

# Sterile, ambidextrous latex cleanroom gloves, offering users flexible comfort

- **Added protection:** BioClean™ Prelude BPSL sterile gloves boast a flexible, dexterous latex design, for easy double-donning, offering wearers an extra level of protection
- **Enhanced features:** These ambidextrous cleanroom gloves feature textured fingers and palms to deliver enhanced grip performance, while their beaded cuff enhances stability around the wearer's arm and prevents tearing when donning
- **Reduced contamination risks:** BioClean™ Prelude BPSL latex, powder-free gloves have undergone gamma irradiation sterilization and are packed in non-particulating EasyTear™ packaging to reduce particulate contamination from entering a cleanroom environment

*CAUTION: Safe use of these gloves by latex-sensitized individuals has not been established. This product contains natural rubber latex, which may cause allergic reactions.*



## KEY FEATURES & BENEFITS

- **Double-donning-friendly design:** Adaptable everyday hand protection
- **Textured surface:** For cleanroom gloves with enhanced grip
- **Non-particulating EasyTear™ packaging:** Reduced packaging waste

### Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Lab and R&D
- Sterile Processing Department

### TECHNICAL DATA SHEET

| Product Information               |  |
|-----------------------------------|--|
| Material                          | Natural Rubber Latex   |
| Color                             | Natural  |
| Shape                             | Ambidextrous   |
| Cuff                              | Beaded   |
| Manufacturing/QMS Audit Standards | ISO 14001, NEBB Certified Cleanrooms   |
| Regulatory/Standard Compliance    | CE 0493, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Food Contact, Category III  |
| Packaging                         | <p>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).</p> <p><b>More sustainable packaging:</b> These sterile gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases.</p> <p>*Inner wrap, pouch, bag and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.</p> |
| Storage                           | Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.   |
| Country of Origin                 | Malaysia   |
| Available sizes                   | XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10), 2XL (10.5-11)  |
| Powder Content                    | Powder-Free  |
| External Glove Surface            | Textured Fingers and Palm  |
| Internal Glove Surface            | Chlorinated  |
| Sterilization Method              | GAMMA irradiation (25 kGy)   |
| Sterilization Minimum Dose        | 25kGy  |
| Sterility Assurance Level         | 10 <sup>-6</sup>   |
| Cleanroom Class                   | Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms   |
| Shelf Life                        | Five (5) years from date of manufacture.   |
| Protein Level                     | 50 µg/g or less of total extractable protein   |
| Anti-static                       | No   |



# Prelude BPSL

## Sterile Disposable Latex Cleanroom Glove

| Physical Properties  |                             |             |             |             |               |               | Testing Method  |
|--|-----------------------------|-------------|-------------|-------------|---------------|---------------|-----------------|
| Sizes  | XS (5.5 - 6)                | S (6.5 - 7) | M (7.5 - 8) | L (8.5 - 9) | XL (9.5 - 10) | 2XL (10.5-11) | EN ISO 21420    |
| Typical Length (mm/in)   | 300 / 12                    |             |             |             |               |               |                 |
| Palm Width (mm/in)   | 77/3                        | 83/3.2      | 95/3.7      | 106/4.1     | 112/4.4       | 118/4.6       |                 |
| Freedom from Holes   | 1.5 AQL Performance Level 2 |             |             |             |               |               | EN 374-2        |
| Typical Particle Count $\geq 0.5\mu\text{m}$ (counts / $\text{cm}^2$ ) | <1500                       |             |             |             |               |               | IEST-RP-CC005.4 |
| Target Single Wall Palm Thickness (mm/mil)                             | 0.17 / 6.69                 |             |             |             |               |               | EN 455-2        |
| Target Single Wall Finger Thickness (mm/mil)                           | 0.20 / 7.87                 |             |             |             |               |               | EN 455-2        |
| Target Single Wall Cuff Thickness (mm/mil)                             | 0.11 / 4.33                 |             |             |             |               |               | EN 455-2        |
| Force at Break (N) During Aging  | $\geq 6$ N                  |             |             |             |               |               | EN 455-2        |

## IONIC CONTENT

| Concentration in $\mu\text{g}/\text{cm}^2$ | Typical           | Concentration in $\mu\text{g}/\text{cm}^2$ | Typical           |
|--|-------------------|--|-------------------|
| Ammonium                                   | Available on File | Nitrate                                    | 0.67              |
| Bromide                                    | Available on File | Nitrite                                    | 0.67              |
| Calcium                                    | 0.37              | Phosphate                                  | 0.07              |
| Chloride                                   | 0.97              | Potassium                                  | 0.03              |
| Fluoride                                   | Available on File | Sodium                                     | 0.02              |
| Lithium                                    | Available on File | Sulphate                                   | Available on File |
| Magnesium                                  | 0.003             | Zinc                                       | Available on File |

## ORDERING INFORMATION

| SIZE        | XS (5.5 - 6) | S (6.5 - 7) | M (7.5 - 8) | L (8.5 - 9) | XL (9.5 - 10) | 2XL (10.5-11) |
|-------------|--------------|-------------|-------------|-------------|---------------|---------------|
| REORDER NO. | BPSL-5055    | BPSL-6065   | BPSL-7075   | BPSL-8085   | BPSL-9090     | BPSL-1010     |

## PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE



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