

Keystone Safety and Cleanroom Products Unveils New Autoclave Bags and Covers to Ensure EU Annex 1 Compliance in Steam Sterilization of Pharmaceutical Change Parts

Pennsauken, New Jersey – 3/17/2025 – Keystone Safety and Cleanroom Products, a leader in pharmaceutical sterilization wrapping solutions, is proud to announce the launch of its new product line, designed specifically to meet the requirements of EU Annex 1 in the steam sterilization of pharmaceutical change parts. This new line has been specifically designed to satisfy the requirements laid out by EU Annex 1, as well as to enhance the quality, efficiency and safety of the pharmaceutical production process, ensuring that operations remain compliant with ever evolving standards and regulations.

Meeting the New EU Annex 1 Standards

Twenty years ago, Tyvek drawstring bags were considered “the gold standard” for wrapping pharmaceutical production equipment for steam sterilization. These were being used as the outer bags for big, heavy filling machine parts like stopper bowls, hoppers, and tracks. Back then, most aseptic pharmaceutical plants were still operating with conventional filling lines, before RABs and isolators became the norm. The primary concern was the fear of generating particles by cutting anything in the Grade A space. This led to top aseptic consultants arguing that the aseptic presentation of the critical equipment needed to be improved and that organizations needed to move away from wrapping parts with cellulose based Bioshield paper and autoclave indicator tape.

In the 2020s, isolators and RABs are now commonplace. These large, outer autoclave bags don’t need to be, nor could they be, effectively opened in Grade A. This is done in Grade B for RABS and in Grade C for companies using isolator technologies. The more important concerns today are ensuring that the autoclaved parts are clean from a particulate standpoint, rendered sterile, dry, and free from any residues. However, the drawstring closure design of larger, Tyvek bags makes it extremely difficult to get the folds and creases of the twisted “gooseneck” closure design completely dry —; and the torturous path closure can be difficult to defend to an outside auditor, or regulatory authority, especially if autoclaved parts are not unloaded and allowed to cool under Grade A LAF before being moved into Grade B/C storage prior to use. From experience, it has become clear that this phenomenon can be exacerbated by the oversized drawstring bag design. The excessive amount of hydrophobic material traps the steam in its gaseous state and allows it to condense into water droplets. When unwrapping, this residual moisture (potentially including the problematic water soluble anti-stat agent in solution) could be dispersed throughout the bag and transferred onto the equipment parts.

Keystone Cleanroom Products has taken a holistic approach to solving this problem and is offering innovative solutions. Keystone's approach begins with 'right-sizing' the bags to ensure a perfect fit; and suggests the consideration of switching from an oversized drawstring closure design to one that can be hermetically sealed, which is, along with dryness verification, a requirement of the new Annex 1 guidelines.

Keystone's newly introduced PureClean™ 1421B Tyvek® material, from DuPont™, might also be considered as a replacement for the legacy 1422A type. We are honored to partner with DuPont™ to offer the next generation Tyvek® to our pharmaceutical manufacturing customers. The PureClean™ Tyvek is essentially the same material as the legacy Tyvek®, except it does not have the anti-stat agent.

Product Features and Benefits

Keystone Cleanroom Products' line of PureClean™ 1421B Tyvek® bags and covers offers a solution to EU Annex 1 compliance in the steam sterilization of pharmaceutical change parts. Product features include:

- **Ability to “right-size” bags in use:** Keystone Cleanroom Products offers a wide range of sizes to ensure a perfect fit for every application."
- **PureClean™ 1421B Tyvek®:** Keystone Cleanroom Products is proud to offer this new material as a potential replacement for the legacy 1422A type as it is essentially the same, just without the anti-stat agent.
- **Hermetically sealed closures:** Keystone Cleanroom Products provides autoclave bags with both heat-seal and self-seal closures, eliminating the challenges posed by the drawstring closures found in larger Tyvek bags. These drawstring closures often make it difficult to fully dry the folds and creases of the twisted “gooseneck” design.
- **Clear Film Side for Visual Inspection:** Keystone Cleanroom Products' PureClean™ Self-Sealing 1421B Tyvek® Autoclave bag with Clear Film Side and Steam Indicator has a clear film side that allows for easy visual inspection without breaking the sterile barrier, as required by Annex 1.

Keystone Safety and Cleanroom Products' Commitment to Innovation and Quality

Keystone Cleanroom Products stands apart from the competition by operating in certified ISO6 and ISO8 cleanrooms through the entire manufacturing process. The rolled good raw materials are introduced to the cleanroom by dedicated material transfer rooms, where the

external protective wraps are removed, before the raw material can enter the ISO 8 spreading and cutting cleanrooms. A fully automated material-spreading process, followed by a Computer-Aided Design (CAD) cutting system ensures precision and reduces operator variability. This minimizes operator interaction with the raw material and eliminates the variability of outputs, compared to when patterns are used, with an operator leaning over the raw materials and cutting it with an electric knife, in a non-cleanroom environment, which is exactly what Keystone's competitors do. However, Keystone Cleanroom Products believes in the importance of starting with clean raw materials and using only the most advanced manufacturing equipment, materials and processes to ensure the quality products that our demanding customers deserve and expect.

Keystone Cleanroom Products also offers a full line of validated sterile (10^{-6} SAL) disposable products that complement our wide range of sterilization wrapping products.

Availability and Further Information

Keystone Safety and Cleanroom Products' line of PureClean™ 1421B Tyvek® bags and covers are available for purchase. If you are interested in receiving samples and more information, please contact us at info@keystonecrp.com.

About Keystone Safety and Cleanroom Products

Keystone Safety and Cleanroom Products, originally founded as Keystone Adjustable Cap in 1925, revolutionized the food service industry with the introduction of the first disposable protective paper cap. Today, as we celebrate our 100 year anniversary, we are known as a trusted leader in disposable protective apparel, offering the most comprehensive range of product solutions, across multiple industries.

In 2018, we launched our Cleanroom Products division to provide customers with everything related to pharmaceutical sterilization packaging and innovative, pre-sterilized disposable products for use in aseptic production. To keep your operation in compliance, we provide expert consultation and continuous support from the start of a project, all the way through validation. We design and manufacture our products in Pennsauken, NJ USA and are subject to routine GMP audits and inspections by our end user customers.

Media Contact

Jackie Ottinger

Marketing Specialist

Keystone Safety and Cleanroom Products

(856) 663-5740 ext. 551

Jackie@keystonecrp.com