



**SPECIFICATION SHEET**



**NON-LATEX POWDER FREE SURGICAL GLOVES, STERILE**

| Size   | Reorder#  | Dimension   |                 |             |
|--|---|---|-----------------|-------------|
|  |   | Target weight (g/pcs)   | Palm Width (mm) | Length (mm) |
| 5.5  | P3355-56G   | 9.0 ± 0.5   | 72 ± 4          | min. 278    |
| 6.0  | P3360-56G   | 9.3 ± 0.5   | 77 ± 5          | min. 280    |
| 6.5  | P3365-56G   | 10.1 ± 0.5  | 83 ± 5          | min. 280    |
| 7.0  | P3370-56G   | 10.3 ± 0.5  | 89 ± 5          | min. 283    |
| 7.5  | P3375-56G   | 11.2 ± 0.5  | 95 ± 5          | min. 287    |
| 8.0  | P3380-56G   | 12.0 ± 0.5  | 102 ± 6         | min. 288    |
| 8.5  | P3385-56G   | 12.5 ± 0.5  | 108 ± 6         | min. 290    |
| 9.0  | P3390-56G   | 13.1 ± 0.5  | 114 ± 6         | min. 290    |
|  |   | <i>*non-release criteria</i>  |                 |             |
| 510K and MDL #   |   | K040503 & D036536   |                 |             |
| Design and Feature   |   | Hand specific, straight fingers, micro roughened surface and beaded cuff  |                 |             |
| Type   |   | Powder free, polymer coated, damp-hand-donnable (DHD™) and Gamma-sterilized surgical gloves   |                 |             |
| Material   |   | Polyisoprene rubber (not made with natural rubber latex)  |                 |             |
| Colour   |   | Green (PMS 325)   |                 |             |
| Surface Treatment  |   | Polymer coating (DHD-PI)  |                 |             |
| Powder Residue (mg/glove)  |   | < 2   |                 |             |
| Single-wall Thickness (mm)<br><i>*All sizes</i>                    | Finger  | 0.22 ± 0.03   |                 |             |
|  | Palm  | 0.18 ± 0.03   |                 |             |
|  | Cuff  | 0.14 ± 0.03   |                 |             |
| Physical Properties  | Tensile Strength (MPa)<br>Ultimate Elongation (%)<br>Stress at 500% (MPa)<br>Force at Break (N) | <u>Unaged</u>   |                 | <u>Aged</u> |
|  |   | Min. 17   |                 | Min. 12     |
|  |   | Min. 650  |                 | Min. 490    |
|  |   | Max. 7.0<br>≥ 9   |                 | N/A<br>≥ 9  |
| Packing Mode   |   | 1 pairs of gloves per inner wrap<br>1 inner wrap per pouch<br>50 pouch per dispenser<br>4 dispenser per carton  |                 |             |
| Glove Marking  |   | The cuff of each glove is marked with 'PROFEEL NON-LATEX', 'Hand & Size'  |                 |             |
| Lot # Identification on Finished Goods                             |   | Lot Number Structure : YMMPPPPSS (9 Digits)<br>Y = Year of packing (e.g. 3 for year 2023, 4 for year 2024, etc.)<br>MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.)<br>PPPP = WRP's Packing Work Order# (PWO)<br>SS = Size (55=5.5, 60=6.0, 65=6.5, 70=7.0, 75=7.5, 80=8.0, 85=8.5 and 90=9.0) |                 |             |
| Shelf Life   |   | 5 years upon manufacturing date   |                 |             |
| Pre-shipment Inspection<br><br><i>*Single-Normal Sampling Plan</i> | Dimension   | N=13 the Median; S-2, AQL 4.0   |                 |             |
|  | Physical Properties   | N=13 the Median; S-2, AQL 4.0   |                 |             |
|  | 1000ml Water Leak   | G-1, AQL 0.65   |                 |             |
|  | Powder Residue  | N=6   |                 |             |
| Major Visual Inspection  | G-1, AQL 1.5  |   |                 |             |
| Minor Visual Inspection  | G-1, AQL 2.5  |   |                 |             |
| Product Conformance  |   | <ul style="list-style-type: none"> <li>Medical Device: in compliance with 93/42/EEC, CE Class IIa</li> <li>EN455 Parts 1, 2, 3 and 4</li> <li>ASTM D3577</li> <li>Health Canada Compliance</li> </ul>   |                 |             |
| Quality Assurance  |   | <ul style="list-style-type: none"> <li>MDSAP ISO 13485:2016 Quality Management System</li> <li>ISO 9001:2015 Quality Management System</li> <li>EN ISO 13485:2016</li> <li>ISO 14001:2015, Environmental Management System</li> </ul>   |                 |             |

WRP ASIA PACIFIC SDN. BHD.

  
  
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