

## Validated sterile nitrile RABS/isolator mitten with ESD properties and ultra-low particle level

- **Specialized protection:** Designed for use in injectable manufacturing and pharmaceutical production areas, the BioClean™ Nitrile Sterile Isolator Mitten GGL30NITM9 is tested against ASTM D6978-05 permeation standard to ensure safe chemotherapy drug handling and resistance to common chemicals
- **Reduced contamination risk:** These autoclavable cleanroom mittens are 100% water leak tested, minimizing the risk of contamination and ensuring effective arm and hand protection
- **Optimized cleanliness:** Made to fit 10" (254 mm) ports, these mittens are ISO 4 cleanroom-laundered and -packaged, ensuring low particle levels
- **Improved fit:** BioClean™ The BioClean™ Nitrile Sterile Isolator Mitten GGL30NITM9 is specially designed to reduce hand fatigue



### KEY FEATURES & BENEFITS

- **ASTM D6978-05-tested:** Certified for the safe handling of cytotoxic drugs
- **100% water leak-tested:** Isolator mittens with reduced contamination risks
- **ISO 4 cleanroom-processed:** Excellent cleanliness levels

### Industries

- Pharmaceutical Manufacturing
- Laboratory Research and Development
- Raw Material and Preparation
- Biotechnology Manufacturing
- Sterile Processing Department
- Semiconductor manufacturing

## TECHNICAL DATA SHEET

<b>Product Reference</b>	GGL30NITM9
<b>Material</b>	Nitrile
<b>Color</b>	White
<b>Shape</b>	Ambidextrous
<b>External Glove Surface</b>	Smooth
<b>Cuff Style</b>	Beaded
<b>Audit Standards</b>	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
<b>Packaging Overview</b>	One piece per sealed inner PE bag; one inner bag per sealed second inner PE bag; one second inner bag per sealed outer PE bag; 20 outer bags per lined inner white Correx polyethylene box (20 pieces)
<b>Storage Instructions</b>	Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.
<b>Country Of Origin</b>	Malaysia
<b>Available Sizes</b>	9.75
<b>Temperature Range</b>	From -10°C to 120°C
<b>Sterilization Method</b>	GAMMA irradiation (25 kGy)
<b>Cleanroom Class</b>	Class 10/ISO 4 & EU GMP Grade A
<b>Shelf Life</b>	Three (3) years from date of manufacture.
<b>Tested For Use With Chemotherapy Drugs</b>	Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)
<b>Protein Level</b>	N/A: contains no natural rubber latex
<b>Standards</b>	ASTM D6978, EC 1935/2004, ISO 11137-1:2006, EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016, EN 455 Part 2, Category III



# GGL30NITM9

Validated Sterile Nitrile RABS / Isolator Mitten

## PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	9.75	
Typical Length (mm/in)	840/33	EN ISO 21420
Palm Width (mm/in)	127/5	EN ISO 21420
Port Size	10"	
Target Single Wall Palm Thickness (mm/mil)	0.50/20	EN 455-2
Target Single Wall Finger Thickness (mm/mil)	0.60/24	EN 455-2
Target Single Wall Cuff Thickness (mm/mil)	0.50/20	EN 455-2

## PROTECTION AGAINST MECHANICAL RISKS, EN 388:2016+A1:2018

Risk	Performance level
Abrasion Resistance	Level 4
Blade Cut Resistance	Level 1
Tear Resistance	Level 0
Puncture Resistance	Level 2

## ORDERING INFORMATION

	PORT SIZE	10"/254mm
	SIZE	9.75
GGL30NITM9	REORDER NO.	GGL30NITM9

### Technology



NO RUBBER LATEX

### Performance Standards and Regulatory Compliance



AJKNOTS

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