STERISHEET®
by STERIMED

TENDERBOOK

STERISHEET® is a brand of

STERIMED
INFECTION CONTROL

FOREWORD

The Sterisheet® range brings to you safe and convenient solutions for wrapping and storage in your CSSD.

- Sterile Barrier Systems for **steam for EO sterilization**
- **US-FDA cleared** through Premarket Notification (Section 510(k) of the Food, Drug and Cosmetic Act)
- Tested for **event-related sterility maintenance, bioburden, bacterial filtration efficiency and non-cytotoxicity**
- Conforming to **ISO 11607-1:2020 and EN868-2:2017**
- With a selection of materials and grades adapted to match the type and weight of devices to pack.

When choosing Sterisheet®, you benefit from:

> **One single stringent quality standard** for all sheets which are manufactured:
- from the production of industrial reels down to sheeting of final Class II medical device
- controlled through certified quality systems

> **Traceability systems and Risk management department** to ensure the safety of users and patients long after goods have left our warehouses
- ability to run full analysis thanks to complete control on production
- ability to recall goods with an efficient traceability system for all materials shipped around the world and all certifications circulated to end users

Beyond standard wrapping materials, you can also get with Sterisheet®:

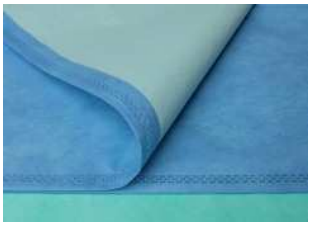
STERISHEET TRAY LINER

Prevention of wet pack and protection of instruments with Sterisheet® Tray Liner.

STERISHEET PAPER BAGS

Ready to use solution for single use and reusable devices.



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1 GENERAL INFORMATION

1.1 MANUFACTURER

The Sterisheet® Brand is manufactured by:

STERIMED Inc.
1301 Charleston Regional
Parkway – Suite 500
Charleston, SC 29492
United States of America

1.2 INTENDED USE OF THE PRODUCTS

Sterisheet® range of sterilization wrapping materials has been designed for use as a sterile barrier system:

- **allows the process of sterilization (safe and efficient for all standard sterilization cycles and protocols)**
- **maintain sterility of the wrapped medical device after sterilization (event-related sterility maintenance)**
- **protects the health of nurses and patients (controlled for bio-compatibility)**
- **limits the risk of contamination in hospital environment (controlled for bioburden)**
- **ensures traceability of products and consistency of delivered material**

Sterisheet® sterilization wraps are designed and tested for use with steam & ethylene oxide processes.

Indication for use: **Sterisheet® sterilization wraps provide protection for medical devices against biological and chemical contamination during the period from sterilization until the moment the package is open.**

1.3 GENERAL CHARACTERISTICS OF THE PRODUCTS

Sterisheet® products are a complete range of sterilization wraps for use in sterilization centers and other patients care facilities, where a sterilization and packaging takes places.

Main characteristics are:

- cellulose, reinforced and non-woven materials for optimal choice in regard with sterilization type to use, target weight to pack and mechanical performance to achieve
- different grammages available to organize & optimize your process
- non-woven products treated to address the need for alcohol repellency when used as sterile fields

1.4 AVAILABLE WRAP SIZES

Main standard sizes (in inches) of the Sterisheet® range are as follow:

15 x 15	30 x 30
20 x 20	36 x 36
24 x 24	40 x 40

Standard sizes always depend on a grade and grammage.

Other sizes not listed in the previous table are considered to be non-standard and may also be available pending on grade of material. The minimum available size is 12 x 12 inches & the maximum available size is 54 x 72 inches

Contact your Sterimed representative to check availability of the sizes of your choice.

STERISHEET® - CELLULOSE BASED PRODUCTS

Pack Weight	Product Designation	Color	Code	Product description	Grammage (g/m^2)	Sterilization processes
LOW WEIGHT	STERISHEET 160 CREPE		0065	100% Cellulose material	60	Steam & EO
MEDIUM WEIGHT	STERISHEET 260 REINFORCED		0099	80% Cellulose Material reinforced with synthetic binders	60	
HEAVY WEIGHT	STERISHEET 360 NW		0681	Combination of cellulose for the highest possible bacterial barrier performance, and synthetic fibers for mechanical strength	60	
	STERISHEET 378 NW		0129		78	

The above materials/colors are standard offers to market.

Bespoke materials (Green color) may also be offered to create color-coded interleaved solutions for better usability all the way from CSSD to Operating Rooms:

- optimal barrier performance
- visual integrity inspection of pack

2 CONFORMITY WITH RIGHT TO OPERATE & SALE

2.1 US FDA REGISTRATION & PRODUCTS CLEARANCE

ESTABLISHMENT REGISTRATION:

- **Sterimed Inc.**
  - Registration Number: **1053306**
  - FEI Number: **1053306**
  - Status: **Active**
  - Date of Registration Status: **2021**
  - Establishment operations: **Manufacturer**

OWNER:

- **Sterimed Inc.**
  - Operator Number: **9005559**

DEVICES LISTING:

- **Sterisheet®**
  - Classification name: **WRAP, STERILIZATION**
  - Product code: **FRG**
  - Device class: **2**
  - Regulation number: **880.6850**
  - Medical specialty: **General Hospital**
  - Premarket submission number: **K931202**

2.2 CONFORMITY TO ISO11607-1:2019 & EN868-2:2017 STANDARDS

In order to meet the requirements of ISO 11607-1:2019 General requirements and test methods for packaging materials and systems for medical devices which are to be sterilized), Sterisheet® sterilization wraps are:

- manufactured, stored, packaged, and supplied under suitable conditions for their use. The measures taken at STERIMED manufacturing sites notably enables it to achieve a bioburden level of less than 100 cfu/100cm² (measured using a protocol complying with standard EN ISO 11737-1:2018)
- produced from meticulously-selected non-recycled raw materials with tested non-toxicity
- compatible with most sterilization processes
- offering an excellent bacterial barrier that is regularly tested in compliance with standard DIN 58953-6 (under humidity/air-permeance) as well as by BFE – Bacterial Filtration Efficiency – tests. This enables pack sterility to be maintained for up to 180 days
- not to show any toxicity and are regularly checked in accordance with the requirements of standard EN ISO 10993-1:2010 and series

Standard EN 868-2:2017 defines requirements and test methods for different categories of sterilization packaging materials, such as:

- Crepe paper (including reinforced crepe)
- Nonwoven

Compliance with EN 868-2:2017 can be used to demonstrate compliance with one or more of the requirements of ISO 11607-1:2020.

Conformity to EN ISO 11607-1:2020 chart and Sterisheet® status

Key properties to be evaluated	Requirements	Compliance demonstrating Tools – Standards & appropriate Test methods	Sterisheet® Status
Microbial barrier	Porous material shall provide an adequate barrier	Tests listed in EN 868-2:2017 Bacterial Filtration Efficiency (ASTM F2101) Germ Proofness (DIN 58953-6 § 3 & § 4)	✓ ✓ ✓
Biocompatibility & toxicological attributes	Sensitization / Irritation / Cyto-toxicity Bio-burden control Chemical properties	ISO 10993 EN 11737-1:2018 EN 868-2:2017	✓ ✓ ✓
Physical & chemical properties	Physical & chemical properties follow-up	Tests listed in EN 868-2:2017	✓
Compatibility with respect to packaging processes	Folding / Drape ability	EN 868-2:2017	✓
Compatibility with respect to intended sterilization	Stability for use in sterilization processes and cycle parameters	EN 858-2:2017 after sterilization	✓
Acceptable useful life	Any shelf-life limitations for pre-sterilization and post sterilization storage	EN 868-2:2017 Bacterial Filtration Efficiency (ASTM F2101) Germ Proofness (DIN 58953-6 § 3 & § 4) on 5 years aged paper*, before and after sterilization.	✓ ✓ ✓ ✓

* STERIMED guarantees a 5 years useful life on the STERISHEET® products and related interleaved solutions.

2.3 CONFORMITY TO QUALITY MANAGEMENT SYSTEM

STERIMED Inc. is:

- operated under audited 21 CFR 820 compliant quality system,
- sourcing its raw materials from its mother company, producing in compliance with ISO13485:2016 "Medical devices - Quality management systems - Requirements for regulatory purposes"

Quality is our prime concern as we strive to produce the finest papers to give our users confidence in the sterility of their applications and the reliability of the wrapping material they choose.

- The processes we use ensure **perfect control** over the air permeance properties of our papers, enabling you to benefit from outstanding post sterilization bacterial barriers. Our products are regularly tested by an independent laboratory for their bacterial barrier properties and consistently achieve **outstanding levels of microbial barrier for the safest product**.
- STERIMED performs regular risk analysis of its range of hospital papers in line with the standard EN ISO 14971, testing for the requirements of EN ISO 11607-1: 2020: maintenance of the sterility, sterilization suitability, cytotoxicity, etc.
- Each batch of paper is tested for all the key properties in our laboratory prior to leaving the mill. Some tests are even carried out on line during the production process itself.
- Our state-of-the-art fault detection sensors ensure that a **very strict quality and cleanliness** control is carried out on all our material.
- Full traceability and daily use of our products in **more than 70 countries** around the world contribute to ensuring the optimal safety of hospitals and patients.

3 WHY CHOOSING STERISHEET®

Far from simply complying with ISO 11607-1:2019 and EN 868-2:2017, Sterisheet® wraps have exceptional properties offering to hospital sterilization centers the highest level of safety throughout their use.

3.1 VALIDATION OF PACKAGING – STERISHEET® EVENT-RELATED STERILITY MAINTENANCE WARRANTY

ISO 11607-1:207 standard requires the validation of the packaging design. When packaging is performed following the recommended way (double sequential envelope folding), STERIMED guarantees the packaging design with the following tests:

Integrity of the SBS / Maintenance of sterility integrity over time:

Event-Related Sterility Maintenance Study (third party laboratories).

This test is performed on double-layer packaging after sterilization and simulates shelf storage – inside a room whose humidity and temperature are regularly recorded – along with weekly handling of the packaged packs. The packs are inspected after a period of 180 days and the results are given as the percentage of uncontaminated packs at the end of the 180 days period. Thanks to initial low Bioburden of the material and excellent Bacterial Filtration Efficiency of the Sterisheet® range, it gives the warranty to keep the medical device sterile until the point of use up to **180 days of storage**.

- **100% of tested packs (cellulose, reinforced, and non-woven interleaved grades) have passed the event-related sterility maintenance test at 180 days shelf life.**

Bioburden

Average measure performed following standard EN ISO 11737-1:2018 on finished products give excellent results far below the limit accepted in the literature: 100 cfu/100 cm^2.

All products, from pure cellulose to non-woven show less than 100 cfu/100 cm^2.

Bacterial Filtration Efficiency (ASTM F2101)

The resistance to bacterial penetration of the Sterisheet® range is validated regularly by external laboratories in order to guarantee its effectiveness. One of the most important tests is the **Bacterial Filtration Efficiency (BFE)**. This test is performed on a double-layer of the material after steam sterilization. It simulates exposure to airborne bacteria and the result is given as an efficiency percentage: percentage of micro-organisms stopped by the sample.

- **99.9% BFE in double-layer for cellulose-based materials in double layer**
- **from 96% up to 99% BFE in double-layer for non-woven materials.**

3.2 BEYOND THE STANDARDS – STERISHEET® DRAPABILITY, RESISTIVITY AND ALCOHOL REPELLENCY

Complementary to base requirements of EN868-2:2017 standard, Sterisheet® wraps bring additional safety and services to your CSSD.

Drapeability

The drapeability is tested and reaches the technical requirement following standard EN 868-2:1999.
Drapeability contributes to ease and secure procedures at the following stages:

1. **during packaging:** easier process
2. **upon the opening of the pack:** low memory of the wraps, means lesser risk of wrapping material returning to its folded state and contaminating the sterile tray in the process
3. **during use as a sterile field:** better fit to table shape

Sterisheet® has maintained its technical requirement as per the previous standard.

Alcohol Repellency

Sterile fields are addressed through EN13795.
Decision has been taken to remove reference to Sterile field within EN868-2:2017.

It should nevertheless be noted that

- EN13795 standard does not address the topic of Alcohol Repellency
- Previous version of EN868-2:1999 (§4.4.1.9) was detailing that if the sterile field presents some likelihood of being used in a contract with low surface tension liquids (such as the ones exhibited by disinfectants), alcohol repellency had to be featured in the device

As a result, Sterisheet® has decided to maintain a choice of wrapping materials demonstrating alcohol-repellency in a specific part of its product range.

3.3 STERISHEET® BIOCOMPATIBILITY & TOXICOLOGICAL WARRANTY

- Steristeet® has been classified as grade I for the Maximization Sensitization Test (Magnusson and Kingman test) according to EN ISO 10993-10
- Steristeet® has been evaluated as negligible by the primary skin irritation test & the primary irritation index characterization for the extracted text according to EN ISO 10993-10
- Steristeet® meets the USP 27 (United States Pharmacopeia) requirements for non-toxicity when tested according to the iso 10993-5 method for MEM Elution Cytotoxicity

Steristeet® range heavy metal content is far below the acceptable maximum as defined in Directive 94/62/EC.

3.4 STERISHEET® COMPATIBILITY WITH STERILIZATION PROCESSES

The two main sterilization methods used in hospitals are:

- Steam sterilization
- Ethylene oxide sterilization (EO)

These two sterilization methods are described by standard EN ISO 17665-1:2006 for steam and ISO 11135:2014 for EO.

Wraps must:

- allow the sterilizing agent (gas or steam) to penetrate the pack
- retain their mechanical properties and ability to act as a bacterial barrier after sterilization
- and, in the particular case of ethylene oxide sterilization, sterilization wraps must retain a low residual level of ethylene oxide and its derivatives, in compliance with current regulations

Various tests are regularly performed to demonstrate and guarantee the Sterisheet® range's sterilization compatibility.

STEAM STERILIZATION:

100 % steam penetration as a percentage of activated sterilization indicators according to EN ISO 17665:2006
Tested cycles: 134°C (18') – 121°C (20')
Mechanical & barrier properties maintenance

EO STERILIZATION:

100 % EO penetration as a percentage of activated sterilization indicators according to ISO 11135
Tested cycle: 54°C (90') – 600 mg/l EO
PVC & latex EO residues @ 24H OK vs. ISO 10993-7
Mechanical & barrier properties maintenance

WARNING:

Sterisheet® wraps are cellulose based: do not process them with hydrogen peroxide sterilizations as stated in AAMI TIR17: 2017 Technical Information Report for compatibility of materials subject to sterilization

3.5 STERISHEET® RAW MATERIAL SELECTION

We pay particular attention that our raw material does not contain products considered as toxic or dangerous for human health. All of our raw materials are checked to be suitable for food contact and healthcare.
We refer to different regulatory texts, like the Prop.65 of California State, the REACH regulation, and EU packaging wastes directive.
In addition, there is no natural rubber latex contained in any of the Sterisheet® wrapping materials.

3.6 STERISHEET® SUSTAINABILITY & CONFORMITY TO THE PACKAGING AND PACKAGING WASTE DIRECTIVE 94/62/EC

In Process

- Pending on grade of material, pulp used in composition all come from well-managed forests and/or from controlled sources that comply with the following requirements

  1. Evidence of continuing growth of forests areas
  2. Protection of bio-diversity
  3. Evidence of legal lodging
  4. Protection of Human Being Rights
  5. Evidence of no GMO use

  Most of the pulps used are coming from certified forestry management like FSC (Forest Stewardship Council: http: www.fsc.org) or PEFC (Program for the Endorsement of Forest Certification schemes: http://www.pefc.org) program.

- All pulps are 100% produced using Elementary Chlorine Free bleaching process. The pulps are whitened without the use of elementary chlorine, a source of environmentally harmful effluent.
- Energy use is optimized by focusing on re-use of energy primarily generated during paper production and other process improvement actions to minimize the use of energy in manufacturing and converting.
- Waste impact on the environment is limited thanks to re-use of raw material whenever possible and positive energy ratio of cellulose when incinerated.
- Transport impact is minimized thanks to the use of rail and sea-route for most of our destinations and incoming goods.
- Sterisheet® range meets the requirements of European Packaging and Packaging Waste Directive 94/62/EC (low heavy metal content...).

For Product end life

- The Sterisheet® range is suitable for incineration after use. The sterilization wraps are considered as product recoverable in the form of energy recovery as defined in EN13431:2004
- Pure cellulose products can be recycled by the board packaging industry.

STERIMED, YOUR INFECTION CONTROL PARTNER

- Largest range of sterilization packaging substrates in the world
- Sales in more than 70 countries
- Packaging education programs for the medical device industry and hospital staff

COMPLIANCE

Our products are compliant with strict regulations and standards, ensuring maximum protection for patients and hospital staff.

Our products conform with:
- ISO11607-1:2019
- EN868-2:2017

We follow:
- Risk management
- Quality control
- ISO 13485 standards
- ISO 50001

Patient Safety Forum

PROPYPEL&STERISHEET by STERIMED

PATIENT SAFETY FORUM EDUCATIONAL SEMINAR

We help hospital and sterilization center professionals to share knowledge and gain a better understanding of materials used to sterilize medical instruments in CSSDs.

www.patient-safety-forum.com

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- Frequently asked questions

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