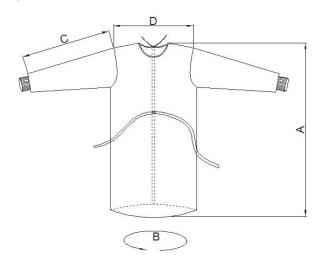


# **Technical Data Sheet**

Model No.: N61A02 BUDI-DI: 697442484L03QB

- Product Name: Sterilized Isolation Gown
- Classification: Class I, according to Annex VIII of Regulation (EU) 2017/745
- Description: Isolation gown is made of high quality SMS+PE, with velcros at neck. White knitted cuffs are used.
- Intended use: Used to isolate the dust and bacteria, prevent the scurf and hair falling.
- **Material:** SMS+PE (minimum 3 layers SMS non-woven material, resistant to liquid penetration within 50-80 H₂ O according to EN 20811:1981 test (European certification body test method) ).
- Size: S-XXL, European standard sizes
- Approvals: CE,ISO 13485
- Manufacturer: Leboo Healthcare Products Limited
- Country of origin: China
- Specification: Detail see specification as below.



Material	Weight	Size	Measurement Location (cm)				Color	Detail
			Α	В	С	D	Color	Detail
SMS+PE	35gSMS +15gPE	S: 120*140cm	120	140	60	67		With elastic, knitted cuffs, Sterile, Individually packed,
		M: 125*140cm	125	140	60	67		
		L: 135x140cm	135	140	60	67		
		XL: 140*140cm	140	140	60	67	Blue	Adjustment at the
		XXL: 150*150cm	150	150	60	67		neck level,
Tolerance			±2	±2	±1	±1		Overlapping closure
								at the back with ties.

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Reinforced at the sleeves: polypropylene and/or polyethylene film, minimum thickness 15 g/m $^2$ , length of reinforcement at least 40 cm.

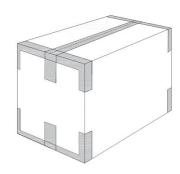
Reinforced at the front: polypropylene and/or polyethylene film, minimum thickness 15 g/m<sup>2</sup>, length from shoulders to hem at least 75 cm.

Gown must comply with EN 13795 standard or equivalent; sewing with laser (ultrasound sewing also accepted).

# Packaging:

- (1) Carton Requirements: Five layers corrugated
- (2) Packing Quantity: 1pc/pouch, 50pcs/ctn5 Layers Carton(Paper)





### **Storage:**

- (1) Store in dry, clean conditions in original packaging.
- (2) Store away from direct sunlight, source of high temperature and solvent vapors.
- (3) Store with the temperature range -5 $^{\circ}$ C to +45 $^{\circ}$ C and with relative humidity below 65%.

#### **Shelf Life:**

Shelf life is 36 months from the date of manufacture when stored as stated above.

## **Cautions and disposal:**

- (1) Do not contact with heavy oils, sparks or flames;
- (2) Do not use in the environment with conditions of excessive heat;
- (3) Replace if damaged, heavily contaminated or in accordance with local practice;
- (4) Hand and dispose of contaminated products with care and in accordance with national regulations.



Keep away from sunlight



Use only once



Keep dry



Don't use when packing damaged and consult instructions for use



Medical device



Caution



EO Sterile



Consult instructions for use or consult electronic instructions for use



CE Symbol

Design: Check: Approve: Date: