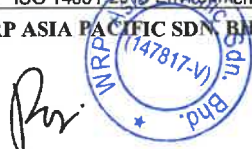




**SPECIFICATION SHEET**

|   |  |   |  |               |
|---|--|---|--|---------------|
| Product Name  |  | Profeel DHD Micro Powder Free Latex Surgical Gloves   |  |               |
| Reorder Number  |  | P33xx-34  |  |               |
| Product Part Number   |  | 362xx.108122040   |  |               |
| <b>Product Description</b>  |  |   |  |               |
| Design and Feature  |  | Hand specific, micro roughened surface, and beaded cuff   |  |               |
| Type  |  | Powder free, polymer coated, Damp-Hand-Donnable (DHD™) and Gamma-sterilized surgical gloves                                   |  |               |
| Material  |  | Natural Rubber Latex  |  |               |
| Colour  |  | Brown   |  |               |
| Surface Treatment   |  | Polymer coating on inner surface to ease donning  |  |               |
| <b>Product Quality Requirement</b>  |  |   |  |               |
| Dimension   | Size   | Palm Width (mm)   | Length (mm)  |               |
|   | 5.5  | 72 ± 4  | Min. 278   |               |
|   | 6.0  | 77 ± 5  | Min. 280   |               |
|   | 6.5  | 83 ± 5  | Min. 280   |               |
|   | 7.0  | 89 ± 5  | Min. 283   |               |
|   | 7.5  | 95 ± 5  | Min. 287   |               |
|   | 8.0  | 102 ± 6   | Min. 288   |               |
|   | 8.5  | 108 ± 6   | Min. 290   |               |
| 9.0   | 114 ± 6  | Min. 290  |  |               |
| Single-wall Thickness (mm)<br>*All sizes  | Finger<br>Palm<br>Cuff   | 0.18 ± 0.03<br>0.15 ± 0.03<br>0.13 ± 0.03   |  |               |
| Powder Residue (mg/glove)   |  | ≤ 2   |  |               |
| Protein Content (µg/dm <sup>2</sup> )   |  | ≤ 50  |  |               |
| Physical Properties   | Standard   | Parameters  | Before Aging   | After Aging   |
|   | EN 455 Part 2  | Force at break (N)  | ≥ 9  | ≥ 9           |
|   | ASTM D3577   | Tensile Strength (MPa)  | Min. 24  | Min. 18       |
|   |  | Ultimate Elongation (%)   | Min. 750   | Min. 560      |
|   | Stress at 500% (MPa)   | Max. 5.5  | N/A  |               |
| Shelf life (upon manufacturing date)  |  | 3 years   |  |               |
| Glove Cuff Printing   |  | The cuff of each glove is marked with 'PROFEEL', Hand and Size.   |  |               |
| Packing configuration   |  | 1 pair of gloves per inner wrapper, 1 inner wrapper per pouch, 50 pouches per dispenser, 4 dispensers per carton (Short Pack) |  |               |
| Pre-shipment Inspection<br>*Single-Normal Sampling Plan   | Standard/Parameters  |   | EN 455 Part 1,2,3  | ASTM D3577    |
|   | Dimension  |   | N=13, Median   | S-2, AQL 4.0  |
|   | Physical Properties  |   | N=13, Median   | S-2, AQL 4.0  |
|   | 1000ml Water Leak  |   | G-I, AQL 0.65  | G-I, AQL 0.65 |
|   | Powder Residue   |   | N=6  | N=5           |
|   | Protein Content  |   | N=8  | N=3           |
|   | Visual Inspection (Major Defects)  |   | G-I, AQL 1.5   | G-I, AQL 1.5  |
| Visual Inspection (Minor Defects)   |  | G-I, AQL 2.5  | G-I, AQL 2.5   |               |
| <b>Product Conformance</b>  |  |   |  |               |
| Medical Device  | EU Compliance: MDR (EU) 2017/745 (CE Class IIa)  |   | EN 455 Part 1,2,3,4  |               |
|   | UK Compliance: UK Medical Device Regulations 2002 Part II (UKCA Class IIa)                     |   |  |               |
|   | US FDA: 510(k): K021784 MDL: D036513   |   | ASTM D3577   |               |
| Personal Protective Equipment   | EU Compliance: PPE Regulation EU 2016/425 (PPE Cat.III)  |   | EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 & ISO 16604:2004 |               |
|   | UK Compliance: Regulation 2016/425 on personal protective equipment, as amended to apply in GB |   |  |               |
| Glove Marking   | Medical Device: CE 2797<br>PPE: CE 2797 & UKCA 0086  |   |  |               |
| Others  | Health Canada Compliance   |   |  |               |
| <b>Quality Assurance &amp; Environment Management System</b>  |  |   |  |               |
| <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 Quality Management System – Regulatory Purpose</li> <li>ISO 14001:2015 Environmental Management System</li> </ul> |  |   |  |               |

WRP ASIA PACIFIC SDN. BHD.



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