BioClean
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BIOCLEAN STERILE NITRILE

RABS / Isolator Gloves

GGL

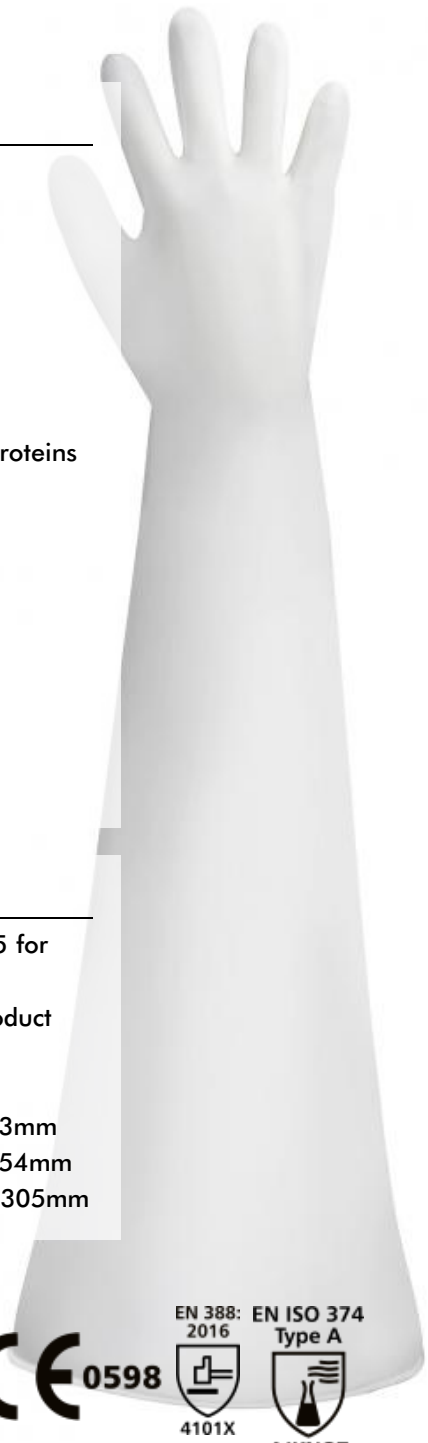
About

BioClean validated sterile RABS and Isolator Gloves are manufactured from nitrile with incredibly low levels of particles and excellent ESD properties. Designed for use in product contact areas, our GGL series of gloves are fully validated for sterility with an SAL (Sterility Assurance Level) of 10^{-6} and are available in a range of port sizes.

100% INSPECTED AND AIR LEAK TESTED

SUITABLE FOR AUTOCLAVING

CAN BE SANITIZED BY VHP OR IPA



Specifications

COMPATIBILITY:
ISO Class 4 & EU GMP Grade A

LENGTH:
840mm/33"

MATERIAL:
Nitrile

PROTEIN LEVEL:
Nitrile contains no natural latex proteins

SURFACE:
Smooth

SHAPE:
5 Finger Ambidextrous Size 9.75

COLOUR:
White

STERILIZATION:
Gamma irradiation

Features

- Tested against ASTM D6978-05 for handling chemo drugs
- Ultra-clean surface ensures product protection
- To fit port sizes:
  GGL15NIT59 - 6 - 8"/152 - 203mm
  GGL20NIT59 - 8 - 10"/203 - 254mm
  GGL33NIT59 - 10 - 12"/254 - 305mm

EN 421:2010 ISO 374-5:2016 VIRUS 0598 EN 388: 2016 4101X EN ISO 374 Type A AJKNOT

Ansell

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 dry,alcoholic and acidic foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.
- Sterilized in accordance with ISO 11137-1:2006
- Mechanical protection EN388:2016
- Complies with the requirements of European Glove Standard EN421 Protection against particulate radioactive contamination.

Physical Properties

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	100% Tested	EN 374-2:2016
Glove Length(mm/in) (-10mm/+50mm)	840/33	EN 420:2003 + A1:2009
Single Wall Thickness (mils/mm) (± 2 mil/0.05 mm)	Cuff: 12/0.30 Palm: 20/0.50 Finger Tip: 24/0.60	EN 455-2:2015
Force At Break During Shelf Life	≥ 9N	EN 455-2:2015

PALM WIDTHS (mm) ± 5mm	
SIZE	9.75
mm	127
TEST METHOD	EN 420:2003 + A1:2009

Sterilization

Method: Gamma irradiation
Minimum Dose: 25kGy
Sterility Assurance Level: 10^{-6}

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.

Protection Against Mechanical Risks, EN 388: 2016+A1:2018

Risk	Performance Level	Risk	Performance
Abrasion Resistance	Level 4	Tear resistance	Level 0
Blade cut resistance	Level 1	Puncture resistance	Level 1
TDM: Cut Resistance	X	Impact Protection	N/A

TO ORDER

Re-order code	Size
GGL15NIT59	9.75
GGL20NIT59	9.75
GGL33NIT59	9.75

Packing

Triple bagged: One piece per sealed inner PE bag; one inner bag per sealed second inner PE bag; one second inner bag per sealed outer PE bag; 20 outer bags per lined inner white Correx polyethylene box (20 pieces).

For additional information visit us at www.bioclean.com, or contact us at;

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2009/GGL/PDS22

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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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