The Philter™

Instructions for Use of Philter Face Mask (PFM) for Healthcare Personnel

The U.S. Food and Drug Administration has notified Philter PPE Devices, Inc. of inclusion of the PFM as an authorized face mask under the Face Mask Emergency Use Authorization (EUA) Letter issued on April 18, 2020. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to use the PFM appropriately.

- **NOT** intended for use as a surgical mask or to provide liquid barrier protection
- **NOT** for use in any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids may be expected
- **NOT** for use without other PPE in a clinical setting where the infection risk level through inhalation exposure is high
- **NOT** for use in the presence of a high intensity heat source or flammable gas
- **NOT** intended for antimicrobial or antiviral protection or related uses.
- **NOT** for use as an infection prevention or to reduce particulate exposure.
- The presence of eyeglasses with stems over the ears can break the seal of the face mask. **USERS WITH GLASSES SHOULD NOT USE THE PFM**.
- **NOT** for use in a sterile environment
- **For multiple uses by single user.** The Face Mask should be washed between uses.
- **THE PFM HAS NOT BEEN FDA CLEARED OR APPROVED**
- The PFM has been authorized by FDA under an EUA for use by healthcare professionals as personal protective equipment to help prevent the spread of infection or illness in healthcare settings and by the general public to help slow the spread of the virus during the COVID-19 pandemic
- The PFM is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner

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