DISPOSABLE STERILE DRAPES IN 2 LAYERS TISSUE AND PE

Sterile surgical drape disposable for operating theatre, manufactured in tissue cellulose laminated to a waterproof layer. The laminated material creates a total bacteriological barrier in both wet and dry conditions and is composed of 2 layers:

- Absorbent light-blue tissue cellulose layer
- PE film waterproof layer

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

DISPOSABLE STERILE SURGICAL DRAPES IN 2 LAYERS TISSUE AND PE

DIMENSIONS	PACKAGING	CODE
CM. 90 X150	50 pcs	270221

TECHNICAL SPECIFICATIONS OF THE MATERIALS			
WATERPROOF LAMINATED TISSUE – 2 LAYERS			
Absorbent tissue cellulose covered with a waterproof layer hot laminated along its entire width with coextruded antistatic PE.			
WEIGHT	g/m^2		47
PHYSICAL PROPERTIES - EN 13795	**UNIT**	**VALUES**	**TEST METHOD**
TENSILE STRENGHT - DRY	N/50 mm	147.00	EN 29073-3
TENSILE STRENGHT - WET	N/50 mm	138.80	EN 29073-3
CLEANLINESS MICROBIAL	$Log(10)cfu/dm^2$	0	EN 1174
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	>200.00	EN 20811
BURSTING STRENGHT - DRY	KPa	313	EN 13938-1
BURSTING STRENGHT - WET	KPa	301	EN 13938-1
LINTING	Log(10)	2.40	ISO 9073-10
PARTICULATE MATTER	Log(10)	2.30	ISO 9073-10