|  |  |  |
| --- | --- | --- |
| **Sponsor Name:**  | **Sponsor Email:** | **Sponsor Address:** |
| **FACE MASKS** |
| **Are Consulting Services Needed?** |
| [ ]  Consultation regarding designing a Face Mask  | [ ]  Sterilization or reprocessing of Face Mask |
| **Do you have a Face Mask ready for testing?** |
| [ ]  Yes | [ ]  No |
| **Where are you looking to market?** |
| [ ]  U.S. FDA (ASTM F2100-9), *specify level below:* [ ]  Level 1 [ ]  Level 2 [ ]  Level 3 | [ ]  Europe (EN 14683), *specify type below:* [ ]  Type I [ ]  Type II [ ]  Type IIR |
| **Who is the targeted end user of these Face Masks?** |
| Click here to enter text. |
| **Type of Testing** | [ ]  **Not sure what I need** |
| [ ]  **ASTM 2100** *(Select all that apply) – the below sample size recommendations are for FDA submission* |
|  [ ]  Bacterial Filtration Efficiency (BFE), ASTM  F2101 [ ]  Differential Pressure EN 14683 | 96 samples (BFE101) *(32 separate samples from 3 non-consecutive lots for BFE; each sample must be 4 x 4 inches minimum or full face mask)*96 samples (DPT110) *32 separate samples from 3 non-consecutive lots for Delta P required; each sample must be 4 x 4 inches minimum or full face mask)* |
|  [ ]  Latex Particle Challenge (PFE), ASTM F2299 [ ]  0.1 ASTM F2100 [ ]  0.3 micron [ ]  0.5 micron [ ]  1.0 micron | 96 samples (PFE115) *32 separate samples from 3 non-consecutive lots (each sample must be 5 x 5 inches (12 x 12 cm) min. or full face mask)* |
|  [ ]  Synthetic Blood Penetration, ASTM F1862 [ ]  80 mmHg (Level 1) [ ]  120 mmHg (Level 2) [ ]  160 mmHg (Level 3) | 3 sets (SBP210), *(32 masks are required from 3 non-consecutive lots for each pressure , 1 extra for setup)* |
|  [ ]  Flammability, 16 CFR Part 1610 | 3 sets (FTS101), *(14 complete masks from 3 non-consecutive lots = 3 sets)* |
| [ ]  **EN 14683** *(Select all that apply)* |
|  [ ]  Bacterial Filtration Efficiency (BFE), ASTM  F2101 [ ]  Differential Pressure EN 14683 | 5 samples (BFE101) *(5 separate samples for BFE; each sample must be 4 x 4 inches minimum or full face mask)*5 samples (DPT110) *5 for Delta P required; each sample must be 4 x 4 inches minimum or full face mask)* |
|  [ ]  Synthetic Blood Penetration, ASTM F1862  [ ]  120 mmHg/16.0 kPa  | Type IIR only, 1 set (SBP210), *(32 masks are required, 1 extra for setup)* |
|  [ ]  Microbial Cleanliness, ISO 11737-1 | 1 set (MCM100), *(set of 5 samples required)* |
| [ ]  **Other** *(Select all that apply)* |  |
|  [ ]  Viral Filtration Efficiency  [ ]  Click here to enter text. | 5 samples (VFE110), (minimum 5 samples recommended; each sample must be 4 x 4 inches (10 x 10 cm) minimum) |
| **Service Offerings** | **Additional Notes and Comments** |
| [ ]  STAT [ ]  GLP | Click here to enter text. |
| **RESPIRATORS** |
| **Where are you looking to market?** |
| [ ]  U.S. FDA (42 CFR 84)  [ ]  N95 (95% filtration pass criteria) [ ]  N99 (99% filtration pass criteria) [ ]  N100 (99.97% filtration pass criteria) | [ ]  Europe (EN 149) [ ]  FFP1 (80% filtration) [ ]  FFP2 (94% filtration) [ ]  FFP3 (99% filtration) |
| *\*N95 ratings are good for general use, however if marketing to an area with a known viral/bacterial outbreak N100 is the most beneficial* |
| **NIOSH for Respirators** |
| [ ]  Sodum Chloride (NaCl) (NRC) | *20 samples* |
| [ ]  Dioctyl Phthalate (DOP) | *20 samples* |
| [ ]  Inhalation and Exhalation (NRC) | *3 samples* |
| [ ]  Valve Leak Test (NRC) | *3 samples* |
| [ ]  Sodium Chloride (NaCl) | *5-7 samples* |

|  |
| --- |
| **GOWNS** |
| [ ]  **ANSI/AAMI PB70** *(Barrier Level Claim (1-4))* |
| Gown Type |
| [ ]  Isolation Gown *(4 critical areas: chest, sleeve seam, tie attachment (if applicable) & back)*[ ]  Surgical Gown *(3 critical areas: chest, sleeve seam, tie attachment (if applicable))*[ ]  Coverall *(4 critical areas: chest, sleeve seam, other seams in critical front area & zipper (if applicable))* |
| [ ]  Level 1: Minimal risk |
|  [ ]  Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| [ ]  Level 2: Low risk |
|  [ ]  Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
|  [ ]  Hydrostatic Pressure Test (HPT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| [ ]  Level 3: Moderate risk |
|  [ ]  Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
|  [ ]  Hydrostatic Pressure Test (HPT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| [ ]  Level 4: High risk |
|  [ ]  Viral Penetration, ASTM F1671 (VPT) | 96 samples per critical area; *(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires minimum of 32 specimens from 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum)* |

***\*\*\*If not needing to compliance with ANSI/AAMI PB70 see below\*\*\****

|  |
| --- |
| [ ]  **Do not need compliance with ANSI/AAMI PB70** *(nor Barrier Level Claim)* |
| [ ]  Isolation Gown *(4 critical areas: chest, sleeve seam, tie attachment (if applicable) & back) x 3 non-consecutive lots* |
|  [ ]  Synthetic Blood Penetration, ASTM F1670  (SBP)**OR** [ ]  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 requires minimum of 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)**(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires minimum of 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
|  [ ]  Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
|  [ ]  Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| [ ]  Surgical Gown *(3 critical areas: chest, sleeve seam, tie attachment (if applicable)) x 3 non-consecutive lots* |
|  [ ]  Synthetic Blood Penetration, ASTM F1670  (SBP)**OR** [ ]  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 requires 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)**(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
|  [ ]  Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
|  [ ]  Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| [ ]  Coverall *(4 critical areas: chest, sleeve seam, other seams in critical front area & zipper (if applicable))* |
|  [ ]  Synthetic Blood Penetration, ASTM F1670  (SBP)**OR** [ ]  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)**(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
|  [ ]  Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
|  [ ]  Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |