

# Sterile disposable latex gloves designed for cleanroom use, offering both flexibility and comfort

- **Heightened comfort and flexibility:** BioClean™ Alpha AL300 protective gloves are anatomically designed and made from sterile natural rubber latex, ensuring both comfort and flexibility
- **Improved durability:** These disposable powder-free latex gloves boast a reinforced cuff design, boosting strength and stability while reducing instances of glove tearing when donning
- **Enhanced usability:** They are also designed with EasyOn technology, enabling double gloving with ease
- **Assured cleanliness:** BioClean™ Alpha AL300 gloves come in non-particulating EasyTear packaging, for genuinely cleanroom-compatible hand protection



## KEY FEATURES & BENEFITS

- **Hand-specific sterile latex design:** Superb comfort and flexibility
- **Reinforced cuff:** Fewer instances of tearing when donning
- **Smooth grip:** For more confident, secure handling

## Industries

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



## Alpha AL300

Sterile Disposable Latex Cleanroom Glove

### TECHNICAL DATA SHEET

|                                   | Product Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material                          | Natural Rubber Latex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Color                             | Natural                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Shape                             | Hand Specific                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Cuff                              | Beaded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Manufacturing/QMS Audit Standards | ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Regulatory/Standard Compliance    | CE 0493, EN ISO 21420:2020, EN 421:2010, EN 455 Part 2, EN ISO 374-1:2016, EN ISO 374-5:2016, Food Contact, Category III, UKCA                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Packaging                         | <p>One pair per inner PE wallet; one wrap 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 latex 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                   | 6, 6.5, 7, 7.5, 8, 8.5, 9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| External Glove Surface            | Textured Fingers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



# Alpha AL300

Sterile Disposable Latex Cleanroom Glove

| Physical Properties                                |                             |        |        |        |       |         |         | Testing Method  |
|----------------------------------------------------|-----------------------------|--------|--------|--------|-------|---------|---------|-----------------|
| Sizes                                              | 6                           | 6.5    | 7      | 7.5    | 8     | 8.5     | 9       | EN ISO 21420    |
| Typical Length (mm/in)                             | 295 / 11.61                 |        |        |        |       |         |         |                 |
| Palm Width (mm/in)                                 | 77/3                        | 83/3.3 | 89/3.5 | 95/3.7 | 102/4 | 109/4.3 | 114/4.5 |                 |
| Freedom from Holes                                 | 1.5 AQL Performance Level 2 |        |        |        |       |         |         | EN 374-2        |
| Typical Particle Count<br>≥0.5µm (counts / cm²)    | <3500                       |        |        |        |       |         |         | IEST-RP-CC005.4 |
| Target Single Wall Palm<br>Thickness (mm/mil)      | 0.20 / 7.87                 |        |        |        |       |         |         | EN 455-2        |
| Target Single Wall<br>Finger Thickness<br>(mm/mil) | 0.24 / 9.44                 |        |        |        |       |         |         | EN 455-2        |
| Target Single Wall Cuff<br>Thickness (mm/mil)      | 0.18 / 7.08                 |        |        |        |       |         |         | EN 455-2        |
| Ultimate tensile strength<br>(MPa) During Aging    | Min. 14                     |        |        |        |       |         |         | ASTM D412-06a   |
| Force at Break (N)<br>During Aging                 | ≥9N                         |        |        |        |       |         |         | EN 455-2        |

## IONIC CONTENT

| Concentration in µg/cm <sup>2</sup> | Typical           | Concentration in µg/cm <sup>2</sup> | Typical |
|-------------------------------------|-------------------|-------------------------------------|---------|
| Ammonium                            | < 0.05            | Nitrate                             | < 0.50  |
| Bromide                             | Available on File | Nitrite                             | < 0.01  |
| Calcium                             | < 1.00            | Phosphate                           | < 0.01  |
| Chloride                            | < 2.50            | Potassium                           | < 0.08  |
| Fluoride                            | < 0.01            | Sodium                              | < 0.08  |
| Lithium                             | < 0.01            | Sulphate                            | < 0.20  |
| Magnesium                           | < 0.05            | Zinc                                | < 1.20  |

## ORDERING INFORMATION

| SIZE        | 6        | 6.5      | 7        | 7.5      | 8        | 8.5      | 9        |
|-------------|----------|----------|----------|----------|----------|----------|----------|
| REORDER NO. | AL300-60 | AL300-65 | AL300-70 | AL300-75 | AL300-80 | AL300-85 | AL300-90 |

## PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE



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