



GSG10NITXLMA

Clean & Sterile Nitrile RABS / Isolator
Sleeve / Glove System

Clean & sterile nitrile RABS / isolator sleeve / glove system with enhanced flexibility and cleanliness

Port size: 203mm/8"

Full assembly length: 995mm $\pm$ 30 mm
(Target: 995 mm)

- **Integrated system:** GSG10NITXLMA contain nitrile sleeve attached to an ambidextrous L-size PCP glove (BioClean™ S-BFAP) via a channel and O-ring
- **Specialized protection:** ASTM D6978-05 tested for safe handling of chemotherapy drugs
- **Reduced contamination risk:** 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 per internal testing) & resistant to VHP and 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 chemotherapy drugs
- **ISO 4 cleanroom-processed:** Excellent 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

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TECHNICAL DATA SHEET

Product Reference	GSG10NITXLMA
Material	Nitrile, Neoprene (Polychloroprene)
Color	White, Green
Shape	Ambidextrous
External Glove Surface	Textured Fingers
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 8.0-8.5 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 cardboard box. More sustainable packaging: These gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases. *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.
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	L
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 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, UKCA



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PHYSICAL PROPERTIES

	Typical Values	Testing Method
Sizes	L	
Palm Width (mm/in)	106/4.2	EN ISO 21420
Port Size	203mm/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

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Technology



Performance Standards and Regulatory Compliance



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