

### **Arm cover**



**100 % impermeable** all over the drape to minimize the risk of strikethrough

Anti-allergic cuff

Functional fold that allows maintaining asepsis

Reference	Size	Color	Unit per box
MANG.010.11	Single	blue	150 un



### **Intended of use:**

Medical devices in this subcategory are intended to create a sterile barrier to prevent transfer of infectious agents during surgical procedures. Therefore, the intended users of these medical devices are healthcare professionals and the patient population are persons undergoing surgical procedures.

Was designed for a single use for general procedures.

### **Product description:**

Arm cover, sterile for a single use.

Arm cover made with a bi-laminated material, 100% polyester anti-allergic cuffs with Oeko-Tex® Standard 100 certified and latex free elastic.

Surgical drape develop for a standard performance.

#### Raw material:

Bilaminate fabric manufactured in polyethylene and viscose e blue with 58,2 g/m2. Low release of fibers, repellent to liquids and flammability.

Materials used are latex free.

### **Folding:**

It's presented with functional fold that allows maintaining asepsis when correctly used by the medical staff during manipulation of sterile product

#### Final fold dimension:

	Reference	Dimension
	MANG.010.11	15x20 cm



### **Packaging:**

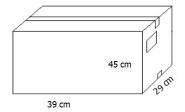
Easy-to-fit thermoformed single package, with two detachable labels in the primary package for full traceability.

Double packaging system with carton and polyethylene bag for added protection against dust, moisture and transport damage, handling and storage.

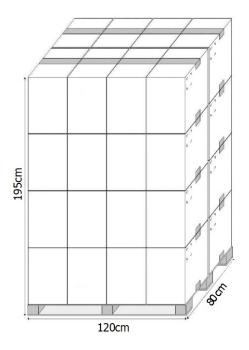




Outer box (39x29x45 cm)



Palletizing system: 32 boxes per pallet:1.20x0.80x1.95 cm.



### **Labeling:**

The product is identified with a label indicating size, image, performance and product description, as well as harmonized regulations according to applicable standards.

Contains two easily to removable traceability labels that contain product reference, expiration, lot and bath information.

Identification label in outer carton.

### **Sterilization:**

Product sterilized by ethylene oxide. According to applicable standards.

### **Shelf Life:**

5 years if storage on the correct way. Product should be protected from sunlight and kept dry.

### **Directive:**

Medical device, class I sterile, rule 1.

Product in compliance with the Essential Requirements of Directive 93/42 / EEC as amended by Directive 2007/47 / EC and applicable standards

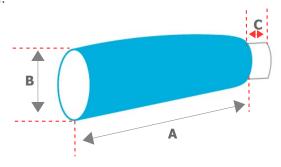


### **Applicable Standards:**

EN 868-5, EN 1041, EN ISO 11135, EN ISO 11607, EN ISO 11737, EN ISO 13485, EN 13795-1, EN ISO 14971, EN ISO 15223

### **General characteristics:**

### 1. General dimension:



A	В	C (cuff)
46	11	7,5

All dimension are represented in cm.