Label and Terms of Use for MNmask Style 3 Face Mask

No representations or warranties are being made about the face mask and user assumes all risk in use of the face mask. This face mask is being made available as a covered countermeasure under the Public Readiness and Emergency Preparedness (PREP) Act of 2005.

(1) This face mask body contact materials are: Non-woven polyester, Rubber bands (some are latex-free and others contain latex), Galvanized steel staples

(2) The face mask is intended for single use only, for source control in accordance with Centers for Disease Control and Prevention (CDC) recommendations.

(2) This face mask has not been FDA cleared or approved. The distribution of this product has been authorized by FDA under its Emergency Use Authorization (EUA) authority for use by the general public for source control to help slow the spread of the virus during the COVID19 pandemic.

(3) This face mask is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of products under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1) (the “Emergency Declaration”), unless the authorization is terminated or revoked sooner. Holders of this face mask should dispose of the face mask once the Emergency Declaration terminates or is revoked.

(4) This face mask should not be used for any purpose other than source control. Without limiting the foregoing, the face mask should not be used (i) in any surgical setting, (ii) where significant exposure to liquid, bodily or other hazardous fluids, may be expected; (iii) in a clinical setting where the infection risk level through inhalation exposure is high; (iv) in the presence of a high intensity heat source or flammable gas, or (v) in the presence of high risk aerosol generating procedures. This face mask is not intended for antimicrobial, antiviral, or infection protection or reduction and is not a respiratory protection device.

(5) The face mask has not been industry tested nor has it been NIOSH approved. No representations are being made as to the safety of the face mask or efficacy for prevention of disease.

(6) Any adverse events with the face mask should be reported to:

    University of Minnesota
    Institute for Engineering in Medicine
    420 Delaware Street SE #725
    Minneapolis MN 55455

This label information may also be found at www.iem.umn.edu/medical-devices-ppe-masks

This face mask is not authorized for resale. This face mask is not to be used in healthcare settings by health care personnel as personal protective equipment (PPE).