

## 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<sup>-6</sup>:** 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

|   |   |
|---|---|
| <b>Product Reference</b>                      | GSG10NITXLMA  |
| <b>Material</b>                               | Nitrile, Neoprene (Polychloroprene)   |
| <b>Color</b>                                  | White, Green  |
| <b>Shape</b>                                  | Ambidextrous  |
| <b>External Glove Surface</b>                 | Textured Fingers  |
| <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 8.0-8.5 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. |
| <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>                        | L   |
| <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, 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 |

### Technology



### Performance Standards and Regulatory Compliance



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