



Nitrile

Validated Sterile Nitrile RABS / Isolator Mitten

BioClean validated sterile RABS and Isolator Mittens are manufactured from nitrile with incredibly low levels of particles and excellent ESD properties. Designed for use in injectable manufacturing & pharmaceutical production areas, our GGL mittens are fully validated for sterility with an SAL (Sterility Assurance Level) of 10^{-6} .

- Tested against ASTM D6978-05 for handling chemo drugs
- 100% water leak tested
- Ultra-clean surface ensures product protection
- Specially designed to minimize hand fatigue
- Fits 10"/254mm Port
- Autoclave compatible
- ISO 4 Cleanroom laundered and packaged
- Resistant to VHP, IPA, & disinfectants



Industries

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





GGL30NITM9

Validated Sterile Nitrile RABS / Isolator Mitten

TECHNICAL DATA SHEET

Product Reference	GGL30NITM9
Material	Nitrile
Color	White
Shape	Ambidextrous
External Glove Surface	Smooth
Cuff Style	Beaded
Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
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
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, CE 0598, 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



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PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	9.75	EN 420
Length (mm/in)	840/33	
Palm Width (mm/in)	127/5	
Port Size	10"	EN 420
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 1

ORDERING INFORMATION

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

Technology



NO RUBBER LATEX

Performance Standards and Regulatory Compliance



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