

## Sterile polyisoprene gloves, designed for Class 100 (ISO 5)/Grade A cleanroom environments

- **Elevated comfort:** Ideal for double gloving, TouchNTuff™ 83-500 polyisoprene cleanroom gloves' ultra-soft polyisoprene offers "second skin"-like comfort and minimizes hand fatigue with prolonged wear
- **Reduced allergy risks:** They contain no latex proteins, meaning they do not pose any threat related to Type I latex allergies and sensitivities
- **Sterility assurance:** These disposable gloves are sterilized by gamma irradiation, with a sterility assurance level (SAL) of 10<sup>-6</sup>



### KEY FEATURES & BENEFITS

- ◊ **Ultra-soft polyisoprene:** "Second skin" comfort and feel
- ◊ **Latex-free design:** Latex Type I allergy risks eliminated
- ◊ **Gamma sterilization:** A sterility assurance level (SAL) of 10<sup>-6</sup>

### Industries

- Laboratory Maintenance & Clean-Up
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing
- Laboratory Research and Development
- Controlled and Critical Environments
- Production and Manufacturing

### Recommended For

- Maintaining lab furniture and equipment
- Spill or leakage cleanup
- Transferring liquids and solids
- Packaging and labeling
- Clean room cleaning and preparing
- Sample taking and processing
- Administering drugs
- Transferring liquids and solids between vessels and tanks and process equipment



## TECHNICAL DATA SHEET

|  | Product Information   |
|--|---|
| Material                               | Polyisoprene  |
| Color                                  | White   |
| Shape                                  | Anatomic with Curved Fingers  |
| Cuff                                   | Beaded with SUREFIT™ Technology   |
| Manufacturing/QMS Audit Standards      | ISO 13485, ISO 9001:2015, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D  |
| Regulatory/Standard Compliance         | AS/NZS 4179, ASTM D3577, ASTM D7160, CE 0493, EN 556-1:2001, EN ISO 21420:2020, EN ISO 374-1:2016 Type B (KPT), EN ISO 374-5:2016, EN 421:2010, Please consult the IFU, ISO 10282, ISO 11193, Category III, UKCA  |
| Packaging                              | <p>1 pair of gloves per inner wallet, 1 inner wallet per inner polybag, 10 inner polybags per outer polybag, 5 outer polybags per plain polybag, 4 plain polybags (200 pairs) per lined carton</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.  |
| Available sizes                        | 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9  |
| External Glove Surface                 | Smooth  |
| Internal Glove Surface                 | Polymer Coated with DERMASHIELD™ Technology   |
| Sterilization Method                   | GAMMA irradiation (25 kGy)  |
| Cleanroom Class                        | Class 100/ISO Class 5, EU GMP Grade A/B and other sterile cleanrooms  |
| Shelf Life                             | 5 Years   |
| Tested for use with Chemotherapy Drugs | Yes, in accordance with ASTM D6978  |
| Protein Level                          | Not Applicable: contains no natural rubber latex  |
| Anti-static                            | No  |
| Vulcanization Chemical Accelerators    | <ul style="list-style-type: none"> <li>• Xanthates</li> <li>• Zinc Dialkyldithiocarbamate</li> </ul> <p><i>Only a very small number of users may be sensitive to this ingredient(s) and hence may develop irritant and/or allergic contact reactions.</i></p>   |

| Physical Properties  |             | Testing Method      |
|--|-------------|---------------------|
| Typical Length (mm/in)   | 300 / 12    | EN 420/ASTM D3767   |
| Freedom from Holes   | 0.65 AQL    | EN 455-1/ASTM D3577 |
| Typical Particle Count $\geq 0.5\mu\text{m}$ (counts / $\text{cm}^2$ ) | $\leq 2500$ | IEST-RP-CC005.4     |
| Force at Break (N) Before Aging  | 9           | EN 455-2            |
| Force at Break (N) During Aging  | 9           | EN 455-2            |

## ORDERING INFORMATION

| SIZE        | 5.5      | 6        | 6.5      | 7        | 7.5      | 8        | 8.5      | 9        |
|-------------|----------|----------|----------|----------|----------|----------|----------|----------|
| REORDER NO. | 83500055 | 83500060 | 83500065 | 83500070 | 83500075 | 83500080 | 83500085 | 83500090 |

## PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE



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## Technology



Pinhole Barrier Technology



Ergonomic Design Technology



Cuff Roll-down Technology



Donning Aid Technology



Skin-friendly, non-sensitizing PI Technology