STERILE INSTRUMENT TABLE DRAPE COVER

Sterile instrument table drape disposable for operating theatre, manufactured of polyethylene film which is applied to a central stripe absorbent non woven.

- Absorbent light-blue Non-Woven Fabric layer
- Polyethylene blue film waterproof

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 DRAPE/ STRIPE NW	PACKAGING	CODE
160 x 190 cm / 60 x 190 cm	25 pcs	270214

TECHNICAL SPECIFICATIONS OF THE MATERIALS			
Low density polyethylene (LDPE) film with a central stripe in absorbent non woven (36 gsm)			
COLOR	Blue		
PHYSICAL PROPERTIES - EN 13795	**UNIT**	**VALUES**	**TEST METHOD**
TENSILE STRENGHT - DRY	N	100.00	EN 29073-3
TENSILE STRENGHT - WET	N	46.70	EN 29073-3
CLEANLINESS MICROBIAL	Log(10)cfu/dm^2	0	EN 1174
LINTING	Log(10)	1.60	ISO 9073-10
PARTICULATE MATTER	IPM	1.50	
RESISTANCE TO MICROBIAL PENETRATION - DRY	Log(10)cfu	0	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION - WET	BI	6.00	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H_2O	> 200	EN 20811
BURSTING STRENGHT - DRY	KPa	171.00	EN 13938-1
BURSTING STRENGHT - WET	KPa	93.20	EN 13938-1