BioClean™

GGL30NITM9

Clean & Sterile Nitrile RABS / Isolator Mitten

RABS/isolator mitten with ultra-low particle level

Port size: 254mm/10”



- **Specialized protection:** Autoclave compatible at 121°C for 30 minutes (15 cycles according to internal testing results), resistant to vaporized hydrogen peroxide (VHP) and isopropyl alcohol (IPA), making it ideal for injectable manufacturing and pharmaceutical production
- **Advanced defense:** Tested to ASTM D6978-05 for safe chemotherapy drug handling and chemical resistance
- **Reduced contamination risk & enhance safety:** These mittens are 100% water leak tested, minimizing risk of contamination
- **Optimized cleanliness:** Washed & packed in an ISO Class 4 cleanroom, ensuring low particulate levels
- **Enhanced comfort:** Designed to reduce hand fatigue and enable easy donning

For cleaning of isolators with other disinfectants or disinfection method, users should conduct evaluation at their discretion for compatibility or seek Ansell consultation.

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

Ansell

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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 cardboard box (20 pieces). **More sustainable packaging:** These gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases. *Inner wrap, pouch, bag and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage Instructions	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country Of Origin	Malaysia
Available Sizes	9.75
Temperature Range	5 to 40 °C
Sterilization Method	GAMMA irradiation (25 kGy)
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
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 0493, EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 388:2016 + A1:2018, Food Contact, UKCA

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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	254mm/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
ISO 13997 Cut Resistance	Level X

ORDERING INFORMATION

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

Technology

NO RUBBER LATEX

Performance Standards and Regulatory Compliance

CE 0493 EN 421 EN ISO 374-1:2016 Type A AJKNOTS EN ISO 374-5 VIRUS

EN 388:2016+A1:2018 4102X UK CA

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