Manufacturing and Distributing Respirators for Health Care Use in the United States During the COVID-19 Pandemic

- To distribute respirators for health care use in the United States, the respirators must be authorized under an FDA EUA.
- For information about the NIOSH Respirator Approval Program, consider the information provided by NIOSH NPPTL* at: Respirator Approval Information
- If you are manufacturing outside the United States, see Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

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**Is the respirator designed to be a disposable Filtering Facepiece Respirator (FFR) (example: N95)?**

**YES**

- **Do you have NIOSH approval?**
  - **YES** The respirator is authorized under the NIOSH-Approved EUA**
  - **NO** Reusable respirators (examples: powered air purifying respirators (PAPR), elastomeric respirators) require NIOSH approval and authorization under the NIOSH-Approved EUA**

**NO**

- The respirator requires NIOSH approval. After NIOSH approval is obtained, it will be authorized under the NIOSH-Approved EUA**

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*N IOSH (National Institute for Occupational Safety and Health (NIOSH)) National Personal Protective Technology Laboratory (NPPTL)

**NIOSH-Approved EUA** refers to the FDA EUA for NIOSH-Approved air-purifying respirators