

NON STERILE LIGHT BLUE SURGICAL CAP WITH ELASTIC		
<p>Non Sterile medical device disposable for hospital use for head protection of operators.</p> <p>Surgical cap in Non Woven Spunlace Softesse[®] – DuPont[™] Medical Fabrics with elastic at the back. The non woven material create a bacteriological barrier while, at the same time, allowing the skin to breathe, so that the body temperature does not rise. Its safeguards against cross-contamination.</p>		
<p>TECHNICAL FEATURES: Dimensional tolerance $\pm 5\%$</p> <ul style="list-style-type: none"> • Dimensions: 29 x 15 CM • Colour: light blue 		
<p>PRODUCTION: The product is produced and packaged in a special clean room with a controlled environment</p>		
<p>CLEAN ROOM WITH CONTROLLED ENVIRONMENT: Class ISO 8 – Standard UNI-EN ISO 14644-1. Environment with constant temperature and humidity; by means of special ventilation and filtering systems, the presence of the bacterial load is kept controlled and at low levels.</p>		
<p>PACKAGING: The packaging consist of a cardboard box in cellulose.</p>		
<p>STERILIZATION: No sterile devices</p>		
<p>QUALITY CONTROL: The quality system adopted by ALLE complies with the following regulations:</p> <ul style="list-style-type: none"> • EN ISO 13485 <p>Controls are carried out at all stages of production: entry, production, packaging.</p>		
<p>STORAGE:</p> <ul style="list-style-type: none"> • 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. 		
<p>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.</p>		
<p>LATEX AND PHTHALATE-FREE:</p> <ul style="list-style-type: none"> • 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. 		
<p>LABELLING: Each individual package is provided with an internal label visible through the transparent packaging; this label is complete with all the information necessary to identify the product:</p> <ul style="list-style-type: none"> • trade name of the product • product code number • manufacturer's name • production batch number • expiry date • single-use symbol • production area • CE marking • warnings <p>There is an adhesive label on the transport packaging bearing all the information required to identify the product as indicated above and the no. of kits per pack</p>		
<p>CND: T0207 (national classification of medical devices)</p>		
<p>PRODUCT CLASSIFICATION: CLASS I Medical Device</p>		
NON STERILE LIGHT BLUE SURGICAL CAP WITH ELASTIC		
SIZE	PACKAGING	CODE
29 x 15 CM	50 pcs	270502



TECHNICAL SPECIFICATIONS OF THE MATERIALS			
SPUNLACE NON WOVEN FABRIC			
Non Woven Spunlace Softesse [®] – DuPont [™] Medical Fabrics is made with 55% woodpulp and 45% polyester. Spunlace create an excellent barrier against liquids and particles, while being, at the same time, highly air permeable. Class I flammability and weight 67 gsm			
WEIGHT	gsm	67	
COLOR	Light-blue		
PHYSICAL PROPERTIES - EN 13795	UNIT	VALUES	TEST METHOD
TENSILE STRENGTH - DRY	N	37.60	EN 29073-3
TENSILE STRENGTH - 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 ₂ O	23.80	EN 20811
BURSTING STRENGTH - DRY	KPa	211.00	EN 13938-1
BURSTING STRENGTH - WET	KPa	260.00	EN 13938-1

