



<b>Brand Name of Product</b>	Steriking® LT-Blueline with Tyvek®, Manufactured by Wipak
<b>Generic Name of Product</b>	Heat Seal Pouches
<b>Product Code Number(s)</b>	LTS7520 NI, LTS1025 NI, LTS1530 NI, LTS2038 NI, LTS2538 NI
<b>Purpose of Product</b>	The STERIKING® LT-Blueline with Tyvek® pouches are intended for use as packing material for items that require low temperature sterilization.
<b>Range of Applications for Product</b>	N/A
<b>Key Specifications of Product</b>	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).

<b>Shipping &amp; Storage</b>	
<b>Storage Conditions for Unprocessed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>When kept in the original packaging, no special storage conditions are required. When stored in the original, closed transportation packaging items are protected from moisture, heat and direct sunlight or other sources of UV- light.</li> <li>Once the pouches and rolls are removed from the packaging, they are to be stored at a temperature of 18-24°C and humidity 30-70%.</li> <li>Pouches should be stored in closed cabinets or otherwise protected from a UV- light and may change color over time, if not stored properly.</li> </ul>
<b>Packaging Contents</b>	N/A
<b>Shelf Life of Unprocessed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>It is recommended that the pouches/rolls are used within 5 years of manufacture. The recommended “best before” date and the manufacturing date are stated on the carton label.</li> <li>Each pouch/roll has a lot number imprinted for traceability. This can be used to determine the manufacture date.</li> </ul>

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	The STERIKING® LT-Blueline with Tyvek® pouches are intended for use as sterile barrier packaging for low temperature sterilization.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization.</li> <li>Place the type of chemical indicator inside the pouch according to your facility guidelines.</li> <li>Ensure that pouch contents and the indicator are away from the seal area and will not get caught in the seal.</li> <li>Confirm that the temperature setting on the heat sealer is appropriate. Recommended sealing temperature for final closing is 120°-130°C (248°-266°F) depending on pressure and time.</li> <li>Leave enough space beyond the seal for the opener to easily grasp (usually ½ - 2 inches).</li> </ol>
<b>Diagrams (drawings, pictures)</b>	
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal.</li> <li>If using a rolling type heat sealer, let the peel pouch move along the guide on its own.</li> </ol>

	3. Once the pouch completes the slide down rolling side verify the pouch is sealed and that material beyond the seal from the opening is ½” to 2 inches to allow for aseptic presentation.
<b>Interpretation of Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• The S STERIKING® LT-Blueline with Tyvek® pouches are meant for low temperature sterilization cycles only. Do not steam sterilize these pouches, as they will melt.</li> <li>• 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.</li> </ul>
<b>Disposal</b>	Please refer to the local/national regulations regarding waste disposal.

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instruction</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>• Materially compatible with VH2O2/O3/EO sterilization.</li> </ul>
<b>Storage for Conditions for Processed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>• The recommended storage conditions are 18-24°C and humidity 30-70%.</li> <li>• Do not exceed 40°C for sterile storage.</li> <li>• Shelf life of processed pouches/rolls is event-related. 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.</li> </ul>
<b>Additional Information</b>	The products are for single use only.

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