



## Isolation Gown- non-sterile

Quotation Sheet				
Fabric	Level	FOB Price (USD/PC)	MOQ	Packing
PP+PE 25GSM	1	1.53	100K	50*40*41cm/14kg, 10pcs/bag,20bags/ctn
PP+PE 35GSM	2	1.71	100K	
PP+PE 45GSM	3	1.88	100K	49*33*50cm/12kg, 10pcs/bag,10bags/ctn
SMS 45GSM reinforced	2	6.34	100K	



PP/SMS/PP+PE Fabric  
Basic coverage/Fluid repellent  
One waist belt  
Stitched or Ultrasonic welding  
Elastic or knitted cuff  
Latex free

## EC Declaration of Conformity

European Authorized Representative	 SUNGO CERTIFICATION COMPANY LIMITED RM 101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON, ENGLAND
Medical Devices	Isolation Gown
Classification Rule	Class I in accordance of Annex IX the Council Directive MDD 93/42/EEC
Conformity Assessment Route	Annex VII MDD 93/42/EEC
We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.	
Identification Number	
Harmonized standard	EN 14126:2003 (E)
Validity	This Declaration of Conformity has a validity from April 10, 2020 to May 26, 2024

### Product description

Isolation gown is made of PP laminated with PE, with elastic cuffs and ties at neck. It's used to isolate liquid such as alcohol, blood, oil, water, provide protection for medical staffs against a risk of splashes from blood and body fluids. It can also Isolate dust and bacterial, prevent the scurf and hair.



中国认可  
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检测  
TESTING  
CNASL3129



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## Testing Report



Job No.:/

Report No.: HQ203060133-R

Date: Jun. 3, 2020

### 1 Tensile Strength

As per requirement of ASTM F 3352-2019 and method ASTM D5034-2009(R17), Grab Test, CRE Machine

	Result	Requirement
Machine Direction (lbf) :	13.4	Min 7.0
Cross Direction (lbf) :	17.1	Min 7.0
Comment :	Pass	
Remark:		
1 lbf=4.45 N		

### 2 Seam Strength

As per requirement of ASTM F 3352-2019 and method ASTM D1683/D1683M-2017(2018), test on provided seam

	Result	Requirement
Shoulder Seam (lbf) :	13.5(FR)	Min 7.0
Armhole Seam (lbf) :	17.5(FR)	Min 7.0
Sleeve Seam (lbf) :	13.0(FR)	Min 7.0
Comment :	Pass	
Remark:		
1 lbf=4.45 N		
FR=Fabric Rupture.		

### 3 Tearing Strength

As per requirement of ASTM F 3352-19 and method ASTM D 5733:1999, trapezoid procedure.

	Result	Requirement
Machine Direction (lbf) :	6.4	Min 2.3
Cross Direction (lbf) :	9.2	Min 2.3
Comment :	Pass	
Remark:		
1 lbf=4.45 N		

Warp test—test in which the warp yarn was torn.

Weft test—test in which the weft yarn was torn.

The test method ASTM D5733:1999 is specified by applicant and this method is out of lab's CMA, CNAS Certification.

#### 4 Water Resistance: Impact Penetration

AATCC 42:2017e, As received.

As per the requirement of the Level 3 in the ANSI/AAMI PB70-2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

	Result(Body)	Requirement
Test Specimen (g) :	0.0	≤1.0
Comment :	Pass	

#### 5 Water Resistance: Hydrostatic Pressure Test

AATCC 127:2017(2018) e,Asreceived,Option 2,The rate of increase of water pressure was  $60 \pm 3$ cm H<sub>2</sub>O/min while the water pressure was applied below the test specimen and the water temperature is  $20 \pm 2$  degree C, testside:face

As per the requirement of the Level 3 in the ANSI/AAMI PB70-2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

	Result(Body)	Requirement
Test Specimen (cmH <sub>2</sub> O) :	133.7	≥50
Comment :	Pass	

Remark:

1kPa=10 cmH<sub>2</sub>O=100 mmH<sub>2</sub>O

\*\*\*\*\*End of Report