

DISPOSABLE STERILE SURGICAL DRAPES IN 2 LAYERS WITH ADHESIVE BAND

Sterile single-use drape for covering the patient during surgery or outpatient operations, made of absorbent medical non-woven fabric coupled with an impermeable layer,

The two-layer material forms a total bacteriological barrier both in wet and dry conditions. It is composed of 2 layers:

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

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

TECHNICAL FEATURES: Dimensional tolerance $\pm 5\%$

PRODUCTION:

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

CLEAN ROOM ENVIRONMENT:

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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DIMENSION DRAPE / ADHESIVE BAND	PACKAGING	CODE
cm <u>50x75</u> / cm 4x50	75 pcs	270206

* The underlined cloth size indicates the side of the cloth on which the adhesive is applied



TECHNICAL SPECIFICATIONS OF THE MATERIALS			
WATERPROOF LAMINATED NON WOVEN FABRIC – 2 LAYERS			
Absorbent viscose Non-Woven Fabric covered with a waterproof layer hot laminated along its entire width with coextruded antistatic microembossed polyolefine.			
PHYSICAL PROPERTIES - EN 13795	UNIT	VALUES	TEST METHOD
TENSILE STRENGTH - DRY	N/50 mm	45.00	EN 29073-3
TENSILE STRENGTH - WET	N/50 mm	30.00	EN 29073-3
CLEANLINESS MICROBIAL	Log(10)cfu/dm ²	1.18	EN 1174
RESISTANCE TO MICROBIAL PENETRATION - DRY	Log(10)cfu	< 1	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION - WET	BI	6.00	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H ₂ O	160.00	EN 20811
BURSTING STRENGTH - DRY	KPa	108	EN 13938-1
BURSTING STRENGTH - WET	KPa	95	EN 13938-1
LINTING	Log(10)	3.20	ISO 9073-10
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]	
TESTED BY THE HUNTINGDON RESEARCH U.K. two series of tests were carried out during which no type of irritation or sensitization was found			
Medical adhesive specifically designed for direct contact with the skin in order to ensure perfect adhesion, leaving the skin totally clean after removal.			

