Abstract:
Seeking FDA Emergency Use Authorization (EUA) approval for an open source half mask design that can be manufactured using high volume production methods such as plastic injection molding or low volume product methods such as 3D printing / Additive Manufacturing. Simplified design allows for the use multiple N95 NIOSH approved filtration media materials to achieve the FDA N95 respirator standard (NZJ) was well as other non-FDA N95 approved media to allow for use as surgical respirator (MSH). Also, seeking review and amendment to NIOSH N95 filter certification test TEB APR STP -0059 to bring in to align with practical requirements.
**Design Intent:**

The design intent of this half mask is to achieve a design that meets the following requirements:

1. Manufactured using multiple production processes such as injection molding to achieve low per unit cost and high-volume production and point of demand production via 3D Printing / Additive Manufacturing (Fused Deposition Modeling)
2. A low cost, semi-disposable but re-usable design to reduce the economic, environmental and logistic impact of disposable facemasks and respirators. All components can be sanitized using conventional methods or replaced.
3. A design that is compatible with multiple N95 sheet / roll stock filtration media or other non-N95 certified filtration media.

The basic half mask design will be used to cover two product codes with the product code being determined by the qualification and specification of the filter media. For the Surgical Respirator (Product Code: MSH) there is no requirement for a NIOSH rating filtration rating per 21 CFR 878.4040. For use as an N95 general purpose respirator (Product Code: NZJ), filtration media that has been given prior or recent FDA EUA approval is required per 21 CFR 880.6260

**Design Configuration:**

The proposed design has four different component elements:

1. The main mask that forms the airtight seal around the nose and mouth. This component will be manufactured using a compliant elastomeric rubber with through plastic injection molding or polymer additive manufacturing processes.
2. The filter retainer is a component that is inserted inside the main mask and is used to provide rigidity to the half mask assembly and act as a locking component to keep the filter media in place. The component will be made of a rigid polymer produced either from plastic injection molding or polymer additive manufacturing processes.
3. The filter media is a small swatch of thin fabric material roughly 3.3 inches x 3.3 inches in size that is used to prevent the transmission of harmful contaminants from the air. It will be cut and processed from roll stock. Filter media selection will be dependent upon product code designation.
4. Elastic bands and associated tensioners will be used to maintain the position of the facemask around the nose and mouth and provide an adjustable level of tension to ensure a secure but comfortable fit. These items will be purchased as Commercial off the Shelf (COTS) items.
5. Additive Manufactured Mask Outer Shells and Filter Retainers will be processed at 100% density (infill) to ensure maximum strength and prevent infiltration of air or liquids.
**Bill of Material**

<table>
<thead>
<tr>
<th>Component</th>
<th>Injection Molding</th>
<th>Polymer Additive Manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mask Outer Shell</td>
<td>Monoprene PR-13250</td>
<td>Fire Resistant TPU</td>
</tr>
<tr>
<td></td>
<td>Thermoplastic Elastomer</td>
<td></td>
</tr>
<tr>
<td>Filter Retainer Insert</td>
<td>Polypropylene</td>
<td>Fire Resistant ABS</td>
</tr>
<tr>
<td>Filter Media</td>
<td>Various depending on overall certification</td>
<td></td>
</tr>
<tr>
<td>Elastic Bands / Tension Clips</td>
<td>Commercial off the Shelf</td>
<td></td>
</tr>
</tbody>
</table>

**Approved Filter Media**

<table>
<thead>
<tr>
<th>Filter Media</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter media rated N95 and approved by the National Person Protective Technology Lab (CDC) under 42 CFR 84</td>
<td>NZJ</td>
</tr>
<tr>
<td>Filter media rated surgical mask grade and approved by the National Person Protective Technology Lab (CDC) under 42 CFR 84</td>
<td>MSH</td>
</tr>
<tr>
<td>Spun Melt filtration media produced by Oak Ridge National Lab / Cummings. (Approved under prior EUA)</td>
<td>NZJ</td>
</tr>
<tr>
<td>Filtra Systems MB95d meltblown Polypropylene MB95d</td>
<td>MSH</td>
</tr>
<tr>
<td>Filtra Systems MB95d meltblown Polypropylene MB95d with nanofiber / polypropylene</td>
<td>NZJ</td>
</tr>
</tbody>
</table>

**Product Labeling:**

**Surgical respirator**

Approved For Use under FDA Emergency Use Authorization
Mfr: Bastech Inc.
Product Code: MSH (Surgical Respirator)
Design Date: April 2020

**N95 General Use Respirator**

Approved For Use under FDA Emergency Use Authorization
Mfr: Bastech Inc.
Product Code: NZJ (N95 Respirator General Public)
Design Date: April 2020

Primary manufacturing and assembly of the facemasks will be performed by Bastech Inc. Bastech has over a 25 year record of light industrial manufacturing and rapid prototyping primarily supporting the aerospace industry. Bastech is ISO9001 and AS9100 certified. The filtration media will be provided predominately by Filtra Systems. Filtra Systems has a 40 year track record of
producing industrial, oil and gas and HVAC filtration systems and media. Filtra Systems is ISO9001 certified as well as certified by American Society of Mechanical Engineers (ASME) and the National Board of Boiler and Pressure Vessel Inspectors. These quality systems and certification are consistent with the guidelines established in 21 CFR 820.

**Certification of Bastech Half Mask with Filtra Systems Melt blown Polypropylene (MB95d)**

Filtra Systems Melt blown Polypropylene (MB95d) is melt blown / spunbound non-woven fabric with a chemical composition of predominantly polypropylene. As produced, it is approximately 0.16 inches thick and in rolls measuring 24 inches wide by 185 years long. This particular filter media is primarily used to produce HEPA filters for residential HVAC filtration systems. However, melt blown polypropylene is the filtration media currently used in surgical mask and N95 respirators due to its biocompatibility, filter efficiency and fire rating.

Certification of the Bastech half mask with Filtra Systems Meltblown Polypropylene (MB95d) is recommend based on supposition and test results. Many of the approaches and methods are patterned after other EUA approved facemasks and respirators such as the Stopgap Face Mask (3DPX-013429)

**Biocompatibility:**

**Bastech Half Mask:**
For the purposes of the half mask design the only portions of the half mask that come in contract with the wearer is the outer shell of the mask and the elastic head bands. The injection molded mask outer shell will be fabricated using Monoprene PR-1320 (a thermoplastic elastomer). The Monoprene PR-1320 is a medical grade elastomer that is available world-wide. For the Additive Manufacturing design TPU is another thermoelastic polymer that is commercially available and has been demonstrated to be biocompatible in ordinary uses. The elastic headbands will be purchased commercially as headbands and assumed to be biocompatible

**Filha Systems MB95d filter media:**
The MB95d is of chemical and physical composition (melt blown polypropylene) of filter media used in other FDA approved devices such as surgical masks that touch the caregiver. Therefore, the supposition that the MB95d filter media is acceptable for this application can be made. In addition, the MB95d filter does not come in direct contact with the wearer in this design.


**Flammability:**

**Bastech Half Mask:**
Both the injection molded thermoplastic elastomer (Mask Outer Shell) and polypropylene (Filter Retainer) have a UL 94 fire rating of HB V0. For the Additive Manufacturing produced design, fire rated ABS (Filter Retainer) and TPU (Mask Outer Shell) will be used.

**Filtra Systems MB95d filter media:**
Notional testing was conducted using a modified test procedure consistent with 16 CFR 1610. A strip of MB95d meltblown polypropylene 2.75” long by 1.5” wide was cut and hung in a vertical orientation. A flame source (propane grill lighter) was used as the ignition source. The MB95d

![Initial swatch of MB95d filter media cut for testing](image1)

Left: Initial swatch of MB95d filter media cut for testing

Right: Test swatch hung in vertical orientation for open flame testing

![MB95d media after 3 second exposure to open flame](image2)

MB95d media after 3 second exposure to open flame. Melting only, flame extinguished after ignition source removed.
was subject to an open flame for a duration of approximately 3 seconds. (16 CFR 1610 calls for a 1 second exposure). As a result, the MB95d material was melted and no flame was produced once the ignition sources was removed. Per these results, the MB95d melt blown polypropylene materials can be considered as having a class 1 fire rating.

In addition, the supposition that the MB95d filter material is acceptable for use can be made from the fact that it is of a similar physical and chemical composition (melt blown polypropylene) that is already used in this surgical mask application on designs approved by the FDA and is use HVAC systems that also have stringent fire, smoke and toxicity requirements. The other components of the half mask are also made of materials that meet these requirements.

**Liquid barrier protection**

Left: Test set up- MB95d media, syringe with 2ml of 2% cow’s milk
Right: Close up of test set up. Small square on right prior exposure to milk to serve as exposure baseline.

Left: Test sample immediately after injection of milk, note the puddling of milk due to hydrophobic behavior of the MB95d media causing the milk to run off the filter media during injection.
Right: Witness paper did not exhibit signs of milk exposure.
**Bastech Half Mask:**
Neither the Mask Outer Shell nor Filter Retainer ring produced via injection molding or Additive Manufacturing (at 100% density) represent a concern for liquid barrier penetration.

**Filtra Systems MB95d filter media:**
Mask liquid barrier protection testing was using an approach similar to the Stopgap Face Mask. Per ASTM F 1862 the intent of the test is to show the ability of the facemask or respirator to act as a barrier to prevent the infiltration of blood or another liquid pathogen from entering the protective device. The fundamental approach of ASTM 1862 is the injection of blood or a blood simulant on to the filter media at a maximum pressure of 160 mm Hg to simulate a cut in a human artery. ASTM F 1862 calls for the use of 2 ml of blood or blood simulant to be injected on to the front of the filter media and verification that no fluid passed through the filter. For testing purposes, a green sheet of paper is used as a witness media. A photo of the green paper exposed to the blood simulant prior to testing is provided.

Similar to the Stopgap Face Mask EUA certification approach commercial cow’s milk (2% milk fat) was used at room temperature (3 hours of exposure to room temperature) and injected using a 23 gauge medical syringe with an internal orifice diameter of 0.34 mm. Based on equations X1.6 and X1.7 of ASTM F 1862 it was determined that injection the 2 ml of cow’s milk in a timeframe of 3.46 seconds or less would result in an impingement pressure of 160 mm Hg or more. Before and after pictures of the experiment are provided below. Two observations can be noted. First, there was no liquid penetration of the cow’s milk under the filter. Second, the external coating of the MB95d filter appeared to be extremely hydrophobic as the puddle of milk was large (ran off the filter media) and appeared to be lacking surface tension with the filter media (formation of large bubble of milk on top of the filter media). As a result of the visual evidence and the fact that the half mask design has the filter media several inches away from contact of the the oral and nasal orifices of the wearer, the MB95d filter media is deemed as providing sufficient liquid barrier protection.

**Filtration performance:**
Per CDC guidelines under 42 CFR 84 to be considered for use in a non-powdered respirator with an N95 rating the filter media must successfully filter 95% of all particles at 0.1 microns in diameter. Typically 0.075 microns is used in testing.

**Bastech Half Mask:**
Neither the Mask Outer Shell nor Filter Retainer ring produced via injection molding or Additive Manufacturing (at 100% density) represent a concern for filtration. The supposition can be made that because the mask outer shell uses an elastomeric polymer (Monoprene PR-13250) with a
medium hardness (Shore A value of 55) and has a compliant design the interface between the mask and wearer a sufficient airtight seal is formed.

**Fitra Systems MB95d filter media:**
With respect to the MB95d filter media. Independent 3rd party testing performed by Blue Haven Technologies showing a greater >97.6% filter efficiency for 0.3 micron particulates and 92% for 0.1 micron. Further testing is currently underway to determine the impact of using an additional nanofilter layer can used with the MB95d to further increase filter efficiency at the 0.1 micron particle layer. Testing was conducted at 400 liters per minute (14.3 CFM). (See attached results)

This flow rate is nearly five (5) times the required flow rate (85 ± 4 liters per minute) required by the CDC per 21 CFR 84. In addition the 85 liters per minute is 8.5 to 14 times greater than the average respiration of an adult 70 kg human male based on medical literature. These facts combined with that fact that filter media efficiency increases with decreases in flow rate it is recommended that the MB95d filter media be given N95 approval pending further testing at appropriate conduction.

It is also recommend that NIOSH testing procedure used to evaluate filter media be evaluated and revised to a testing specification consistent with practical use. The CDC requires testing is to be conducted using the NIOSH standard test procedure TEB APR STP-0059 (13 Dec 2019) titled *Determination of Particulate Filter Efficiency for N95 Series Filters against Solid Particulates for Non-Powered Air Purifying Respirators Standard Testing Procedure (STP).* Procedure 5.3 of this standard test procedure call for a flow rate of 85 ± 4 liters per minute for a single filter respirator design and 42.5 ± 2 liters per minute for a two filter respirator design. The medically accept breathing air flow rate for a 70 kg man is 6-10 liters per minute (12-20 breaths per minute at 500 ml per breath).

It is requested that the 85 liter per minute flow required be evaluated and adjusted to an amount consistent with practical application to support COVID-19 treatment environments.

**Medical Literature cited**

# Air Filter Media Test Report

## Filter Description

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Filtra-Systems Co.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Model</td>
<td>MB35d</td>
</tr>
<tr>
<td>Part Number</td>
<td>N/A</td>
</tr>
<tr>
<td>Generic Filter Type</td>
<td>N/A</td>
</tr>
<tr>
<td>Nominal Dimensions (H x W)</td>
<td>16” x 16”</td>
</tr>
<tr>
<td>Pocket / Pleat Quantity</td>
<td>N/A</td>
</tr>
<tr>
<td>Media Type</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Est. Gross Media Area</td>
<td>1.77 ft²</td>
</tr>
</tbody>
</table>

## Test Conditions

<table>
<thead>
<tr>
<th>Test Aerosol</th>
<th>NaCl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barometric Pressure (In. Hg.)</td>
<td>29.59</td>
</tr>
<tr>
<td>Test Air Temp (degrees F.)</td>
<td>70</td>
</tr>
<tr>
<td>Relative Humidity (%)</td>
<td>40</td>
</tr>
</tbody>
</table>

## Test Results

<table>
<thead>
<tr>
<th>Airflow Rate (CFM)</th>
<th>14.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Face Velocity (FPM)</td>
<td>14.3</td>
</tr>
<tr>
<td>Test Area (ft²)</td>
<td>1.0</td>
</tr>
<tr>
<td>Average Initial Resistance (in. WG)</td>
<td>0.11</td>
</tr>
<tr>
<td>Average Efficiency at 0.3 µm (%)</td>
<td>97.64</td>
</tr>
</tbody>
</table>

## Comments

Tested on VD2 using Aerosolized NaCl and TSI Model 3080 Electrostatic Classifier and TSI Model 3772 Particle Counter. Efficiency calculated for particles at 0.3µm at 14.3 CFM (14.3 fpm)

Individual test results found on page two.

## Requestor Information

<table>
<thead>
<tr>
<th>Test Requestor</th>
<th>Cory Elliott</th>
<th>Phone: 614-777-8222</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name</td>
<td>Filtra-Systems Company</td>
<td>Email: <a href="mailto:cle@troffilters.com">cle@troffilters.com</a></td>
</tr>
<tr>
<td>Company Address</td>
<td>1720 Westbelt Drive Columbus, Ohio 43223</td>
<td>Date Requested 3/27/2020</td>
</tr>
</tbody>
</table>

## Test Operator Information

| Test Performed by | Evan Sparks | Completion Date 4/14/2020 |
**Data - Initial Resistance**

<table>
<thead>
<tr>
<th>Velocity (FPM)</th>
<th>Initial Resistance (in. WG)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample 1</td>
</tr>
<tr>
<td>14.27</td>
<td>0.11</td>
</tr>
</tbody>
</table>

**Data - Particle Removal Efficiency**

<table>
<thead>
<tr>
<th>Particle Size (µm)</th>
<th>Efficiency %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample 1</td>
</tr>
<tr>
<td>0.3</td>
<td>97.64</td>
</tr>
</tbody>
</table>
# Product Data Sheet

## Attributes & Properties

<table>
<thead>
<tr>
<th>Name:</th>
<th>MB95d Air Filtration Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media Type:</td>
<td>Polypropylene (Meltblown &amp; Spunbond)</td>
</tr>
<tr>
<td>Color:</td>
<td>Upstream: Blue Downstream: White</td>
</tr>
<tr>
<td>Basis Weight:</td>
<td>5.69 oz / sq. yard (192 g / sq. meter)</td>
</tr>
<tr>
<td>Efficiency:</td>
<td>97.64 % @ 0.3 micron</td>
</tr>
<tr>
<td>Resistance:</td>
<td>0.11 in. WG (27.4 Pa)</td>
</tr>
<tr>
<td>Thickness:</td>
<td>0.16 inches (4 millimeters)</td>
</tr>
</tbody>
</table>

Testing performed using Aerosolized NaCl, TSI Model 3080 Electrostatic Classifier and TSI Model 3772 Particle Counter using a 1 sq.ft test area and Nominal Face Velocity of 14.3 FPM
**Bastech PPE**

**Reusable N95 Mask**

- Conforming fit—Provides secure seal for the best protection
- Comfortable, lightweight design
- Re-usable Mask with replaceable filter media

The unique design of the Bastech PPE N95 Mask provides the user with the best protection and comfort available in a re-usable mask. Engineered with only 2 parts, it is comfortable, lightweight and easy to use. To change out the filter and clean the mask the user only needs to pull out the internal retainer, lay the new filter over the retainer and reinstall it inside the mask. The Mask and Retainer are able to be sterilized for repeated use.

**Design Features:**

- Superior fit: The section of the mask that comes into contact with the face is contoured and flexible resulting in a more comfortable fit and better seal. No custom fitting required!
- Fits multiple face sizes and shapes
- Superior breathability: The large filter area is open and unrestricted so that the entire filter is used for maximum air flow
- Interference design with the N95 filter media provides a secure seal for more security
- Designed with only two parts; the Bastech Mask needs only the Mask and internal retainer. Only having two parts makes it easier to use and fewer parts to sterilize!
- Can be used with other filter material for other applications and needs
Certificate of Registration
This certifies that the Quality Management System of

Filtrasonic Co.
2500 Haggerty Road
Farmington Hills, Michigan, 48335, United States

has been assessed by NSF-ISR and found to be in conformance to the following standard(s):

ISO 9001:2015

Scope of Registration:
The design, manufacture, test and service of filtration systems for industrial liquid/solid separation with fabrication in Conover-Elle, TN.

Certificate Number: 9001-0256
Certificate Issue Date: 11/28/2018
Expiration Date: 11/27/2021

Page 1 of 2

Certificate No. 5732 (2 Copies)
July 16, 2018 through July 15, 2021

Certificate of Registration
This is to certify that the Quality Management System of

BasTech
MAKING THE FUTURE

BasTech, Inc.
9233 North Dixie Drive, Dayton, Ohio 45414 US
Site definition: Single

Has been assessed by EAGLE Registrations Inc. and
conforms to the following standard:

AS9100D including ISO 9001:2015
This assessment was performed in accordance with the requirements of AS9100D:2012
EAGLE Registrations Inc. is accredited under the Aerospace Registrar Management Program

Scope of Registration
Manufacture of Conventional Machining and 3D Printing / Additive Manufacturing for
Parts and Assemblies in Both Metal and Polymer Materials.

Director of Certification
40 N. Main Street, Suite 1180 | Dayton, OH 45423 USA | 937.263.2000 or 800.705.3061
www.eaglecertificationgroup.com

Page 1 of 1