DATA SHEET STERIL SHEET BLUE NON-WOVEN FABRIC FOR STERILIZATION	Mod. ST41 EN Rev. 10 July 2023

MANUFACTURER IDENTIFICATION

E.C.S. S.R.L
Via Como 71
23883 Brivio (LC)
Italy
Tel. 0341.681602
info@ecssrl.com – www.ecssrl.com

PRODUCT IDENTIFICATION

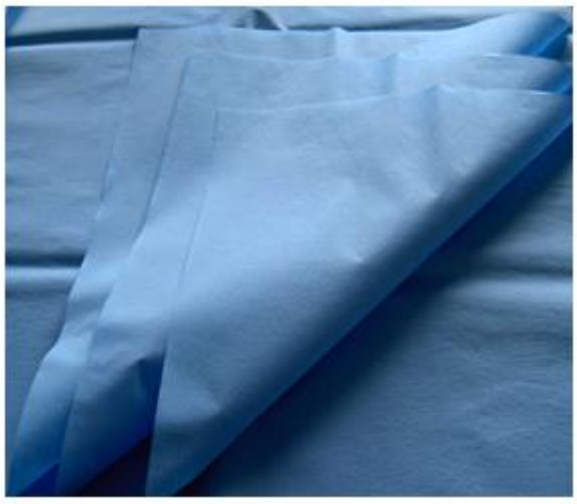
Class, Definition:

Non-invasive devices, class I, rule number 1 - ANNEX VIII - of Regulation (EU) 2017/745.

"All non-invasive devices are classified as Class I, unless one of the following rules applies."

«none of the rules following rule n°1 are applicable».

PRODUCT IMAGE



PRODUCT DESCRIPTION

The non-woven fabric STERIL SHEET BLUE is used for packaging the packages to be sterilized and has been approved for medical use.

This fabric is made from synthetic fibers and wood pulp which give the product a good flexibility, drapability and liquid repellency.

Furthermore, in compliance with Regulation (EU) 2017/745, the company ECS Srl declares that:

1. the family of the "BLUE SMS" medical device does not incorporate, as an integral part, a substance or a derivative of human blood referred to in point 7.4 of Annex I of the aforementioned regulation;
2. no tissues of animal origin have been used in the production referred to in the directive 2003/32/EC.

Brivio, July 2023

The direction

TECHNICAL DATA

PROPERTY'	UNIT OF MEASURE	METHOD	RESULT
Grammage	g/m2	BS ISO 536	57
Air permeability		EN 868-2 app.F	18/l/mn/100cmq
Breaking load long. dry	KN/m	EN ISO 1924-2	2.1
Breaking load trans. dry	KN/m	EN ISO 1924-2	0.9
Breaking load long. wet	KN/m	EN ISO 3781	1.7
Breaking load trans. wet	KN/m	EN ISO 3781	0.7
Tensile failure MD	%	EN ISO 1924-2	11
CD tensile failure	%	EN ISO 1924-2	10
Tear resistance MD	mN	ISO 1974	1050
Tear resistance CD	mN	ISO 1974	1550
Dry burst strength	kPa	ISO 2758	210
Wet burst strength	KPa	ISO 3689	180
Drape CUISICK TEST	%	ISO 9073-9	75
High porosity	l /mn/100 cm2	ASTM D 737-074	18
MASON JAR	MIN	EDANA 170-1-02	110
Alcohol repellency		IST 80-8	8
Crepe paper thickness	Um	ISO 12625-3	215
Fluorescence	%	DIN 58953-6	Nil
PH extracted water		ISO 6588-2	7
Sulphate content	%	ISO 9198	0.010
Chlorine content	%	ISO 9197	0.015
Surface resistivity	Ohm	BS 6524	7.7X10 and 11
Flammability		CFR16 part 1610	>3.5 seconds

* values may vary slightly in different production batches.

TECHNICAL FEATURES

Non-woven fabric for the preparation of packages to be sterilized with Steam, Ethylene Oxide and Gamma Rays.

It has a grammage (weight in grams of a square meter of paper) capable of constituting an effective barrier for microorganisms.

HEALTH & SAFETY

If the STERIL SHEET BLUE packages are used correctly (take only the sheets you need and close the package; operate in a low-contamination environment; etc.) for the packaging of material intended for sterilization, there are no special precautions to take both in handling them than in using them.
These packs do not contain any agents or materials currently known to be toxic or irritating.
In the light of the materials chosen, it can now be declared that the products are free of phthalates and the presence of carcinogenic, mutagenic or toxic substances for reproduction

NDT CLASSIFICATION – DIRECTORY NUMBER

Commercial name	**NDT classification**	**Repertory No**	**Manufacturer**
STERIL SHEET BLUE	S0199 – Non-woven fabric for sterilization	104732/R	E.C.S. S.R.L.

PACKAGING

CODE	**DIMENSION**	**PIECES PER PACK**
TNT40	40X40	500
TNT50	50X50	500
TNT60	60X60	500
TNT75	75X75	250
TNT90	90X90	250
TNT100	100X100	250
TNT120	120X120	100

On each box, in addition to the product name, information is given such as: manufacturer's name, product code, lot number, production date, expiration date, n. of sheets per package, size in cm of the sheets and the reference standards.
Primary packaging : the sheets are wrapped in transparent film in order to guarantee protection from dust even after the secondary packaging has been opened.
Secondary packaging : cardboard boxes.

LABELS

A label is applied to each carton, produced in compliance with the indications of the UNI EN UNI CEI EN ISO 15223-1:2021 and UNI CEI EN 1041:2013 standards, where all the information are reported as per the ISO 11607 series standards and the EN 868 series.

LIMITATION IN USE

The non-woven sheets cannot be used for hot air sterilization with temperatures above 140°C.

PRODUCT SHELF LIFE AND STORAGE CONDITIONS

The product has a shelf life of five years from the production date
Avoid direct exposure to the sun or sources of heat and humidity and store in environments with low contamination.
Place the packages where possible not in direct contact with the floor and walls (the material is sensitive to temperature and humidity)
Use in the order of arrival and handle with care.
Do not use if damaged.

DISPOSAL

Non-woven sheets are considered as normal municipal waste when in small quantities, and special waste in the case of large quantities.

REGULATORY COMPLIANCE

The non-woven sheets for sterilization are produced in compliance with the regulations:

- Regulation (EU) 2017/745;
- UNI CEI EN ISO 14971: 2020 «Application of the management of the risks to the medical devices»;
- Official Italian Pharmacopoeia, current edition;
- European Pharmacopoeia, current edition;
- Standards of the ISO 11607 and EN 868 series

MARKING PROCESS

On the basis of the indications given in article 52, paragraph 7, the manufacturer has prepared all the documentation referred to in annexes II and III of Regulation (EU) no. 2017/745

CE Declaration of Conformity

The undersigned Ivano Redaelli

As PRRC of the company E.C.S. S.r.l.

based in Headquarters: Via Como, 71 – 23883 – Brivio (LC)

VAT number: 02207200136 SRN: IT-MF-000036233

declares

that the product: BLUE STERIL SHEET - NON-WOVEN FABRIC FOR STERILIZATION

Model and code:
TNTXX
TNTXXX
TNTXX/XX

Class: I disposable

GMDN: 13735

Basic UDI-DI:

Product family	Basic UDI-DI
STERIL SHEET BLUE NON-WOVEN FABRIC	803298667F022042

It was built in compliance with the following directives and standards:

- Regulation (EU) n.745/2017 Regulation on medical devices
- Standard IEC 61882:2016 Risk analysis method according to the HAZOP method
- Standard CEI EN 61511-1 used for the residual risk calculation method LOPA
- UNI CEI EN ISO 15223-1:2021 Title: Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements
- UNI CEI EN 1041:2013 Information supplied by the Manufacturer with medical devices
- UNI CEI EN 14971:2020 Application of risk management to medical devices
- Standards of the ISO 11607 and EN 868 series;

E.C.S. S.r.l., manufacturer of these products, is certified in accordance with the UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 standards.

And it is therefore compliant with current directives and regulations.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Location: Brivio – via Como 71; 23883 (LC)

Signature:

Date: 21/07/2023

Rev. 1

E.C.S. S.R.L.