STERISHEET STERILIZATION WRAPS

STERISHEET 363 SMS

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.

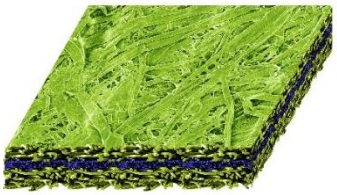
COMPOSITION

100% synthetic fibers made of polypropylene.

Spunbond / **M**eltblown / **S**punbond

Spunbond network consist of long, strong and thick polypropylene filaments.

Meltblown layers are made of short and thin polypropylene microfibers.



SUITABLE FOR STERILIZATION METHODS

- Steam
- EO
- Plasma

APPLICATION

For large and heavy instrument trays.

SIZES AVAILABLE

Choose standard sizes to optimize your costs.

Other sizes are also available upon request.

60x60 cm	100x100 cm
75x75 cm	120x120 cm
90x90 cm	137x137 cm

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COLORS

PERFORMANCES

Mechanical and bacterial barrier properties are internally tested on a routine basis according to 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 till 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 ingression of microorganism into the pack.

Excellent mechanical properties will provide you additional safety while using our materials. Optimal strength and resistance provided in every sheet.

STERISHEE 363 SMS	
PROPERTIES	TYPICAL
Basis Weight	63g/m²
Air permeability	80l/min/dm2
Thickness	410µm
Hydrost Test	50mBar
Tensile strength SM	2.5kN/m
Tensile strength ST	1.1kN/m
Elongation SM	45%
Elongation ST	45%
Burst	290kPa
Tears SM	9000mN
Tears ST	14000mN

Bacterial Properties

Sterilization wraps must prevent microorganisms' ingression inside the package.

To reach this performance, different types of testing have to be performed on the products to reproduce both kind of ingression vehicles possible:

- Airborne ingression
- Waterborne ingression

For instance, according to the TNO final pack test method, validating the materials & the folding technique, STERISHEET 363 SMS exhibits a BARRIER PROTECTION > 99,99%

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COMPLIANCE TO STANDARDS

Sterisheet products range is classified as a Class I Medical Device according to the European Medical Device Directive (MDD). Its CE marking illustrates the relevant compliance.

Sterisheet products conform with the standards below:

EN ISO 11607-1:2017

EN 868-2:2017

OUR WRAPS MANUFACTURING CERTIFICATION

ISO 13485 standards

PACKAGING PRIOR TO USE

Sheets presentation 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 product ID.

- SECONDARY TRANSPORT PACKAGING

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

LABELLING

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 a 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. As per AAMI ST79 "*Comprehensive guide to steam sterilization and sterility assurance in health care facilities"* recommendations in chapters 8.3 Package configurations and preparation subchapter 8.3.1 General considerations: "Before use, packaging materials should be held at room temperature (20°C to 23°C) and at a relative humidity ranging from 30% to 60% for a minimum of 2 hours shall be followed as a good practice for optimum use performances.

EXPIRY DATE

Provided the above storage conditions are met, the upper limit of the time interval during which the performance characteristics of the sterile barrier system 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.