***DATA SHEET***

**PROFEEL®**
**DHD™ Micro Powder Free**
**Latex Surgical Gloves**

## Powder Free Latex Surgical Glove

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|---|---|---|
| Reorder#/Size | | 5½ : P3355-34 7½ : P3375-34<br>6 : P3360-34 8 : P3380-34<br>6½ : P3365-34 8½ : P3385-34<br>7 : P3370-34 9 : P3390-34 |
| Design and Features | | Hand specific, curved fingers, Bisque-Finish and beaded cuff |
| Type | | Microsurgical, powder free, polymer coated – DHD™-technology (damp-hand-donning) – and gamma-sterilized surgical glove |
| Material | | Natural rubber latex |
| Colour | | Brown |
| Surface Treatment | | Polymer coating for easy donning |
| Protein Content (µg/g) | | ≤ 50 |
| Powder Residues (mg/glove) | | ≤ 2 (powder free) |
| Dimensions – Palm width (mm) | | 5½ : 72 ± 4 7½ : 95 ± 5<br>6 : 77 ± 5 8 : 102 ± 6<br>6½ : 83 ± 5 8½ : 108 ± 6<br>7 : 89 ± 5 9 : 114 ± 6 |
| Dimensions - Length (mm) | | 5½ : min. 278 7½ : min. 287<br>6 : min. 280 8 : min. 288<br>6½ : min. 280 8½ : min. 290<br>7 : min. 283 9 : min. 290 |
| Single wall thickness (mm) | Finger<br>Palm<br>Cuff | Specification / Typical Value<br>0.18 ± 0.03 — 0.18<br>0.15 ± 0.03 — 0.16<br>0.13 ± 0.03 — 0.14 |
| Physical Properties | Tensile Strength (MPa)<br>Elongation (%)<br>Force at break (N) - specification<br>Typical Force at break (N) | Before aging / After aging<br>: min. 24 — : min. 18<br>: min. 750 — : min. 560<br>: min. 12 — : min. 9<br>: 16.5 — : 15.0 |
| Packing mode | Inner Wrapper<br>Pouch<br>Dispenser<br>Outer carton | 1 pair of gloves<br>1 inner wrapper<br>50 pouches<br>4 dispensers |
| Glove marking | | The cuff of each glove is marked with"PROFEEL" and the respective hand (L/R) & size |
| Lot number | | Lot number structure: YMMPPPPSS<br>Y = year of packing P = internal reference no.<br>MM = month of packing SS = size |
| Shelf life | | 3 years from date of manufacture |
| Pre-shipment Quality Inspection | Dimensions<br>Physical Properties<br>1000ml Water Leak<br>Major Visual Inspection<br>Minor Visual Inspection<br>Protein Content<br>Powder Residues | N=13 (EN 455-2)<br>N=13 (EN 455-2)<br>G-I, AQL 0.65 (EN 455-1)<br>G-I, AQL 1.5<br>G-I, AQL 4.0<br>N=8 (EN 455-3)<br>N=3 pairs (EN 455-3) |
| Product Conformance | | • Medical Device in compliance with European Medical Device Directive 93/42/EEC (CE Class IIa): EN 455 Parts 1, 2, 3 & 4<br>• Personal Protection Equipment in compliance with European Regulation (EU) 2016/425 (category III, type tested to EN ISO 21420:2020, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016), CE 2797<br>• Regulation 2016/425 on personal protective equipment, as amended to apply in GB (in UK), UKCA 0086<br>• ASTM D3577 |
| Quality Assurance | | • ISO 9001<br>• ISO 13485 Quality Management System<br>• ISO 14001 Environmental Management System<br>• US FDA Quality System Regulation (QSR) |

*Note: The above information is a guideline of typical performance values and characteristics of the product and not to be used as actual product specifications.*