

# STERISHEET STERILIZATION WRAPS

## STERISHEET BONDED RANGE



### DESCRIPTION

Sterisheet sterilization wraps are best in class Sterile Barrier Systems for CSSDs in hospitals and clinics.

Sterisheet SMS products are available as interleaved, bonded or single sheets.

**STERISHEET Bonde** by Sterisheet are designed as sealed two layers of SMS.

Double non-sequential wrapping with Sterisheet Bonded™ is performed in one single step, saves time during wrapping and unwrapping.

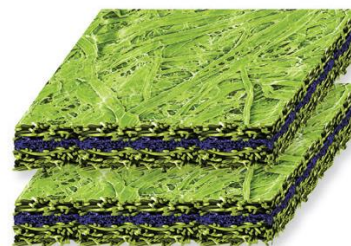
### COMPOSITION

The selected combination of two SMS thermally sealed together.

100% synthetic fibers made of polypropylene.

Combo of two different colors (green & blue) for effective and easy defects detection.

4 grades for different strength level (80 – 125 gsm).



### SUITABLE FOR STERILIZATION METHODS

- Steam
- EO
- Plasma

### APPLICATION

For small, medium-size and heavy trays depending on the grade selected.

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Recommended use of Sterisheet Bonded product according to the weight of the tray intended to be packed.

Type of product \_\_\_\_\_ Tray Weight

Sterisheet Bonded 2 . . . . 0 – 5 kg

Sterisheet Bonded 3 . . . . 6 – 9 kg

Sterisheet Bonded 4 . . . . 10 – 13 kg

Sterisheet Bonded 5 . . . . 14 – 16 kg

Recommended weights are indicative only, selection of appropriate wrapping material is subject to internal procedures and standards.

Selection criteria should be based on risk analysis for each hospital and (or) sterilization center (i.e. loading cart systems, instrument trays profile...)

The choice of packaging should take into account assembly, sterilization method, transport and storage conditions.

### SIZES AVAILABLE

Choose standard sizes to optimize your costs.

PRODUCT NAME	STANDARD SIZE			
	90x90 cm	100x100 cm	120x120 cm	137x137 cm
Sterisheet Bonded 2	✓	✓	✓	
Sterisheet Bonded 3	✓	✓	✓	
Sterisheet Bonded 4	✓	✓	✓	✓
Sterisheet Bonded 5	✓	✓	✓	✓

Other sizes are also available upon request.

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### COLORS



### PERFORMANCES

Mechanical and bacterial barrier properties are internally tested on a routine basis according to the regulatory requirements of all of our products. Combining them with random tests conducted by external and accredited laboratories leads Sterimed to secure the best performances on Sterisheet products.

#### Mechanical Properties

Preservation of pack integrity from closure until the point of use depends on the materials resistance to tearing, puncturing and breaching stresses generated all along the distribution with the hospital. Any mechanical weaknesses will increase the risks of event-related ingress of microorganisms into the pack. Excellent mechanical properties will provide you additional safety while using our materials. Optimal strength and resistance provided in every sheet.

Higher the number used in products' name (from Bonded 2 to Bonded 5) higher the total grammage of the product and stronger the wrap.

#### Bacterial Properties

Sterilization wraps must prevent microorganisms' ingress inside the package. To reach this performance, different types of testing have to be performed on the products to reproduce both kind of ingress vehicles possible:

- Airborne ingress
- Waterborne ingress

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### COMPLIANCE TO STANDARDS

Sterisheet products range is classified as a Class I Medical Device according to the European Medical Device Device Regulation (MDR 2017/745/EU). Its CE marking illustrates the relevant compliance.

Sterisheet SMS products conform to the standards below:

EN ISO 11607-1

EN 868-2

### OUR WRAPS MANUFACTURING CERTIFICATION

ISO 13485 standard

### PACKAGING PRIOR TO USE

Sheets displays is optimized by adjusted folding depending on the size and type of the product. We have carefully tested the best solution to ensure the most convenient handling for end users.

- PRIMARY TRANSPORT PACKAGING

Number of sheets is optimized and wrapped in transparent polyethylene bag with quick product ID

- SECONDARY TRANSPORT PACKAGING

Secondary packaging is a neutral brown color cardboard box providing transportation stress resistance

### LABELING

Product traceability is fully insured through labelling according regulations on each transport packaging.

### STORAGE CONDITIONS

Sterimed recommends the following storage conditions for best performance of sterilization wraps: Storage in cool, dry location away from direct exposure to natural light, strong artificial light & UV sources. Cardboard boxes should never be stored in direct contact with the floor. Storage of the products shall be done in areas that are not subject to extreme temperature changes such as in contact with heated objects, vents or cold walls.

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As per AAMI ST79 “*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*” recommendations: Before use, hold packaging materials at room temperature (20°C to 23°C) and a relative humidity ranging from 30% to 60% for a minimum of 2 hours is a good practice for optimum use performances.

### USE BY DATE

Provided the above storage conditions are met, the upper limit of the time interval during which the performance characteristics of sterilization wrap are demonstrated is 5 years of the manufacturing date.

### ENVIRONMENTAL IMPACT & WASTE MANAGEMENT

Oil derived product, renewable content 0%.

Disposal as per local regulations after use.