



Instructions for Use: Steriking® LT-Blueline with Tyvek® Heat Seal Pouches

Brand Name of Product	Steriking® LT-Blueline with Tyvek®, Manufactured by Wipak
Generic Name of Product	Heat Seal Pouches
Product Code Number(s)	LTS7520 NI, LTS1025 NI, LTS1530 N
Purpose of Product	The Steriking® LT-Blueline with Tyvek® pouches are intended for use as packing material
	for items that require low temperature sterilization.
Range of Applications for Product	N/A
Key Specifications of Product	The Steriking® LT-Blueline see-through packages are constructed with Tyvek® that is heat-
	sealed together with a multiply PET/PE-plastic laminate (12/50 microns).

Shipping & Storage		
Storage Conditions for Unprocessed Pouches/Rolls	 When stored in the original packaging: No special storage conditions are required. Closed transportation packaging items are protected from moisture, heat, and direct sunlight or other sources of UV light. Once the pouches and rolls are removed from the packaging, recommended long- 	
	term storage conditions are: o Temperature of 18- to 24 °C (64.4- to 73.4 °F) o Humidity 30–70% rh. • Pouches should be stored in closed cabinets or otherwise protected from a UV-light and may change color over time if not stored properly.	
Packaging Contents	N/A	
Shelf Life of Unprocessed Pouches	 It is recommended that the products are put to their end use within three (3) years of manufacture. The recommended "Best before" date and the manufacturing date are stated on the carton label. Each pouch/roll has a lot number imprinted for traceability. This can be used to determine the manufacture date. 	

Instructions for Using Product	
Description of Use (s)	The Steriking® LT-Blueline with Tyvek® pouches are intended for use as sterile barrier
	packaging for low temperature sterilization.
Preparation for Use	 Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization. Place the type of chemical indicator inside the pouch, according to your facility guidelines. Ensure pouch contents and the indicator are away from the seal area and will not get caught in the seal. Confirm the temperature setting on the heat sealer is appropriate. Recommended sealing temperature for final closing is 120- to 130 °C (248°- to 266 °F) depending on pressure and time. Leave enough space beyond the seal for the opener to easily grasp; usually up to two (<2) inches.
Diagrams (drawings, pictures)	

Steps for Use of Product	1. Hold the pouch taut (stretched or pulled tight) in the sealer to prevent wrinkles or air bubbles from forming in the seal.
	 If using a rolling-type heat sealer, let the peel pouch move along the guide on its own. Once the pouch completes the slide down rolling side, verify the pouch is sealed and material beyond the seal from the opening is up two (<2) inches to -allow for aseptic presentation.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	 The Steriking® LT-Blueline with Tyvek® range of peel packages conform to the international product standards and norms: ISO 11607-1, ISO 11607-2, EN 868-5. The products are registered by FDA under 510(k) Premarket Submission Nos.: K973827. Wipak Oy is certified to ISO 9001; ISO 13485; OHSAS 18001 and ISO 22000.
Special Warnings and Cautions	 The Steriking® LT-Blueline with Tyvek® pouches are meant for low-temperature sterilization cycles only. Do not steam sterilize these pouches, as they will melt. Pouches should be stored in closed cabinets or otherwise protected from a UV light source. The process indicator is sensitive to UV light and may change color over time if not stored properly.
Disposal	Please refer to the local/national regulations regarding waste disposal.

	Reprocessing Instructions
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instruction	N/A
Packaging	N/A
Sterilization	Materially compatible with VH2O2/O3/EO sterilization.
Storage for Conditions for Processed	Recommended long term-storage conditions:
Pouches/Rolls	o Temperature: 18- to 24 °C (64.4- to 73.4 °F)
	○ Humidity 30–70% rh
	 Do not exceed 40 °C for storage.
	 Facilities should develop a policy identifying events that may compromise the sterility of packaged items. This could include a maximum period of time for storage.
Additional Information	• The products are for single-use only.
	 Sterilized heat seal pouches were tested to three (3) years of accelerated and real- time aging.

Related Healthmark Products	N/A
Other Product Support Documents	N/A
Reference Documents	Sterilization Packaging Brochure, Sterilization Packaging Price List
Customer Service Contact	US Distributor:
	Healthmark Industries Company, Inc.
	18600 Malyn Blvd.
	Fraser, MI 48026
	1-586-774-7600
	healthmark@hmark.com
	hmark.com