

Validated sterile nitrile RABS/isolator sleeve/glove system for handling chemo drugs

- **Integrated system:** The BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NIT85, consists of a nitrile sleeve attached to a size 8.0 hand-specific, PCP glove (BioClean™ BPZS) by a channel ring and O ring
- **Specialized protection:** To ensure optimal protection for workers handling chemotherapy drugs, the GSG10NIT85 Glove system is tested against ASTM D6978-05
- **Reduced contamination risk:** The BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NIT85 is 100% visually inspected, reducing the risk of contamination and affording effective arm as well as hand protection
- **Enhanced features:** This white RABS/isolator sleeve/glove system fits 8" (203 mm) ports and is autoclave compatible (sleeve only)



KEY FEATURES & BENEFITS

- **ASTM D6978-05-tested:** Certified for the safe handling of cytotoxic drugs
- **ISO 4 cleanroom-processed:** Exceptional 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
- Sterile Processing Department
- Semiconductor manufacturing





GSG10NIT85

Validated Sterile Nitrile RABS / Isolator Sleeve/Glove System

TECHNICAL DATA SHEET

Product Reference	GSG10NIT85
Material	Nitrile, Neoprene (Polychloroprene)
Color	White
Shape	Hand Specific
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 system - consisting of sleeve, size 8.5 glove (marked L) and channel ring/O-ring assembly packed in inner PE bag; One system - consisting of sleeve, size 8.5 glove (marked R) and channel ring/O-ring assembly packed in inner PE bag; two inner bags (two systems - one L & one R) 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	8.5
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, ISO 11137-1:2006, EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 420:2003 + A1:2009, EN 455 Part 2, Category III



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PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	8.5	
Palm Width (mm/in)	108/4.3	EN 420
Port Size	8"	
Target Single Wall Palm Thickness (mm/mil)	0.15 / 5.91	EN 455-2
Target Single Wall Finger Thickness (mm/mil)	0.18 / 7.09	EN 455-2
Target Single Wall Cuff Thickness (mm/mil)	0.50/20	EN 455-2

ORDERING INFORMATION

	PORT SIZE	8"/203mm
	SIZE	8.5
GSG10NIT85	REORDER NO.	GSG10NIT85

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Technology



Performance Standards and Regulatory Compliance



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