

## TUBING SLEEVE WITH BLUE ADHESIVE STRIP

Sterile single-use equipment sleeve with a blue non-woven fabric adhesive fastening strip for use in dental practices and/or outpatient departments. Sterile single-use sleeve allowing the operator to cover instruments quickly and easily whilst considerably reducing the risks of cross-contamination.

- Non-reflective polyethylene tube sleeve
- Open-end polyethylene tube sleeve
- Adhesive strip made from an overlay of blue non-woven fabric to secure the ends
- 2 non-woven fabric strips of 5 x10 cm with 3.8 x 10 cm adhesive

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

### PRODUCTION:

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

### 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.

### PACKAGING:

Individually-folded sterilisation sleeve in a pouch/blister made from medical paper with plastic film overlay and peel-open system indicating the sterilisation batch. 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.

### EXPIRY:

This product is valid for 59 months from the sterilisation date (MONTH-YEAR). The expiry date indicated refers to the product in its unopened and correctly preserved packaging.

### QUALITY CONTROL:

The quality system adopted by ALLE complies with the following regulations:

- **EN ISO 13485**

Controls are carried out at all stages of production: entry, production, packaging, sterilization.

### GENERAL PRECAUTIONS AND WARNINGS :

This product should only be used by qualified and trained personnel. Always read 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:** T030102 - INSTRUMENT COVER SLEEVES (National classification of medical devices IT)

**GMDN:** Not applicable

**PRODUCT CLASSIFICATION: CLASS IS Medical Device**

SIZE	PACKAGING	CODE
120x7 CM	50 UNITS	270302



TECHNICAL CHARACTERISTICS OF THE MATERIALS		
<b>POLYETHYLENE TUBE SLEEVE</b>	Tube sleeve made from 0.05 mm thick polyethylene film	
<b>MEDICAL GRADE ADHESIVE</b>	Adhesive: synthetic rubber adhesive – Substrate: polyester transparent film	
	<b>MEAN VALUES</b>	<b>TEST</b>
THICKNESS	102 μ Adhesive + 107 μ Substrate= Total 209 μ	[TEST: ATM-T07/010]
COLOUR	Transparent adhesive/Blue substrate	
ADHESION	N/m 350 - 458 (90°C polyethylene adhesion)	[TEST: ATM-T04/097]
SUBSTRATE DETACHMENT GRADING	g/m 1260	[ATM-T13/001]

