

Clean air suit, SMS blue, non sterile



Tunic with round neckline, short sleeve and front pockets

Adjustable pants with belt and back pockect

High opacity raw material.

References	Size	Units per box
FPCAS01LB	S	40 units
FPCAS02LB	M	40 units
FPCAS03LB	L	40 units
FPCAS04LB	XL	40 units
FPCAS05LB	XXL	40 units



Intended use:

Clean air suit, Intended to minimize contamination of the operating wound by the wearer's skin scales carrying infective agents via the operating room air, thereby preventing the risk of wound infection. Therefore, the intended user of these medical devices are healthcare professionals and the patient population are persons undergoing surgical procedures

Product description:

Clean air suit in SMS polypropylene light blue.

Round neckline tunic, short sleeve and front pockets.

The pants have a pocket on the right side and are adjustable with belt.

Both pieces are packed in a polyethylene bag.

Single use product, not sterile.

Raw materials:

SMS polypropylene 43 gr/m2 with high opacity.

Raw material with anti-static treatment, resistant to traction, free of latex and low flammability. Latex free.

Folding:

The product is presented with functional fold that allows a correct use without indications of use.

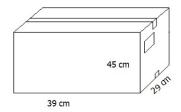
Final fold dimension: 27x27 cm

Packaging

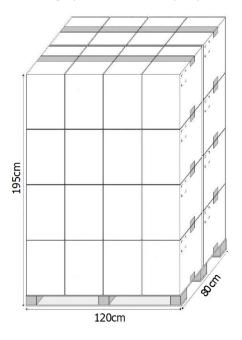
Product packaged in polyethylene bag for added protection against dust and outer box.



Outer box (39x29x45 cm)



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



Labelling:

Identification label in outer box.

The label provides information regarding the product reference, designation, manufacturer and harmonized symbols for single use, in the non sterile status, protection against moisture and sunlight, batch.

Shelf life:

5 years if storage on the correct way.

Product should be protected from sunlight and kept dry.

Regulation:

Medical device: Class I non sterile

Product in compliance with General Safety and Performance Requirements of Regulation (EU) 2017/745 (MDR)

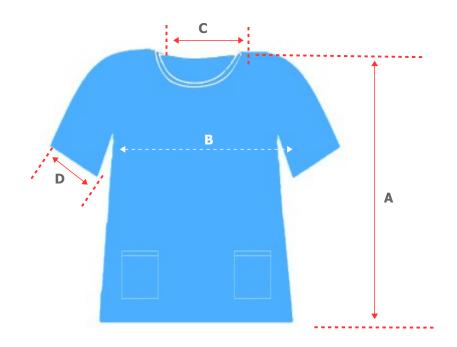


Applicable Standards:

EN 1041, EN ISO 11737, EN ISO 13485, EN 13795-2, EN ISO 14971, EN ISO 15223

Measures:

1. Tunic dimension:

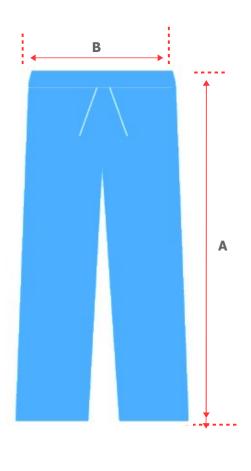


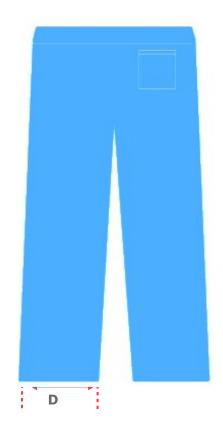
	Α	В	С	D
S	71	56	21	21
М	74	59	21	22
L	75	64	22	23
XL	77	69	22	23
XXL	81	74	23	23,5

All measure are in cm



1. Pants dimension:





	А	В	С	D
S	106	50	78	21
М	111	52	79	21
L	114	56	80	22
XL	117	60	80	22
XXL	122	66	82	22

All measure are in cm