

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

BioClean Ultimate Sterile Polychloroprene Gloves

About

Providing exceptional grip, sensitivity and cytotoxic protection, BioClean Ultimate[™] Sterile Polychloroprene Gloves have excellent antistatic properties and offer both chemical protection and outstanding tactility. Part of the BioClean-C[™] Chemotherapy range, the Ultimate is latex-free and powder-free.

Specifications

COMPATIBILITY: ISO Class 4 & EU GMP Grade A

LENGTH: 300mm (12")

MATERIAL: Polychloroprene

PROTEIN LEVEL: Polychloroprene contains no natural latex proteins

SURFACE: Textured

SHAPE: Hand specific

COLOUR: Natural

STERILIZATION: Gamma irradiation

Features

- Textured for improved grip
- Powder-free & latex-free
- Antistatic properties
- Beaded cuff for strength
- Excellent chemical resistance
- Double-donnable
- Non-particulating EasyTear™ packaging



www.carter-health.com 407.296.6689 info@Carter-Health.com



POWDER-FREE

LATEX-FREE

EXCEPTIONAL TACTILITY

ANTISTATIC

EXCELLENT CHEMICAL RESISTANCE

Ms.G.Love[™] represents BioClean's range of cleanroom gloves





Carter-Health Disposables, LLC Phone: (407) 296.6689 Web: www.Carter-Health.com

Quality Standards

- Manufactured in a facility holding ISO 9001: 2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Processed in an NEBB certified ISO Class 4 environment
- Complies with the requirements of Glove Standard EN420:2003 and EN374-1, 2 & 3:2003
- Physical properties comply with European Medical Glove Standard EN455-2:2009
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Sterilized in accordance with ISO 11137-1:2006

Physical Properties

CHARACTERISTICS VALUE **TEST METHOD** Freedom From Holes AQL 0.65 EN 374-2:2003 Performance Level 3 Minimum Length (mm/inches) 290/11.4 EN 420:2003 Single Wall Thickness Cuff: 3.54 Palm: EN 455-2:2009 Minimum (mils) 4.33 Finger Tip: 5.51 Force At Break ≥9 N EN 455-2:2009 **During Shelf Life**

Glove Cleanliness Characteristics

PARTICLES					TYPICAL PARTICLE COUNT			TEST METHOD
≥ 0.5µm(counts/cm²)					<1300			IEST-RP-CC005.3
TYPICAL EXTRACTABLE IONS								TEST METHOD
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.3
(µg/cm²)	ND	0.494	ND	ND	0.795	ND	0.041	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(µg/cm²)	ND	0.123	0.005	0.378	0.582	0.025	NT	
ND = Not Detected, NT = Not Tested								

Product Numbers

BUPS65	X-Small	1 pr/pk, 10 pks/mb, 20 mbs/cs
BUPS70	Small	1 pr/pk, 10 pks/mb, 20 mbs/cs
BUPS75	Medium	1 pr/pk, 10 pks/mb, 20 mbs/cs
BUPS80	Large	1 pr/pk, 10 pks/mb, 20 mbs/cs
BUPS85	X-Large	1 pr/pk, 10 pks/mb, 20 mbs/cs
BUPS90	2X-Large	1 pr/pk, 10 pks/mb, 20 mbs/cs





Method: Gamma irradiation Minimum Dose: 25kGy Sterility Assurance Level: 10⁻⁶

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.

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	115		
TEST METHOD				EN455-2:2009					

