

Face Shield Labeling

* This product has been authorized by FDA under an EUA dated April 18, 2020 and updated April 24, 2020 for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic. The product has not been FDA cleared or approved and 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 Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner. This product is a Face Mask (Face Shield).

* This product is not recommended for use in a clinical setting where the infection risk level through inhalation exposure is high.

* Body Contacting Materials:

- Polystyrene Shields
- Galvanized Steel Staples
- Polyethylene Headband
- Polyurethane Foam Headband (if equipped on select models)