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Face Shield Instructions and Regulations

On April 9, 2020, as amended April 13, the FDA issued an EUA (Emergency Use Authorization) see: https://www.fda.gov/media/136842/download. Millennium believes it is in full compliance with this EUA.

SANITIZE BEFORE USE

The FDA states we must mention this Face Shield is "either a single-user, single use, or for multiple uses by the same user". We have cleaned these shields with full strength bleach, alcohol, and even acetone which is not recommended by the manufacturer of the plastics, all with no crazing or clouding of the clear plastic.

Our shield does not contain any materials that cause flammability, as the FDA calls out in the EUA. Our hook and loop fasteners have passed rigorous automotive flammability ratings. The PETG plastic used in our 20mil and 40mil materials is itself FDA approved, and the lighter polyester film material is similar in non-flammability. Our various foams are polyester polyurethane foams and have passed Federal Motor Vehicle Standards for flammability.

Nylon and Polypropylene for the hook and loop, and polyester polyurethane foam are the materials that directly touch the body. The shield itself is PETG, or Polyester Film, and may come in contact with the body.

The FDA wants us to tell users: "the authorized face shield alone will [not] prevent infection from microbes or viruses, [and] that it is [not] effective ... radiation protection. "(We'd love to find a shield that prevents viruses and protects from radiation!) This product has not been FDA cleared or approved, but has been authorized by FDA under EUA for use by healthcare providers as personal protective equipment.

Finally, the EUA may expire when the Covid19 crisis comes under control.

NY State called out (wrongly we believe) ANSI Z87.1 which calls for a minimum thickness of 39.2 mils. Only our 40 mil shield meets this reg.