

**PPE Reference Chart**  
(09 June 2020)

PPE Type	EUA Conditions of Use	EUA	Enforcement Policy	GMP	Registration with FDA	Submission to FDA Required?	PREP Act Eligible?	Additional Information
<b>Non-Surgical Face Masks</b>	<p>1. For use as source control by members of the general public, and by health care provider (HCP) in healthcare settings, in accordance with CDC recommendations</p> <p>2. Not intended for use by HCPs as PPE</p>	<a href="https://www.fda.gov/media/137121/download">https://www.fda.gov/media/137121/download</a>	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	No	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Required labeling:</b> <ol style="list-style-type: none"> <li>1. List the body contacting materials</li> <li>2. Not intended for surgical use or liquid barrier protection</li> <li>3. Recommend against high-risk clinical use</li> <li>4. May not represent product prevents or protects against infection</li> <li>5. May not represent product as a respiratory protective device</li> <li>6. Warn against use in aerosol generating procedures</li> </ol>
<b>Surgical Masks Intended to Provide Liquid Barrier Protection</b>	Currently there is only an enforcement policy for these types of masks. There is not a separate EUA.	N/A	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	No	Yes, IF the mask is cleared by FDA OR authorized under an individual EUA, AND requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Must meet these criteria:</b> <ol style="list-style-type: none"> <li>1. List the body contacting materials</li> <li>2. Fluid resistance testing (liquid barrier performance) standard ASTM F186</li> <li>3. Class I or II flammability standard, or warning label against use near high-intensity heat source</li> <li>4. Not intended for any use that would create an undue risk in light of the public health emergency</li> </ol>
<b>NIOSH-Approved Respirators</b>	For use in healthcare settings by HCPs in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages	<a href="https://www.fda.gov/media/135763/download">https://www.fda.gov/media/135763/download</a>	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	No	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<ol style="list-style-type: none"> <li>1. Includes expired respirators</li> <li>2. Includes decontaminated respirators</li> </ol>

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<b>Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators – NOT FROM CHINA</b>	For use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages	<a href="https://www.fda.gov/media/136403/download">https://www.fda.gov/media/136403/download</a>  Exhibit 1: <a href="https://www.fda.gov/media/136731/download">https://www.fda.gov/media/136731/download</a>	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	Manufacturers and/or importers must email request to FDA to be added to Exhibit 1 approved list	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Authorized models as of June 9:</b> 1. 3M 8205 Japan 2. 3M 8822 South Korea 3. 3M 9320+ UK, Singapore, Turkey 4. 3M 9322+ UK, Singapore, Turkey 5. Dromex Model 1020 South Africa
<b>Non-NIOSH-Approved Disposable Filtering Facepiece Respirators FROM CHINA</b>	For use by HCPs in a hospital setting to prevent the wearer exposure to pathogenic biological airborne particulates during FFR shortages	<a href="https://www.fda.gov/media/136664/download">https://www.fda.gov/media/136664/download</a>  Appendix A: <a href="https://www.fda.gov/media/136663/download">https://www.fda.gov/media/136663/download</a>	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	Manufacturers must email request to FDA demonstrating compliance with EUA criteria to be added to Appendix A approved list	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Must meet one of these criteria:</b> 1. Manufactured by entity that holds one or more NIOSH approvals for other models of FFRs 2. Has regulatory authorization from another jurisdiction (incl. China/ NMPA) 3. Previously listed under Appendix A, has had particulate filtration efficiency assessed by NIOSH within 45 calendar days of May 7 EUA, and results of NIOSH testing indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent

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<b>Face Shields</b>	For use by HCP as PPE in healthcare settings in accordance with CDC recommendations	<a href="https://www.fda.gov/media/136842/download">https://www.fda.gov/media/136842/download</a>	<a href="https://www.fda.gov/media/136449/download">https://www.fda.gov/media/136449/download</a>	Waived	Waived	No	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Must be intended for use by HCP as PPE in healthcare settings and:</b> <ol style="list-style-type: none"> <li>1. Labeled accurately to describe the product as a face shield for medical purposes and includes a list of the body contacting materials</li> <li>2. Not integrated with any other article of PPE</li> <li>3. Labeled with duration of use and recommended cleaning process</li> <li>4. No flammable materials, or meet Class I or II flammability requirements, or labeled with recommendation against use near high heat source</li> <li>5. Not intended for any use that would create an undue risk in light of the public health emergency</li> </ol>
<b>Gowns, Surgical Caps, Shoe Covers, Surgical Helmets</b>	For use by HCP as PPE in healthcare settings in accordance with CDC recommendations	<a href="https://www.fda.gov/media/138326/download">https://www.fda.gov/media/138326/download</a>	<a href="https://www.fda.gov/media/136540/download">https://www.fda.gov/media/136540/download</a>	Waived	Waived	No	Yes, IF requirements and conditions of the EUA AND the PREP Act declaration are met	<b>Required labeling:</b> <ol style="list-style-type: none"> <li>1. State "non-surgical" gown</li> <li>2. List the body contacting materials</li> <li>3. Identify the appropriate healthcare setting where the product is and is not to be used</li> <li>4. Provide the flammability classification, or warning</li> <li>5. Indicate whether for single use or reuse, with appropriate cleaning instructions</li> <li>6. May not represent product prevents or protects against infection</li> </ol>