STATEMENT ON STERIKING® LT BLUELINE TYVEK PRODUCTS COMPATIBILITY - ASP STERRAD® AND STERIS® V-PRO® STERILIZATION SYSTEMS

STERIKING® LT Blueline with Tyvek pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in ASP STERRAD® Sterilization Systems and STERIS® V-Pro® Sterilization Systems. STERIKING LT Blueline with Tyvek pouches are allowing sterilization of the enclosed devices and maintain the sterility of the enclosed devices for up to 3 years.

WIPAK STERIKING® LT Blueline with Tyvek® products have been validated to be compatible with ASP STERRAD® Sterilization Systems and STERIS® V-Pro® Sterilization Systems and their different cycles.

The STERIKING® LT Blueline pouches are validated for use in following STERRAD® sterilization cycles:

NX Standard

NX Advanced

100NX Duo

100NX Flex

100NX Standard

100NX Express

Please see the maximum loads and lumen diameters and lengths from IFUs.

The STERIKING® LT Blueline pouches are validated for use in following STERIS® V-Pro® sterilization cycles:

Lumen Cycle

Non Lumen Cycle

Flexible Cycle

Fast Non-Lumen Cycle

Please see the maximum loads and lumen diameters and lengths from IFUs.

Sterilant penetration studies confirm that LT Blueline with Tyvek products can be used when single or double pouching and that the sterilant can penetrate into the pouches, demonstrating that a minimum of 1.0×10^6 Geobacillus stearothermophilus spores were killed in all used cycles (6-log reduction) using a worst-case, end of shelf-life injection volume. Pouches maintained sterility of their contents following a whole package of microbial aerosol challenge after processing. Furthermore, the pouches material properties remained stable and kept their integrity when exposed to aging process after the sterilization.

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