MFG-HP-HCP-01

Manufacturing Plan

For Community Face Filtering Respirators Used In a Health Care Provider (HCP) Facility and Manufactured Using the HP Multi Jet Fusion (MJF) Process under the COVID Emergency Use Authorization (EUA)
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1. **Manufacturing Requirements, General:** This manufacturing plan establishes requirements for mask parts manufactured using the HP Multi Jet Fusion process for use in a Health Care Provider (HCP) facility under the Emergency Use Authorization (EUA).

2. **Manufacturing Process Parameters and Materials:**
   a. **AM Printer Information:**
      i. HP Multi Jet Fusion Model 4200 or equivalent HP Powder Bed Fusion Printer with the ability to print HP PA12 Nylon
   b. **Printer Process Settings:**
      i. Recommended Process Parameter Set: Balanced Setting
   c. **Part Orientation:**
      i. Follow HP best 3D printing practices
   d. **Material Information:**
      i. HP 3D High Reusability PA 12 Nylon

3. **Fabrication:**
   a. **Geometric Dimensioning and Tolerance:**
      i. Interpret dimensions and tolerance in accordance with ASME Y14.5-2009
      ii. Overall part dimensions are annotated on the AM TDP for reference and quality self-checks.
      iii. Post processing and part breakout shall remove all PA12 powder that is not intended to form the printed part.
   b. **Cleaning and Disinfecting:**
      i. Follow Disinfecting Procedure CLN-TAC-AF-FFM to clean and disinfect mask.

4. **Quality:**
   a. **Manufacturing Quality System:**
      i. 21 CFR 820 (Quality System Regulation) requirements have been waived under the Covid Emergency Use Authorization (EUA) for HCP and Community Masks.
   b. **Manufacturing Quality Assessment:**
      i. 100% visual inspection of each AM part is required to validate that no gross distortion or defects are present.
      ii. A representative sample of parts shall be inspected per part build using the overall part dimensions identified in the AM TDP. A sampling plan is at the discretion of the manufacturing location.
      iii. Masks shall be assembled completely prior to packaging and shipment.
      iv. Product acceptance is determined based on acceptable component assembly fit.

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1 Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (Covid-19) Public Health Emergency (Revised), Guidance for Industry and Food and Drug Administration Staff, March 25, 2020
v. Additional QA provisions are at the discretion on the manufacturing location.

5. **Mask Assembly Marking and Delivery:**
   a. **Top Level Assembly Marking:**
      i. Mask assembly part number is identified on the inside of the mask body.
   b. **Packing:**
      i. A packing list for all delivered items will be included for all deliveries.
      ii. The packing list shall include sender and recipient information and date of shipment.
      iii. A copy of the HCP label and Disinfecting Methods document shall be included with each delivery.

6. **Manufacturing Tracking and Adverse Event Reporting:**
   a. **Tracking:**
      i. All masks manufactured and delivered shall be recorded and a list maintained by the manufacturer.
      ii. Masks shall be tracked in batches of 50 complete masks consisting of one or more sizes.
      iii. Each mask shall have a legible part number to identify the mask.
      iv. Records of shipments can be made available to the Food and Drug Administration (FDA) upon request.
   b. **Adverse Event Reporting:**
      i. Form FDA 3500 from the U.S. Department of Health and Human Services shall be used to report adverse events and be made available to manufacturer and recipient of delivered masks.