Puritan
Quality since 1919

STERILIZATION OF MEDICAL DEVICES

Puritan Medical Products Company, LLC (Puritan) has received inquiries about the safety of swabs manufactured for COVID-19 testing. False claims and misinformation about Ethylene Oxide and Ethylene Chlorohydrin residuals have been posted on social media (i.e., TikTok, Facebook, Instagram, etc.) and have brought unwarranted concerns regarding swabs used for COVID-19 testing. The most recent false claims and misinformation on social media suggest that swabs used for COVID-19 testing are mutagenic (alter DNA) and carcinogenic (cause cancer) due to their sterilization process with ethylene oxide.

As a company committed to the health and safety of each person our product touches—we would like to take this opportunity to swab the deck of misinformation clean.

SWABS AS MEDICAL DEVICES

Puritan-manufactured sterile swabs that are known to be used for COVID-19 testing are medical devices intended to collect products (i.e., biological samples) from the body for subsequent diagnostic analysis by a multitude of testing methodologies.

STERILIZATION

The definition of sterile is: “free of viable microorganisms”. Sterilization destroys all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item, such as the use of a swab to collect patient sample. Medical devices are sterilized in a variety of ways, including using moist heat (steam), dry heat, radiation, ethylene oxide gas, vaporized hydrogen peroxide, and other sterilization methods. Methods of sterilization are determined by material compatibility, process availability and location, and legacy regulatory approval. Literature demonstrates that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide, as that may be the only method that effectively sterilizes and does not damage the device during the sterilization process.

Medical devices that have contact with sterile body tissues or fluids, like Puritan swabs, are considered critical items and should be sterilized prior to use to prevent microbial contamination and eliminate serious risk to patient safety. The swab sterility guarantees that no contaminants are transferred from the swab to the patient, ensuring both patient safety and the quality of the diagnostic results.

Standardized and internationally recognized sterilization symbols are printed on the labels of any sterile product manufactured by Puritan Medical Products Company, LLC. The two (2) possible symbols on the labeling indicate that the swab has been sterilized using, respectively, Irradiation (R) or ethylene oxide (EO).

continued on page 2

STERILIZATION OF MEDICAL DEVICES

continued from page 1

Puritan can assure its customers that the Ethylene Oxide sterilization process is tightly controlled and safe. Ethylene Oxide has been widely used for decades to keep medical devices safe and its use makes up around 50% of all sterile medical devices in the United States. The Ethylene Oxide sterilization process ensures the Ethylene Oxide gas is removed from the product (i.e., evacuation, and air washes) so that residuals are below that of the safety levels set by International Standards. The validation of Puritan's Ethylene Oxide sterilization process, and the evaluation of post-sterilization residuals are executed per the below U.S. Food and Drug Administration (FDA) Recognized Consensus Standards:

- ANSI AAMI ISO 11135:2014, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices,

- ANSI/AAMI/ISO 10993-7:2008, "Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals" extraction method for determining EO residuals.

Puritan's Ethylene Oxide sterilization process is routinely revalidated per ISO 11135, and swabs sterilized by Ethylene Oxide are tested on a routine basis per, ISO 10993-7, which specifies the safe limits and specific methods used to evaluate residual Ethylene Oxide and Ethylene Chlorohydrin. Additionally, Puritan utilizes Ethide Laboratories, an ISO 13485:2016 certified testing laboratory, to conduct residual testing. The results of residual testing continuously demonstrate that Ethylene Oxide and Ethylene Chlorohydrin residual levels are far below the specification limits of 4.0 mg/l and 9.0 mg/l. These specification limits of ISO 10993-7 were established by Technical Committee ISO/TC 194, which is the international team of experts for the biological and clinical evaluation of medical devices. Therefore, Ethylene Oxide and Ethylene Chlorohydrin residues are verified to be of a safe level and pose minimal carcinogenic, mutagenic, and/or toxic risk, prior to shipment of swabs to our customers.