

Date: Mar. 14, 2022

Product Technical Sheet

Product Description

Product: soft PP shirt open cuffs

Item No.: 412452/412453/412454/412456/412457

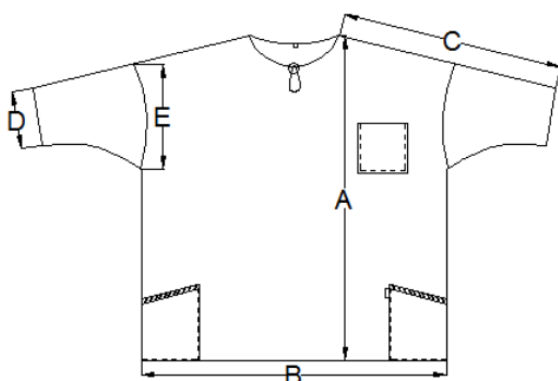
Colour: blue

Material: PP

Thickness: 47g

Size: Please see below table

Dimension of finished products(cm)						
	S	M	L	XL	2XL	Tolerance
A	71	73	75	77	79	±2
B	53.5	58.5	63.5	68.5	73.5	±2
C	35	36	36	37	39	±2
D	22	23	24	24	25	±1.5
E	24	26	29	29	30	±1



Packing: 10pcs/bag, 50pcs/ctn

Carton dimension :

Size of carton(CM)	
S	39.5*26*24
M-L	39.5*26*26
XL-2XL	39.5*26*28

Suggested Sterilization

ETO: (pre-treatment cycle 16-72 hrs)

(gas contact – 3 hrs/850 mg)

(evaporation 48 hrs at 40°C)



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Suggested Storage:

Temperature : between -5°C and 40°C
Humidity : below 80%
Sunlight : not to expose to direct sunlight
Shelf-Life : 5 years

Intended Use: Used to minimize the spread of infective agents to patients' surgical sites and equipment, through prevention of dispersal of bacteria-carrying skin scales from the operating room staff, thereby helping to prevent post- operative surgical site infections.

Applicable Directive/Regulation:

Medical Device Regulation (EU) 2017/745

Applicable Standards:

ISO13485:2016
ISO10993-5:2019
ISO10993-10:2019

Risk Analysis

The raw material is approved to be safe to human health (refer to the manufacturer's safety data sheet).
As for the product, no hazard is foreseeable to the safety and health of user.

Instruction for Use:

Usage :

1. Take it out from the package (box or polybag), then unfold it
2. Put arms into the hole of sleeves, fasten the button on the neck.

Cautions:

1. This product is for single use. Do not re-use it.
2. This product is for protection of part of body, not for overall protection.
3. This product is for hygienic protection, not for any other personal protection against potential risk.
4. This product is non-sterile. It must be sterilized before being used as sterile wear.
5. Choose right size according to the user's stature and figure.