

Validated sterile nitrile RABS/isolator sleeve/glove system granting optimal protection

- **Integrated system:** The BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NITXLMA comprises a nitrile sleeve attached to an L size, ambidextrous PCP glove (BioClean™ S-BFAP), by a channel ring and O ring
- **Specialized protection:** The GSG10NITXLMA Glove System is tested against ASTM D6978-05 to optimize protection for workers handling chemotherapy drugs
- **Reduced risk:** In addition, the BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NITXLMA is 100% visually inspected, lowering the risk of contamination and ensuring effective arm as well as hand protection
- **Enhanced features:** The BioClean™ Isolator Sleeve Glove System GSG10NITXLMA is autoclave compatible (sleeve only), fits port size 8"/203 mm and features an extra length of 39"/995 mm that allows greater flexibility and comfort



KEY FEATURES & BENEFITS

- **ASTM D6978-05-tested:** Certified for the safe handling of chemotherapy drugs
- **ISO 4 cleanroom-processed:** Excellent cleanliness levels
- **Sterility Assurance Level (SAL) of 10⁻⁶:** Sterile hand protection product

Industries

- Pharmaceutical Manufacturing
- Laboratory Research and Development
- Raw Material and Preparation
- Biotechnology Manufacturing
- Hospital and Clinic Department
- Semiconductor manufacturing



GSG10NITXLMA

Validated Sterile Nitrile RABS / Isolator Sleeve/Glove System

TECHNICAL DATA SHEET

Product Reference	GSG10NITXLMA
Material	Nitrile, Neoprene (Polychloroprene)
Color	White, Green
Shape	Ambidextrous
External Glove Surface	Textured Fingers
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 system - consisting of sleeve, size 8.0-8.5 ambidextrous glove and channel ring/O-ring assembly packed in inner PE bag; One system - consisting of sleeve, size 8.0-8.5 ambidextrous glove and channel ring/O-ring assembly packed in inner PE bag; two inner bags (two systems) packed per outer PE bag; 10 outer bags (20 systems) per lined white corrugated carton.
Storage Instructions	Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.
Country Of Origin	Malaysia
Available Sizes	L
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, CE 0493, ISO 11137-1:2006, EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III



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PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	L	
Palm Width (mm/in)	106/4.2	EN ISO 21420
Port Size	8"	
Target Single Wall Palm Thickness (mm/mil)	0.10 /3.94	EN 455-2
Target Single Wall Finger Thickness (mm/mil)	0.12 / 4.72	EN 455-2
Target Single Wall Cuff Thickness (mm/mil)	0.50/20	EN 455-2

ORDERING INFORMATION

	PORT SIZE	8"/203mm
	SIZE	L
GSG10NITXLMA	REORDER NO.	GSG10NITXLMA

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Technology



Performance Standards and Regulatory Compliance



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