

# About

BioClean Alpha Sterile Latex Gloves provide exceptional flexibility, and are anatomically shaped for enhanced wearer comfort. An extra thick beaded cuff adds strength and stability on the arm, and reduces the risk of the gloves tearing when donning.

# Specifications

COMPATIBILITY: ISO Class 4 & EU GMP Grade A

LENGTH: 300mm (12")

MATERIAL: Latex

PROTEIN LEVEL: Less than 50µg/gram

SURFACE: Textured

SHAPE: Hand specific

COLOUR: Natural

STERILIZATION: Gamma irradiation

### Features

- Exceptional flexibility and comfort
- Extra thick beaded cuff to reduce tearing when donning
- Powder-free
- EasyOn technology allows for easy double-donning
- Non-particulating EasyTear packaging





# EXTRA THICK CUFF

ANATOMICALLY SHAPED

**EXCEPTIONAL FLEXIBILITY & COMFORT** 

DOUBLE-DONNABLE





# Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- 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 European Glove Standards EN420:2003 +A1:2009 and EN374-1:2016, EN374-5:2016
- Physical properties comply with European Medical Glove Standard EN455-2:2015
- Sterilized in accordance with ISO 11137-1:2006
- Suitable for contact with dry, alcoholic and acidic foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.
- 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	EN 374-2:2016		
Glove Length +/-10mm (mm/inches)	290/11.4	EN 420:2003 + A1:2009		
Single Wall Thickness Minimum (mils/mm)	Cuff: 6.30/0.16 Palm: 7.09/0.18 Finger Tip: 7.87/0.20	EN 455-2:2015		
Force At Break During Shelf Life	≥9 N	EN 455-2:2015		

PALM WIDTHS (mm) ± 5mm							
SIZE	6.0	6.5	7.0	7.5	8.0	8.5	9.0
mm	77	83	89	95	102	108	114
TEST METHOD			EN 420:2003 + A1:2009				

### Sterilization

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

### Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.





### **Glove Cleanliness Characteristics**

PARTICLES				TYPICAL PARTICLE COUNT		TEST METHOD		
$\geq 0.5 \mu m (counts/cm^2)$				<3500		IEST-RP-CC005.4		
	TYPICAL EXTRACTABLE IONS						TEST METHOD	
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.4
(µg/cm <sup>2</sup> )	0.002	2.480	NT	NT	0.900	NT	0.290	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(µg/cm <sup>2</sup> )	NT	0.070	ND	0.135	1.525	0.001	NT	
ND = Not Detected, NT = Not Tested								

# TO ORDER

Re-order code	Size
AL300-60	6.0
AL300-65	6.5
AL300-70	7.0
AL300-75	7.5
AL300-80	8.0
AL300-85	8.5
AL300-90	9.0

### Packing

One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

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

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#### AL300/1909/PDS42

Caution: This product contains natural rubber latex (latex) which may cause allergic reactions in some users. Safe use of this glove by or on latex sensitized individuals has not been established.

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves for a specific application.

\*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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