



March 29<sup>th</sup>, 2021

Dear Valued Customers,

Thank you for your inquiries and concerns regarding Puritan's use of Ethylene Oxide as a method of sterilization. Puritan recognizes that the COVID-19 pandemic brings challenges and concerns to communities and families around the world, as we all continue to respond to COVID-19.

The most recent concerns, brought on by social media, are regarding schools testing for COVID-19 with equipment that have been sterilized with Ethylene Oxide. Such social media has communicated false claims/information regarding COVID-19 testing, where it has incorrectly associated the risk of long-term Ethylene Oxide exposure, to single-use (short-term) devices, such as swabs. The misinterpretation of information originated from the EPA's stance concerning Ethylene Oxide processing facilities and from OSHA's and CDC's recommendations against use of Ethylene Oxide sterilization for personal protective equipment (respirators). All of which have potential for long-term exposure and their own associated risks.

Sterilization processes have always been essential for medical device industries. However, the COVID-19 pandemic resulted in the emergency situation of single-use device shortages, and requires the urgent need for the rapid sterilization of medical equipment to battle the virus. Ethylene Oxide gas has been used for decades and is used by manufacturers to keep medical devices safe and makes up around 50% of all sterile medical devices in the United States. The sterilization process ensures the Ethylene Oxide gas is removed from the product (i.e., evacuation, and air washes) so that Ethylene Oxide gas is below that of the safety levels set by national and international standards.

Puritan utilizes a validated Ethylene Oxide method of sterilization and the sterilization process is tightly controlled to ensure medical devices are safe to use. Additionally, and the sterilization process is revalidated on a routine basis, where sterilized samples are tested for Ethylene Oxide residual levels using the international standard ANSI/AAMI/ISO 10993-7:2008, "Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals" extraction method for determining EO residuals.

Puritan wants to emphasize our commitment to your health and safety during these challenging times and reassure our customers that we rely on the best available data, science, and manufacturing practices to achieve our goals.

Sincerely,

Bharat Moorthy

*Director - Quality Systems & Regulatory Affairs*