

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

- **Integrated system:** The BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NIT80, comprises 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:** The GSG10NIT80 Glove system is tested against ASTM D6978-05 to ensure optimal protection for workers handling chemotherapy drugs
- **Reduced contamination risk:** The BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NIT80 is 100% visually inspected, minimizing the risk of contamination and ensuring effective hand as well as arm 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<sup>-6</sup>:** Sterile hand protection product

## Industries

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



# GSG10NIT80

Validated Sterile Nitrile RABS / Isolator Sleeve/Glove System

## TECHNICAL DATA SHEET

<b>Product Reference</b>	GSG10NIT80
<b>Material</b>	Nitrile, Neoprene (Polychloroprene)
<b>Color</b>	White
<b>Shape</b>	Hand Specific
<b>External Glove Surface</b>	Smooth
<b>Cuff Style</b>	Beaded
<b>Audit Standards</b>	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
<b>Packaging Overview</b>	One system - consisting of sleeve, size 8.0 glove (marked L) and channel ring/O-ring assembly packed in inner PE bag; One system - consisting of sleeve, size 8.0 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.
<b>Storage Instructions</b>	Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.
<b>Country Of Origin</b>	Malaysia
<b>Available Sizes</b>	8.0
<b>Temperature Range</b>	From -10°C to 120°C
<b>Sterilization Method</b>	GAMMA irradiation (25 kGy)
<b>Cleanroom Class</b>	Class 10/ISO 4 & EU GMP Grade A
<b>Shelf Life</b>	Three (3) years from date of manufacture.
<b>Tested For Use With Chemotherapy Drugs</b>	Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)
<b>Protein Level</b>	N/A: contains no natural rubber latex
<b>Standards</b>	ASTM D6978, CE 0493, 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 455 Part 2, Category III



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## PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	8	
Palm Width (mm/in)	102/4	EN ISO 21420
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
GSG10NIT80	REORDER NO.	GSG10NIT80

For additional information visit us at [www.ansell.com](http://www.ansell.com), or call us at

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## Technology



## Performance Standards and Regulatory Compliance



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