PRODUCT DATA SHEET

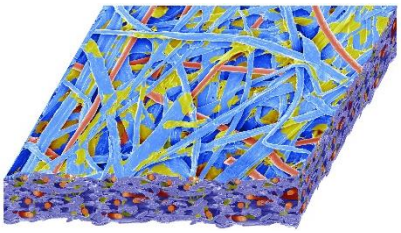
STERISHEET STERILIZATION WRAPS

STERISHEET 366 NW

DESCRIPTION

Sterisheet sterilization wraps are high quality Sterile Barrier Systems for CSSDs in hospitals and clinics. Our production is 100% healthcare dedicated.

STERISHEET NW (Non Woven) offers superb combination of fluid repellency, drapeability, softness and strength.



COMPOSITION

Belongs to family of wet laid nonwoven made of cellulose, reinforced with up to 30% synthetic fibers and 20% synthetic binders.

SUITABLE FOR THE FOLLOWING STERILIZATION METHODS

- Steam
- EO
- Low temperature
- Steam Formaldehyde (LTFS)

APPLICATION

For larger trays and heavy-duty packs, orthopedics sets.

Inner wrap for reusable containers.

SIZES AVAILABLE

The following are standard sizes available for all our customer's needs. Choose standard sizes to optimize your costs. Other sizes are also available upon request.

60x60 cm 75x75 cm 90x90 cm

100x100 cm 120x120 cm

RECOMMENDATIONS:

- ✓ Be sure to use 2 layers of sterilization wraps
- ✓ Our interleaved solutions save your time while wrapping and storage space in your CSD
- ✓ In case of excessive humidity, the use of Non Woven materials should be considered vs 100 % Polypropylene materials.

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COLORS

PRODUCT PROPERTIES

Mechanical protection and bacterial barrier properties are tested carefully. Our internal laboratory provides standardized tests on all of our products. Together with tests conducted by external independent laboratories we secure the best possible results on Sterisheet products.

Why STERISHEET Non Woven?

- ✓ Higher fluid repellence, drapeability
- ✓ Softness for daily work
- ✓ Strength and tear resistance improved by using synthetic fibres and binders

Mechanical Properties

Preservation of pack integrity from closure till the point of use depends on the materials resistance to tearing, puncturing, breaching stresses generated all along the distribution, handling and storage 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.

PROPERTIES	TYPICAL
Substance	66 g/m²
Thicknes (Bulky material)	240 µm
Tensile strength MD	2.10 kN/m
Tensile strength CD	1.30 kN/m
Burst Strength	150 kPa
Tearing strength MD	900 mN
Tearing strength CD	1000 mN

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

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COMPLIANCE TO STANDARDS

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

EN ISO 11607-1

EN 868-2

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 tested carefully the best solution to ensure the most convenient handling for end users.

- PRIMARY TRANSPORT PACKAGING

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

- SECONDARY TRANSPORT PACKAGING

Secondary packaging is a neutral brown color cardboard box with 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, before use, holding packaging materials at room temperature (20°C to 23°C) and at 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 the sterilization wrap are demonstrated is 5 years of the manufacturing date.

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ENVIRONMENTAL IMPACT & WASTE MANAGEMENT

STERIMED Infection Control is committed to the protection of the environment and the communities it belongs to.

STERISHEET 366 NW – renewable content and low bulkiness ratio are the features that contributes to positive environmental scoring.

Disposal as per on local regulations after use.