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STERIKING® LT-Blueline Pouches and Reels

STERIKING® LT-Blueline Heat Sealable Pouches and Reels have been designed for use as packaging material for medical devices for low-temperature (hydrogen peroxide, EO and FO gases) and irradiation sterilization in health care establishments. The packages are printed with a process indicator for vaporized hydrogen peroxide sterilization processes.

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, 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 label of the transport carton.

The products are registered by FDA under 510(k) Premarket Submission Nos. 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). Raw materials are FDA approved.
Recommended sealing temperature for final closing is 120-130°C (248-266°F) depending on pressure and time.

Specific Product Features

Dimensions and Tolerances

Width (pouches):	nominal +/- 1 mm
Width (reels):	nominal +/- 2 mm
Length (pouches):	nominal +/-3 mm
Length (reels):	nominal +500, -0 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

Pouches and reels:	minimum 1.5 N/15 mm (tail supported)

Splices/ Joints

Pouches:	none
Reels:	max. 1 per reel

Lot Coding

Each pouch and reel bears a code number enabling traceability of the production history.
The code is YYMM (year / month). Converting lane numbering offers added value for production traceability.

Chemical Indicator

conforms to ISO 11140-1:2005 class 1: Process indicators.
Hydrogen vaporized hydrogen peroxide indicator changes from yellow/orange/shade of beige to a shade of blue.

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	74,6	71,2-78,0
Tensile strength, MD	ISO 1924-2	kN/m	7,6	>6,0
Tensile strength, CD	ISO 1924-2	kN/m	8,2	>6,0
Tear strength, MD	ISO 1974	mN	3425	>2135
Tear strength, CD	ISO 1974	mN	3514	>2313
Burst strength	ISO 2758	kPa	1227	>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 sterilizable 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 5 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 five 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 packages are not suitable for sterilization by hot, dry air or by steam

Sales and Transport Packing

Pouches are bound with a plastic or paper strip into bundles: flat pouches à 100. 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).

Each reel of 100 m is wrapped in polyethylene (LDPE) dust covers and then packed into an unbleached corrugated cardboard case.

The cases are 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.

Labeling: Each case bears a label with the necessary information/instructions for the contents of the case in accordance with ISO 11607-1:2006 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.

STERIKING® is a registered trademark of Wipak Oy.

Tyvek® is a registered trademark of DuPont.

Steriking® LTS Tyvek® Flat Pouches

Art. Code	Size	Sales Packing (Pouches/Case)	New units (Pouches/Case)
LTS7520	75 x 200	1 200	1 000
LTS1025	100 x 250	1 200	1 000
LTS1530	150 x 300	1 200	1 000
LTS1644	160 x 440	1 200	600
LTS1660	160 x 600	600	600
LTS2038	205 x 380	1 200	1 200
LTS2538	250 x 380	1 200	600
LTS2550	250 x 500	600	600

Steriking® LTR Tyvek® Flat Rolls

Art. Code	Size	Sales Packing (Rolls/Case)
LTR40	75 x 100	1
LTR41	100 x 100	1
LTR42	150 x 100	1
LTR43	200 x 100	1
LTR43A	225 x 100	1
LTR44	250 x 100	1
LTR45	300 x 100	1
LTR46	350 x 100	1
LTR47	400 x 100	1
LTR49	500 x 100	1