

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 10⁻⁶:** 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

| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Reference | GSG10NIT80 |
| 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 8.0 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. |
| Storage Instructions | Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light. |
| Country Of Origin | Malaysia |
| Available Sizes | 8.0 |
| 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 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, or call us at

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Technology



Performance Standards and Regulatory Compliance



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