

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

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



GSG10NIT80

Validated Sterile Nitrile RABS / Isolator Sleeve/Glove System

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

Europe, Middle East & Africa Region

Ansell Healthcare Europe NV
T: +32 (0) 2 528 74 00
F: +32 (0) 2 528 74 01

Asia Pacific Region

Ansell Global Trading Center
T: +603 8310 6688
F: +603 8310 6699

North America Region

Ansell Healthcare Products LLC
US T: +1 800 800 0444
US F: +1 800 800 0445
CA T: +1-800-363-8340

Latin America & Caribbean Region

Ansell Commercial Mexico S.A. de C.V.
T: +52 442 248 1544 / 248 3133

Australia

Ansell Limited
T: +61 1800 337 041
F: +61 1800 803 578

UK

Ansell Nitritex
T: +44 1638 663338
F: +44 1638 668890

Technology



Performance Standards and Regulatory Compliance



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