

# Accelerator-free sterile nitrile gloves, offering users enhanced protection

- **Reduced allergy risks:** BioClean™ Excell BEXS sterile nitrile gloves are powder-free, latex-free and chemical accelerator-free, eliminating Type I latex and Type IV chemical allergies and sensitivities
- **Clean processed:** They undergo deionized washing to reduce surface particulates, ionic extractables and non-volatile residues
- **More sustainable packaging:** Packed in recyclable\* plastic packaging and delivered in recycled cardboard shipper cases
- **Decreased contamination risks:** Non-particulating packaging reduces potential contaminant hazards in the cleanroom environment

*\*Always check your local recyclable status as these materials may not be considered suitable for recycling in your location*



## KEY FEATURES & BENEFITS

- **Chemical resistance:** Protection from chemicals and chemotherapy drugs
- **Hand-specific ergonomic design:** Improved dexterity for skilled handling
- **Gamma irradiation sterilized:** Sterility assurance level (SAL) of  $10^{-6}$

## Industries

- Sterile Processing Department
- Biotechnology Manufacturing
- Controlled and Critical Environments
- Laboratory Research and Development
- Medical Device Manufacturing
- Pharmaceutical Manufacturing

### TECHNICAL DATA SHEET

|  | Product Information   |
|--|---|
| Material                               | Nitrile   |
| Color                                  | White   |
| 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 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Food Contact, Category III, UKCA   |
| Packaging                              | 1 pair per inner wrap; 1 inner wrap per pouch; 10 pouches per outer bag; 20 outer bags per lined carton (200 pairs)<br><br><b>More sustainable packaging:</b> These sterile nitrile gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases.<br>*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 |
| 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 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   |
| Tested for use with Chemotherapy Drugs | Yes   |
| Protein Level                          | N/A: contains no natural rubber latex   |
| Anti-static                            | Yes   |



# Excell BEXS

Sterile Disposable Nitrile Cleanroom Glove

| Physical Properties  |                     |     |        |     |     |         |     | Testing Method  |
|--|---------------------|-----|--------|-----|-----|---------|-----|-----------------|
| Sizes  | 6                   | 6.5 | 7      | 7.5 | 8   | 8.5     | 9   | EN ISO 21420    |
| Typical Length (mm/in)   | 300 / 12            |     |        |     |     |         |     |                 |
| Palm Width (mm/in)   | 79                  | 84  | 89/3.5 | 95  | 101 | 108/4.2 | 115 |                 |
| Freedom from Holes   | 1.5 AQL Performance |     |        |     |     |         |     | EN 374-2        |
| Typical Particle Count $\geq 0.5\mu\text{m}$ (counts / $\text{cm}^2$ ) | <1200               |     |        |     |     |         |     | IEST-RP-CC005.4 |
| Target Single Wall Palm Thickness (mm/mil)                             | 0.14 / 5.51         |     |        |     |     |         |     | EN 455-2        |
| Target Single Wall Finger Thickness (mm/mil)                           | 0.17 / 6.69         |     |        |     |     |         |     | EN 455-2        |
| Target Single Wall Cuff Thickness (mm/mil)                             | 0.11 / 4.33         |     |        |     |     |         |     | EN 455-2        |
| Ultimate tensile strength (MPa) During Aging                           | Min. 15             |     |        |     |     |         |     | ASTM D412-06a   |
| Force at Break (N) During Aging  | $\geq 9$ 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                                    | <0.25             |
| Bromide                                    | <0.01             | Nitrite                                    | Available on File |
| Calcium                                    | <0.55             | Phosphate                                  | <0.01             |
| Chloride                                   | <0.35             | Potassium                                  | <0.10             |
| Fluoride                                   | < 0.01            | Sodium                                     | < 0.05            |
| Lithium                                    | < 0.01            | Sulphate                                   | <0.05             |
| Magnesium                                  | < 0.01            | Zinc                                       | < 0.05            |

## ORDERING INFORMATION

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

## PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE



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