

STERIKING® Bonded Wrap Regular BW-2

STERIKING® Bonded wrap consists of STERIKING® SMX-2 blue regular and SMX-2 white regular. Combination of two colors provides easy detection of possible material defects and eases the packing process when separate outer and inner layers are interleaved together. Bonded wrap is two layers of SSMMS wrap sealed together with ultrasonic sealing process ProWrap SMX2 & SMX2 combination is suitable for steam and gas sterilization.

STERIKING® ProWraps have 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 suitable for all purposes even most demanding applications because of multi-layer structure. Bonded Wraps are for single use only.

Conformity to International Standards

STERIKING® ProWraps conform requirements set out in the Medical Devices Regulation (EU) 2017/745 (MDR) and international product standards and norms: ISO 11607-1 and EN 868-2

condition are class 1 accessories by the MDR Annex VIII, Chapter III, Rule 1.

STERIKING® sterilization packing materials are designed, validated, and manufactured to suit their intended purposes.

The Steriking® sterilization packaging materials, which are supplied by Wipak in non-sterile

Technical Data

| Properties | Units | Standards or Methods | SMX2 Typical Value | SMX2 Typical Value |
|--------------------|-----------------------------------|----------------------|--------------------|--------------------|
| Basis weight | g/m ² | ISO 536 | 47 | 47 |
| Grab tensile MD | N | ASTM D 5034-09 | 93 | 93 |
| Grab tensile CD | N | ASTM D 5034-09 | 78 | 78 |
| Grab elongation MD | % | ASTM D 5034-09 | 48 | 48 |
| Grab elongation CD | % | ASTM D 5034-09 | 69 | 69 |
| Trap tear MD | N | ASTM D 5587-15 | 44 | 44 |
| Trap tear CD | N | ASTM D 5587-15 | 36 | 36 |
| Hydrostatic head | mm H ₂ O | AATCC 127-2008 | 450 | 450 |
| Air permeability | m ³ /m ² /s | ASTM D 737-04 | 0,35 | 0,35 |

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.

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.

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 11607-1:2019 and EN 868-2:2017.

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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