

# Product Specification

Form Ref. 69190SMX1 Rev.: A3

Date: 1 June 2016



# STERIKING® ProWrap SMX-1 Blue Light

Our STERIKING® ProWrap SMX product range offers high performance wrapping sheets. State-of-the-art technology has resulted in a unique Multilayer SMX concept combining three spun-bonded (S) and two melt-blown (M) layers of polypropylene (PP) into a SSMMS construction providing superior toughness and a reliable barrier filter against contamination. The binding texture of the PP layers provides excellent surface strength which effectively eliminates any risk of linting.

STERIKING® ProWrap Blue Light has been developed for use as a wrap for sterile packs of surgical dressings and instruments intended for sterilization by steam, EO and FO gas or gas plasma. It is perfect choice for a container inner wraps or for small or medium size trays. It is also ideal to be used in combination with traditional crepe papers or nonwovens. ProWraps are for single use only.

### **Conformity to International Standards**

STERIKING® ProWraps conform to the international product standards and norms: ISO 11607-1:2006/Amd 1:2014 and EN 868-2:2009.

The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive 2007/47/EC. To show

compliance with MDD 2007/47/EC the CE mark is printed on the label of the transport carton.

STERIKING® sterilization packing materials are designed, validated and manufactured to suit their intended purposes. They are manufactured under ISO 9001 certification.

#### **Technical Data**

Properties	Units	Standards or Methods	Typical Value
Basis weight	g/m²	ISO 536	37
Grab tensile MD	N	ASTM D 5034-09	106
Grab tensile CD	N	ASTM D 5034-09	79
Grab elongation MD	%	ASTM D 5034-09	65
Grab elongation CD	%	ASTM D 5034-09	75
Trap tear MD	N	ASTM D 5587-15	44
Trap tear CD	N	ASTM D 5587-15	37
Hydrostatic head	mm H₂O	AATCC 127-2008	496
Air permeability	m³/m²/s	ASTM D 737-04	0,57

### Storage Recommendation & Shelf Life

No special precautions need to be taken in respect of storage or transportation of STERIKING® ProWraps. However, they should not be exposed to very high humidity or to direct sunlight.

The shelf life is event-related and not time-related. If stored according to the instructions the shelf life of STERIKING® ProWraps is at least 5 years from the date of manufacture.

#### **Sales and Transport Packing**

STERIKING® ProWraps are packed in recyclable, hard carton cases. As an inner cover against moist and dust the sheets are wrapped in a recyclable polyethylene sheet.

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

Labelling: Each case bears a label with the necessary information/instructions for the contents in accordance with ISO 11607-1:2006 and EN 868-2:2009.





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#### **Restrictions of Use**

STERIKING® ProWraps are not suitable for sterilization by hot, dry air or irradiation.

#### In Case of Complaint

In the 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.

This specification refers to the named product group and shall be valid until the next revision. Other product related documents may be available upon request.

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