

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

Product Reference	GGL30NITM9
Material	Nitrile
Color	White
Shape	Ambidextrous
External Glove Surface	Smooth
Cuff Style	Beaded
Audit Standards	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
Packaging Overview	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)
Storage Instructions	Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.
Country Of Origin	Malaysia
Available Sizes	9.75
Temperature Range	From -10°C to 120°C
Sterilization Method	GAMMA irradiation (25 kGy)
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture.
Tested For Use With Chemotherapy Drugs	Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)
Protein Level	N/A: contains no natural rubber latex
Standards	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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