STERIKING® LT-Blueline Self-sealable Pouches

The STERIKING® LT-Blueline Self-sealable Pouches are designed for use as packaging material for medical devices in low-temperature (hydrogen peroxide, EO and FO gases) sterilization in health care establishments.

Conformity to International Standards

The STERIKING® LT-Blueline range of peel packages conform to the international product standards and norms: ISO 11607-1:2006, ISO 11607-2:2006/ Amd 1:2014, EN 868-5:2009.

The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive 93/42/EEC and its amendment 2007/47/EC. To show compliance with MDD the CE mark is printed on the label of the transport carton.

The products are registered by FDA under 510(k) Premarket Submission No.: K973827.

Wipak Oy is certified to ISO 9001:2008; ISO 13485:2003; ISO 14001:2004; OHSAS 18001: 2007 and ISO 22000:2005.

STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes

Technical Data & Performance Characteristics

The STERIKING® LT-Blueline packages are constructed of uncoated HDPE non-woven, named Tyvek®, (grade 1073 B) which is heat sealed together with a multiply BOPET/PE plastic laminate (12/50 microns).
Pouches are intended for closing tightly with adhesive strip according to instructions printed.

Specific Product Features

Dimensions and Tolerances	
Width:	nominal +/- 1 mm
Length:	nominal +/-3 mm
Heat Seal Design	
The seal is formed to facilitate easy opening. The width and the strength of the seal are specified in order to achieve the optimum strength necessary for autoclaving and at the same time to facilitate easy opening of the pack. The seal is ribbed having 3 aligned sealed lines and the total width is minimum 6 mm.	
Heat Seal Strength	
Minimum:	1.5 N/15 mm (tail supported)
Lot Coding	
Each pouch bears a code number enabling traceability of the production history.	
The code is YYMM (year / month) e.g. 1701 = January 2017	
Converting lane numbering offers added value for production traceability.	

The HDPE non-woven (Tyvek®) complies with the requirements of the European standard EN 868-9:2009 for uncoated HDPE non-wovens. Tyvek® consists of pure HDPE fibers. It is free from dirt, toxic substances and odor. It does not release any fluff or fibers during normal use. All components of Tyvek® 1073B are listed with the FDA and have an assigned Drug Master File.

Tyvek® 1073B				
Property	**Test Method**	**Unit**	**Typical**	**Tolerances**
Grammage	ISO 536	g/m^2	74,7	71,2-78,0
Tensile strength, MD	ISO 1924-2	kN/m	8,7	>6,0
Tensile strength, CD	ISO 1924-2	kN/m	8,6	>6,0
Tear strength, MD	ISO 1974	mN	3200	>2135
Tear strength, CD	ISO 1974	mN	4000	>2313
Burst strength	ISO 2758	kPa	1237	>827
Air permeance	ISO 5636-3	µm/Pa•s	5,8	3,6-16
Gurley porosity	ASTM D 726	s/100 ml	22	8-36
Sterilization method	Gas, irradiation, plasma			

The film is transparent, non-toxic and heat sealable with Tyvek ® 1073 B. It is sterilisable by all the low temperature (below 100°C/212° F) sterilization methods and by irradiation. The materials have been permitted for use in contact with food and drugs by the German BGA and the American FDA.

Transparent film PE/PET 1250			
Property	**Method**	**Unit**	**Nominal**
Thickness		µm	62
Weight		g/m^2	65
Tear strength, MD	ISO 6383-2	mN	250
Tear strength, CD	ISO 6383-2	mN	250
Elongation at break, MD	ISO 527-3	%	60
Elongation at break, CD	ISO 527-3	%	60
Heat resistance		°C	100
Sterilization method	Gas, irradiation, plasma		

MD= machine direction, CD= cross direction Test conditions: 23ºC, 50 RH-%

Storage Recommendations & Shelf Life

It is recommended that the STERIKING® products are kept in the original, closed transport carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture.

It is recommended that the products are put to their end use within 3 years of manufacture. The recommended “Best before” date and the manufacturing date are stated on the carton label. However, depending on the requirements of the user, products older than three years may still be useable if the storage conditions have been according to the recommendations. No collapsing of performance of the product will take place either after the recommended expiry date, but if it has been exceeded it is advisable to test the product prior to use.

Restrictions in Use

The STERIKING® LT-Blueline Self-sealable pouches are not suitable for sterilization by hot, dry air, by irradiation or by steam.

Sales and Transport Packing

Pouches are bound with a plastic or paper strip into bundles of 100 pieces. These bundles are first packed into a bleached cardboard dispenser, 2 bundles each. The dispensers are then packed into an unbleached corrugated cardboard case (partially recycled and further recyclable). The case is closed with adhesive coated polypropylene tape. Cases are palletized to reusable wooden EUR size pallet and covered by plastic pallet-tightening bands (PET). Partially recycled and further recyclable cardboard-sheet is placed on the bottom of the pallet.

Please refer to the local/national regulations regarding waste disposal.

Labelling: Each case bears a label with the necessary information/instructions for the contents of the case in accordance with ISO 11607-1:2006/ Amd 1:2014 and EN 868-5:2009.

In Case of Complaint

In event of any complaint, the lot number and identification code must be provided by the complainant. For evaluation of claimed product, a defective sample (or a digital photo) and description of the defect together with an unused specimen must be made available to Wipak.

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Steriking® LTSS Self Seal Pouches

Code	Size (mm)	Sales Packing (Pouches/Case)
LTSS1 NI	90 x 200	1 000
LTSS2 NI	90 x 250	1 000
LTSS4 NI	130 x 270	1 000
LTSS4A NI	130 x 380	1 000
LTSS5A NI	190 x 330	1 000
LTSS6 NI	250 x 400	600
LTSS7 NI	300 x 450	600