

# BIOCLEAN STERILE

Sleeve/Glove System

# GSG10NITXLMA

## About

Clean & sterile sleeve/glove system, Nitrile sleeve attached to a size 8.0-8.5 ambidextrous Polychloroprene (BioClean S-BFAP) glove by a channel ring and O'ring. Sold by the pair, individually packaged.

## Specifications

**COMPATIBILITY:**  
ISO Class 4 & EU GMP Grade A

**LENGTH:**  
Complete System: 36"/914mm

**MATERIAL:**  
Nitrile sleeve/polychloroprene glove (S-BFAP)

**PROTEIN LEVEL:**  
Nitrile contains no natural latex proteins

**SURFACE:**  
Textured glove

**SHAPE:**  
Ambidextrous glove

**COLOUR:**  
White sleeve/green glove

**STERILIZATION:**  
Gamma irradiation

## Features

- Sleeve & glove tested against ASTM D6978-05 for handling chemo drugs
- Ultra-clean surface ensures product protection
- Sleeve 100% inspection & air leak tested (prior to being guillotined)
- Fits Port Size: 10-12" / 254-305mm

SLEEVE SUITABLE FOR AUTOCLAVING

SLEEVE CAN BE SANITIZED BY VHP OR IPA



EN 421:2010 ISO 374-5:2016



VIRUS



EN ISO 374



## Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and PPER 2016/425 Module D
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Regulation (EU)2016/425
- Processed in an NEBB certified ISO Class 4 environment
- Complies with the requirements of Glove Standard EN420:2003+A1:2009, EN374-1:2016, EN374-5:2016
- Physical properties comply with European Medical Glove Standard EN455-2:2015
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Suitable for contact with all foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.
- Sterilized in accordance with ISO 11137-1:2006
- Complies with the requirements of European Glove Standard EN 421 Protection against particulate radioactive contamination.

## Physical Properties

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	AQL 0.65 Performance Level 3 (Glove)	EN 374-2:2016
Glove Length +/-10mm (mm/inches)	914/36 (System Length - Sleeve & Glove)	EN 420:2003 + A1:2009
Single Wall Thickness Minimum (mils/mm)	Cuff: 2.76/0.07 Palm: 3.94/0.10 Finger Tip: 4.72/0.12	EN 455-2:2015
Force At Break During Shelf Life	≥ 9N (Glove)	EN 455-2:2015

PALM WIDTHS (mm) ± 5mm	
SIZE	8.0-8.5
mm	106
TEST METHOD	EN 420:2003 + A1:2009

## Sterilization

Method: Gamma irradiation  
Minimum Dose: 25kGy  
Sterility Assurance Level: 10<sup>-6</sup>

## Shelf Life & Storage

Three (3) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

## TO ORDER

### Re-order code

GSG10NITXLMA

### Size

8.0-8.5

### Packing

One system - consisting of sleeve, size 8.0-8.5 glove and channel ring/O-ring assembly packed in inner PE bag; One system - consisting of sleeve, size 8.0-8.5 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 Correx box.

For additional information visit us at [www.bioclean.com](http://www.bioclean.com), or contact us at;

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\*Warning: No glove provides complete protection against all chemicals. Users must test the gloves against the particular chemicals and environment in which they will be used.

\*\*Please see product validation pack or contact Ansell customer service for specific data on use of gloves with cytotoxic drugs. Gloves used for protection against such drugs must be selected specifically for the type of chemicals used.

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