowns
- > Surgical isolation gowns
- > Non-Surgical gowns



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# Gowns – ASTM F2407 Tests

- Tensile Strength: ASTM D5034, ASTM D1682
- Tear Resistance: ASTM D5587 (woven), ASTM D5587 (nonwoven), ASTM D1424
- Seam Strength: ASTM D751 (stretch woven or knit)
- Lint Generation: ISO 9073 Part 10
- Water Vapor Transmission (breathability): ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75

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# Gowns – Additional Testing (US)

Labeling	Testing (Safety)	Quality/Performance Tests
Country of Origin	Flammability	CF to Crocking
Producer Markings/UPLR	Prop 65 - Lead	CF to Laundering
Textile Fiber Identification	Prop 65 - Phthalates	CF to Perspiration
Care Instructions	Prop 65 - Cadmium	Appearance after Laundering
	Fiber Content Analysis	Dimensional Stability
	Sharp Points/Sharp Edges	Dimensions
	Formaldehyde	Workmanship
		Attachment Strength
		CF to Water

CF = Colorfastness

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# Gowns – Additional Labeling Requirements

- Includes labeling that accurately describes the product
- Includes recommendation against use in surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected
- Includes a recommendation against use in a clinical setting where the infection risk level is high
- Makes no claims regarding flammability
- Makes no claims of antimicrobial or antiviral protection
- Makes no claims of infection prevention or reduction

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# Gloves - ASTM Standards

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
- ASTM D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D6977-19 Standard Specification for Polychloroprene Examination Gloves for Medical Application

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# Gloves – Materials Used

GLOVE TYPE	DEFINITION	ADVANTAGE	PROTECTION LEVEL
Latex Gloves	Made of natural rubber	Highest comfort, flexibility, fit and tactile sensitivity	Bacteria, viruses
Nitrile Gloves	Made of synthetic material	Stretchy, durable	Chemicals, viruses
Vinyl Gloves	Made of synthetic material, sometimes referred to as synthetic	Cost-efficient synthetic option, comfortable	Chemicals

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# Gloves – FDA Policy for Labeling

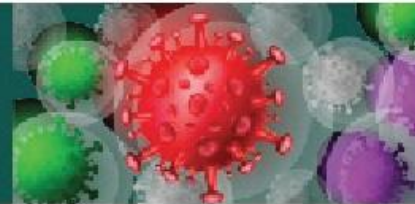
- Accurately describe the product as an “unpowdered glove” (as opposed to a “surgeon’s glove”);
- Accurately describe the product’s sterility status (i.e., non-sterile);
- Does not claim that product is latex-free
- Include a list of the body contacting materials
- Include recommendations and general statements that would reduce the risk of use. For example:
  - Statement that the gloves have not been cleared by FDA
  - Recommendation against using when FDA-cleared gloves are available
  - Recommendation against using in surgical settings

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# Covid-19

## PPE & Promotional Products



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# Prop 65 60-Day Notices

AG Number	Date	Chemicals	Source
2013-00309	03/25/2013	Di(2-ethylhexyl)phthalate (DEHP), Lead	Suction Cup Hooks, <b>Safety Goggles</b> , Placemats, Gripper Pads, Liners, Turkey Lifters, Shower Curtains, Garlands
2017-01305	5/11/2017	Di(2-ethylhexyl)phthalate (DEHP)	ESM Terry Cloth Thermal Gripper Construction Gloves
2016-00682	7/6/2016	Di(2-ethylhexyl)phthalate (DEHP)	LBD Protective Clothing PVC Rain Suit, Style No. 9835
2018-00807	05/22/2018	Di(2-ethylhexyl)phthalate (DEHP)	4mil Clear Protective Sleeve
2019-00653	4/5/2019	Di(2-ethylhexyl)phthalate (DEHP)	kids protective gear
2019-00654	4/5/2019	Diisononyl phthalate (DINP)	kids protective gear

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# Resources

- **PPAI:** [www.ppai.org](http://www.ppai.org)
- **PPAI Product Responsibility:** <http://www.ppai.org/inside-ppai/corporate-responsibility/product-responsibility/>
- **FDA:** <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>
- **QIMA:** [www.qima.com](http://www.qima.com)
- **Questions?** [AnneS@ppai.org](mailto:AnneS@ppai.org)

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# Speaker's Contact Info

Susan DeRagon

Susan.deragon@qima.com

Mobile: 860-416-5846

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