

End-User Information Sheet

GENTL Disposable Face Mask 3-Layer (MERV13 Filter)

v1.04

NOTICE: STRAP MAY CONTAIN LATEX. SAMPLES ARE FOR EVALUATION ONLY AND NOT INTENDED FOR CLINICAL USE

For More Information:

Please reach-out to GENTLmask@epam.com or visit <https://solutionshub.epam.com/solution/gentl-mask>

Design:

The GENTL Mask is an **Open Source face mask** reference design that utilizes readily available materials and incredibly simple manufacturing processes to enable localized manufacturing to help close the PPE supply gap. The 3L GENTL mask consists of a flat-cut, three-layer design that utilizes industrial grade filter material, sealed between two layers of non-woven polypropylene. This mask is not intended to provide equivalent protection to an N95 mask; but integrates a MERV 13 filter to provide filtration beyond a surgical mask. The GENTL mask conforms to the face, providing a comfortable and safe fit. Heat sealed edges force air through the filter and non-woven sheets, while a simple, single loop strap secures it in place.

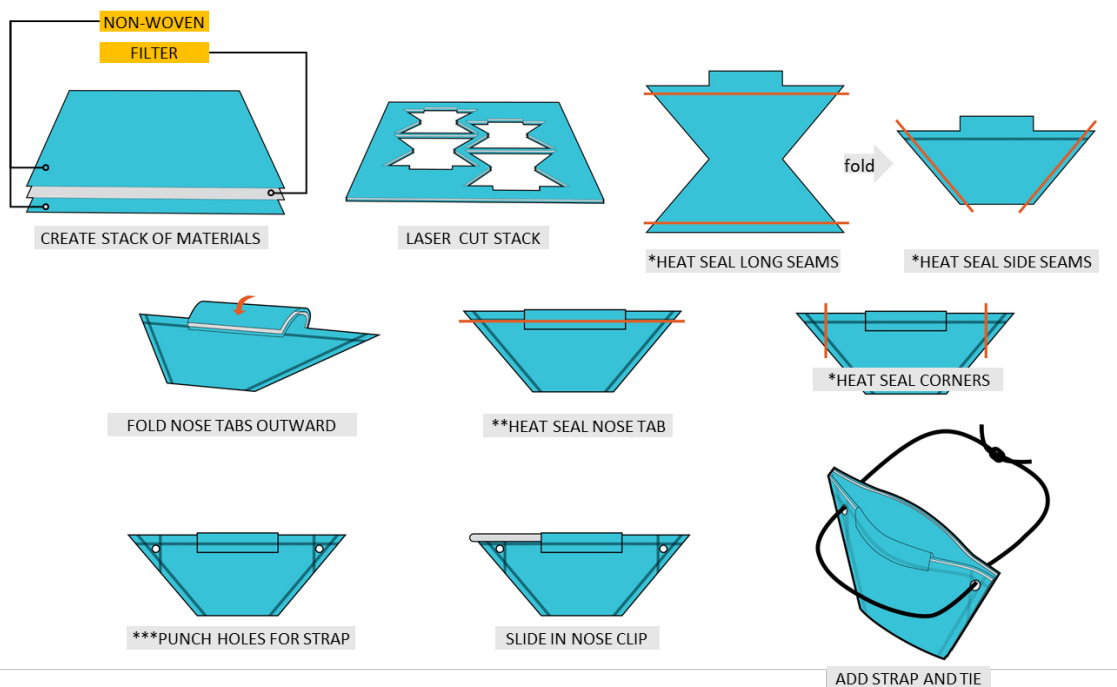


Item	Description	Material in Prototype
1	Braided Elastic	https://www.mcmaster.com/88225k61
2	Non-woven Polypropylene Surgical Drape	https://www.medline.com/product/Sterile-Economy-Surgical-Drape/Z05-PF06931#mrkSpec
3	Honeywell Elite Allergen MERV13 Air Filter	https://www.homedepot.com/p/Honeywell-30-in-x-30-in-x-1-in-Elite-Allergen-Pleated-FPR-10-Air-Filter-91001-013030/203641970
4	Aluminum Sheet 0.016"	https://www.mcmaster.com/89015k15

Manufacturing:

These masks were produced by hand (builders were gloved and masked) at EPAM-Continuum's prototyping shop using the following manufacturing procedures. Full build documentation including a video of the process can be found on the website at the top of this document.

- Laser cutter, to cut soft material layers
- Aluminum sheet metal shear and sander, to cut nosepieces to size (and round edges)
- Heat sealer, to seal layers together
- Rotary handheld cutter, to cut strap to size and remove excess soft material
- Leather punch, to create holes for strap]



Design Validation:

The GENTL mask is an improvised face mask and is intended to be used as a reference design for manufacturing. This mask has not yet been put through any necessary regulatory review as may typically be associated with medical design and development. Functional testing is ongoing and testing documentation can be requested by contacting the team at the email address above.

Disclaimers for use:

The GENTL Mask is a rapid response to an emergency situation. If you run a healthcare facility and determine this could be a better option than what you are facing right now, we hope this provides you an added layer of protection in this moment in time. EPAM Continuum is offering the GENTL Mask design idea as an Open Source offering to the community during this public health emergency. These statements and the GENTL Mask are not intended to diagnose, treat, cure or prevent specific any diseases. The statements made with respect to the GENTL Mask have not been evaluated by the U.S. Food and Drug Administration or any other regulatory authority. The GENTL Mask has not been tested, nor has it been put through any necessary regulatory design review as may typically associated with medical design and development. Individuals or organizations that manufacture masks utilizing the design and specifications are responsible for any federal or state regulatory requirements that apply to the manufacture or distribution of masks intended for medical use. Individuals and organizations are free to use, copy, modify and share this design and specifications, including for commercial manufacture, without payment of any fees or charges, but may not assert ownership in the design and specifications or "GENTL Mask" mark, ownership of which belongs to EPAM Continuum. EXCEPT WHERE SPECIFICALLY PROHIBITED BY LAW, NO WARRANTIES OF ANY KIND ARE OFFERED FOR THE MASK DESIGN AND SPECIFICATIONS, INCLUDING WARRANTIES OF NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.