Reviewer comments

Dear author,
In order to proceed with review or your submission we need additional information regarding manufacturing methods - what is material used for production of your mask? And more clarification regarding filter media suggested for the mask. Do you have testing or verification data for material? in question?
Please update at your earliest convenience.
Thank you.
Sincerely,
VA REVIEW TEAM

Response to reviewer comments

1) What is the material used for production of your mask?

The material used is Thermoplastic polyurethane (TPU), the commercial name is MDFlex manufactured by Copper3D Inc. Copper 3D MDFlex is an innovative antimicrobial filament developed with a high-quality TPU 98A compound and a patented, scientifically validated and highly effective Copper additive. MDFlex is compliant with the European Union norms: No. 10/2011, No. 1935/2004 and No. 2023/2006, Antibacterial action has been scientifically validated eliminating more than 99.99% of fungi, viruses, bacteria and a wide range of microorganisms, clinically tested in prosthesis for amputees with excellent results, manufactured in the Netherlands according to ISO 9001/2015 certified manufacturing standards.

2) Clarification regarding filter media suggested for the mask?

The filtering material use is from patches from already approved surgical masks (Polypropylene used in the Isolation Face Mask, SKU NON27122 by Medline); One surgical mask can provide 5 filter filtration patches.

3) Do you have testing or verification data for material?

DECLARATION OF CONFORMITY (DoC)
Equipment: Face Mask
Trademark(s) and Model(s): SHABRI's Last Resort Mask
Manufacturer: SHABRI LLC
FDA under 21 CFR 878.4040 as
Equivalent or similar to Medline NON27402: Yes

Fluid resistance: We performed a test comparable to ASTM F1862. Specifically, a pass/fail test was performed using a 2 ml of fluid solution prepared with a red dye to aid in visual detection. The red fluid was sprayed onto the surface of the face mask. The impact of the fluid solution was performed at velocities of approximately 450–635 cm/sec corresponding to arterial blood pressures ranging from 80–120 mm Hg. After visual inspection of the back side of mask was observed for red fluid penetration. After three trials it was verified that the mask passed the test showing no red fluid penetration. Our printing specifications resulted in fused layers, stopping fluid molecules that are 0.282 N/m. We used a wall thickness of 1.7 mm. This minimum wall thickness resulted in three extrusions side by side producing a double seal of the mask. The specific settings for the slicer software to accomplished fluid resistance are as follows:

Layers: Layer height- .2mm, First layer height:0.25mm, Perimeters:2, Avoid crossing perimeters: X, Eternal Perimeters first: X, Start end overlap: 140%, Merge overlapping lines: X, Expand thin walls: X, Top solid layers: 9, Bottom solid layers: 9, Infill Fill density: 100%, Infill type: lines starting angle: 0, Infill

overlap: 0.9mm, Fill thin gaps: X, Speed infill: 20mm/s, Top solid infill: 20mm/s, raft: 100%, inside perimeters: 20mm/s, outside perimeters: 20mm/s, Support material: 20mm/s, bridges: 25mm/s, Travel: 130mm/s, First layer speed: 20mm/s
Retraction: Speed: 70mm/s
Extrusion: Extrusion multiplier: 1.5, First layer: 160%, Outside perimeters: 160%
Printer: Any desktop 3D printer that allows these settings.

Viral or bacterial filtration performance: The item described in this document is not certified for viral infections. However, according to the manufacturer specifications the filtration material used in the SHABRI's Last Resort Mask (Polypropylene used in the Isolation Face Mask, SKU NON27122 by Medline) has a Bacterial Filtration Efficiency (BFE) ranging from 98%, blocking up to 97% of particulates, making our filtration system more effective at blocking particulate material than the a simple surgical mask. The filtration material and mask have been evaluated using a qualitative a pass/fail fit test that relies on the end-user response to a test agent. According to the Occupational Safety and Health Administration (OSHA) protocol, we use the saccharin dust test. The subject dons the mask and a fit test hood. Saccharin is sprayed inside the hood while the end-user performs prescribed exercises, such as normal breathing, deep breathing, moving head side to side and up and down, as well as talking. If the end-user is not able to taste the test sweetness of saccharin dust during these exercises, the mask passed the test. If the end-user, however, is able to taste the test sweetness of saccharin dust, the mask fails the test. The fit test procedure requires about 15 to 20 minutes. This is a simple qualitative assessment. We currently coordinating the use of a PortaCount system to perform a quantitative assessment of our products.

Biocompatibility: The material used to manufacture SHABRI's Last Resort Mask (MDFlexTM, manufactured by Copper3D Inc) has been considered as "non-cytotoxic" and safe for skin contact under ISO 10993-5 Biological Evaluation of Medical Devices-Part 5 (Tests for in vitro cytotoxicity), ISO 10993-10 Biological evaluation of medical devices Part 10 (Tests for irritation and skin sensitization) and ISO 1093-12 Biological evaluation of medical devices Part 12 (Sample preparation and reference materials).

Based on the information presented above we conclude that the filtration material used in the SHABRI's Last Resort Mask is equivalent or superior to Medline NON27122.

The following manufacturer/importer/entity (located in the USA) is responsible for this declaration:
Company name: SHABRI LLC

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Date: June 1,2020