

BIOCLEAN P-ZERO

Sterile Polychloroprene Gloves
BPZS

About

BioClean P-Zero Sterile Polychloroprene Gloves provide chemical resistance* together with ESD properties and low particle count. They are also latex-free, powder-free and offer flexibility and comfort for the wearer enabling good dexterity.

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

CHEMICAL RESISTANT*

LATEX-FREE

POWDER-FREE

Features

- Powder-free & latex-free
- ESD properties
- Beaded cuff for strength
- Chemical resistant*
- Non-particulating EasyTear packaging

EN 421:2010 ISO 374-5:2016



EN ISO 374



KOT

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, 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 all foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- 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: 4.33/0.11 Palm: 5.91/0.15 Finger Tip: 7.09/0.18	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: 10⁻⁶

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.

Glove Cleanliness Characteristics

PARTICLES					TYPICAL PARTICLE COUNT			TEST METHOD
$\geq 0.5\mu\text{m}(\text{counts}/\text{cm}^2)$					<1300			IEST-RP-CC005.4
TYPICAL EXTRACTABLE IONS								TEST METHOD
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.4
($\mu\text{g}/\text{cm}^2$)	ND	0.25	ND	ND	1.63	ND	0.070	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
($\mu\text{g}/\text{cm}^2$)	ND	0.15	0.005	0.42	0.929	ND	NT	
ND = Not Detected, NT = Not Tested								

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)