

## USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

**EXCELLENT CHEMICAL RESISTANCE** 

# **BioClean P-Zero Sterile Polychlorophrene Gloves**

BIOCLEAN P-ZERO™

Sterile Polychloroprene Gloves BPZS

## **About**

BioClean P-Zero™ Sterile Polychloroprene Gloves provide exceptional chemical and cytotoxic protection together with antistatic properties and outstanding tactility and grip. Part of the BioClean-C™ Chemotherapy range, the P-Zero is latex-free and powder-free.

**POWDER-FREE** 

LATEX-FREE

**BEADED CUFF** 

**ANTISTATIC** 

# **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
- BioClean-C™ chemotherapy range
- Non-particulating EasyTear<sup>™</sup> packaging











# **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
Minimum Length (mm/inches)	290/11.4	EN 420:2003
Single Wall Thickness Minimum (mils)	Cuff: 4.33 Palm: 5.91 Finger Tip: 7.09	
Force At Break During Shelf Life	≥ 9 N	EN 455-2:2009

### 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.

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		EN455-2:2009					

### **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	0.25	ND	ND	1.63	ND	0.070	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(µg/cm²)	ND	0.15	0.005	0.42	0.929	ND	NT	
ND = Not Detected, NT = Not Tested								

## **Product Numbers**

BPZS65	X-Small	1 pr/pk,	10 pks/mb,	20 mbs/cs
BPZS70	Small	1 pr/pk,	10 pks/mb,	20 mbs/cs
BPZS75	Medium	1 pr/pk,	10 pks/mb,	20 mbs/cs
BPZS80	Large	1 pr/pk,	10 pks/mb,	20 mbs/cs
BPZS85	X-Large	1 pr/pk,	10 pks/mb,	20 mbs/cs
BPZS90	2X-Large	1 pr/pk,	10 pks/mb,	20 mbs/cs



