

TECHNICAL DATA SHEET (TDS)

DELIVERING PRODUCT SOLUTIONS[™]

	n Gowns: Tri-Layer SMS Medium Weight Isolation Gowns							
Product Code	Description				Sterility	Case	Qty.	Case Dimensions
60-3050	Tri-Layer SMS Medium Weight Isolation Gown, L			own, L	Non-Sterile	100E	4	21x13x14" (53x35x36cm
60-3051	Tri-Layer SMS Medium Weight Isolation Gown, XL				Non-Sterile	100E	4	21x13x14" (53x35x36cm
Materials:	Tri-Layer SMS Material with Antistatic Properties							
Usability:	Single-Use (Disposable)							
Sterilization:	• Non-Sterile: If a product is delivered non-sterile and is ultimately for use in sterile environments, it is intended to be sterilized by the re-packager. This includes further packaging and sterilization according to the validated processes of the re-packager. These products are to be sterilized by ethylene oxide (EO). Other methods of sterilization have not been validated by GRI-Alleset. Other methods of sterilization, multiple sterilizations, or reuse could cause a device malfunction and possibly result in injury to the patient							
Storage Conditions:	Store at room temperature/general warehouse conditions							
Shelf Life:	• Non-Sterile: Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, the product should be performance tested to ensure compliance to specifications							
Certifications:	 • EN ISO 13485:2016 • ANSI/AAMI PB70:2012 Level 2 Liquid Barrier Protection • CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1 • US FDA: Class 1 							
Declarations:		e with natural rubbe and DEHP Free	er latex				C	
GMDN Code and Term:	 Isolation gown, single-use (35492) 					B		
Country of Origin:	Manufactured and packaged in Vietnam							D
	Arm Hole Width	B: Total Length	C: Chest Length	D: Tie Length				
	" (26.7cm)	46" (116.8cm)	28.5″ (72.4cm)	68″ (172.7				
	5" (29.2cm) 5" (1.3cm)	48" (121.9cm) ±1" (2.5cm)	30.5" (77.5cm) ±1" (2.5cm)	70" (177.8 ±1" (2.5c		Tri-Laye Propert		terial with Antistatic
GRI-Alleset 4142 Industry Way Flowery Branch, G USA www.gri-alleset.co	A 30542,	18 31 PE W	RI Medical & Elec 805 Honggao Roa 4031 Jiaxing, Zh COPLE'S REPUBLI ww.gri-alleset.co 5 FDA Establishm	ad, iejiang C OF CHINA om			EC R	EP Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague The Netherlands www.emergobyul.com

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