

## Clean & sterile nitrile RABS / isolator sleeve / glove system with excellent cleanliness for chemo drug handling

**Port size:** 203mm/8"

**Full assembly length:** 900mm  $\pm$  30mm  
(Target: 900mm)

- **Integrated system:** GSG10NIT80 combines a nitrile sleeve with a size 8.0 hand-specific PCP glove (BioClean™ BPZS) using a channel and O-ring
- **Specialized protection:** ASTM D6978-05 tested for safe handling of chemotherapy drugs
- **Reduced contamination risk:** Undergoes 100% visual inspection to minimize contamination and ensure full hand and arm protection
- **Enhanced features:** Autoclave compatible (sleeve only) at 121°C for 30 minutes (15 cycles according to internal testing results), resistant to vaporized hydrogen peroxide (VHP) and isopropyl alcohol (IPA)



*For cleaning of isolators with other disinfectants or disinfection method, users should conduct evaluation at their discretion for compatibility or seek Ansell consultation.*

### 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

Clean & 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                     | <p>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 &amp; one R) packed per outer PE bag; 10 outer bags (20 systems) per lined cardboard box.</p> <p><b>More sustainable packaging:</b> These gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases.</p> <p>*Inner wrap, pouch, bag and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.</p> |
| Storage Instructions                   | Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.                                                                                                                                                                                                                                                                                                                                                                                          |
| Country Of Origin                      | Malaysia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Available Sizes                        | 8.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Temperature Range                      | 5 to 40 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Sterilization Method                   | GAMMA irradiation (25 kGy)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Cleanroom Class                        | Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 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, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, UKCA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |



## GSG10NIT80

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### PHYSICAL PROPERTIES

|                                              | Typical Values | Testing Method |
|----------------------------------------------|----------------|----------------|
| Sizes                                        | 8              |                |
| Palm Width (mm/in)                           | 102/4          | EN ISO 21420   |
| Port Size                                    | 203mm/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 |

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### Technology



### Performance Standards and Regulatory Compliance



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