DISPOSABLE STERILE SURGICAL DRAPES IN Spunlace Softesse® – DuPont ™ Medical Fabrics

Sterile surgical drape disposable for operating theatre, manufactured in Non Woven Spunlace Softesse® – DuPont ™ Medical Fabrics. This material creates a total bacteriological barrier in both wet and dry conditions.

- Weight: 67 gsm

Drapes with concertina folds to guarantee rapid draping without dispersion of fine dust particles (low lint)

TECHNICAL FEATURES: Dimensional tolerance ± 5%

PRODUCTION:
The product is produced and packaged in a special **clean room with a controlled environment**

CLEAN ROOM ENVIROMENT:
ISO class 8 - UNI-EN ISO 14644-1 standard.
Constant temperature and humidity environment maintained by ventilation and filtering systems that also allows to keep the bioburden at low levels.

PACKAGING:
Sterile drape, packed in bag for sterilization with peel-open opening and sterilization indication, packed in cardboard boxes.

STERILIZATION:
Sterilization is carried out with ethylene oxide; the sterilization process is regularly validated and kept under constant control by routine analysis; and the residue of the sterilizing gas is kept within the limits established by the current legislation. Sterilization is performed by a specialized laboratory.
The sterilisation process is validated in accordance with the harmonised European standard EN 550 and the ISO 11135 standard, as well as with F.U.I. and F.E.

SHELF LIFE :
The validity of the sterile device is 59 months from the sterilization date (MONTH-YEAR). The expiration date indicated refers to the device in its intact and correctly stored package.

QUALITY CONTROL: ALLE has implemented a Quality Management System which complies with the following standards:

- **EN ISO 13485**

GENERAL PRECAUTIONS AND WARNINGS:
The device must be used only by qualified and trained personnel. Read the information reported on the label.

STORAGE:

- The items are stored in the original cardboard boxes, in a closed and clean environment protected from sunlight
- The integral sales package is guaranteed impermeable to direct and indirect light sources.

PRODUCT DISPOSAL:
The device listed in this document can be disposed of as non-hazardous waste in authorized plants, including incineration, in accordance with current regulations.
However, if the device used during surgical procedures in the operating room is exposed to contact with the patient's biological fluids, it must be treated and disposed of as hospital waste.

LATEX AND PHTHALATE-FREE:

- The device does not contain natural rubber latex (Latex free)
- The device does not contain phthalates (PVC free)
- The device does not contain elements (adhesives, chemicals, etc.) that could cause allergies or any skin reaction.

CND: T020199 (national classification of medical devices)

PRODUCT CLASSIFICATION: CLASS IS Medical Device

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DIMENSIONS	PACKAGING	CODE
75 X100 cm	40 pcs	270222

TECHNICAL SPECIFICATIONS OF THE MATERIALS			
SPUNLACE NON WOVEN FABRIC			
Non Woven Spunlace Softesse® – DuPont ™ Medical Fabrics is made with 55% woodpulp and 45% polyester. This non-woven fabric is treated with water-repellent substances that serve to form a barrier to blood and alcoholic solutions. The T.N.T. Softesse is made up of tightly woven fibers that do not allow bacteria to penetrate but allow the free circulation of air; it is soft, drapeable and has good dry and wet resistance. The fact of being disposable avoids cross contamination.			
WEIGHT	g/m^2		67
COLOR	Light-blue		
PHYSICAL PROPERTIES - EN 13795	**UNIT**	**VALUES**	**TEST METHOD**
TENSILE STRENGHT - DRY	N	37.60	EN 29073-3
TENSILE STRENGHT - WET	N	40.90	EN 29073-3
CLEANLINESS MICROBIAL	$Log(10)cfu/dm^2$	0	EN 1174
LINTING	Log(10)	3.70	ISO 9073-10
PARTICULATE MATTER	IPM	3.40	ISO 9073-10
RESISTANCE TO MICROBIAL PENETRATION - DRY	Log(10)cfu	0	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION - WET	BI	3.70	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H_2O	23.80	EN 20811
BURSTING STRENGHT - DRY	KPa	211.00	EN 13938-1
BURSTING STRENGHT - WET	KPa	260.00	EN 13938-1

MEDICAL-GRADE ADHESIVE		
	MEAN VALUES	**TEST**
THICKNESS	Adhesive 102 µ + Support 107 µ = Total 209 µ	[TEST: ATM-T07/010]
COLOUR	Transparent adhesive/White support	
ADHESION	N/m 350 - 458 (90°C polyethylene adhesion)	[TEST: ATM-T04/097]
DETACHMENT FROM SUPPORT	g/m 1260	[ATM-T13/001]