

**DATA SHEET**

**PROFEEL®**

DHD™ Platinum

Powder Free Surgical Gloves

**Powder Free Latex Surgical Glove**

Reorder#/Size		5½ : P3355-01      7½ : P3375-01 6 : P3360-01      8 : P3380-01 6½ : P3365-01      8½ : P3385-01 7 : P3370-01      9 : P3390-01
Design and Features		Hand specific, straight fingers, Bisque-Finish and beaded cuff
Type		Powder free, polymer coated – DHD™-technology (damp-hand-donning) – and gamma-sterilized surgical glove
Material		Natural rubber latex
Colour		Natural
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 6 : 77 ± 5      8 : 102 ± 6 6½ : 83 ± 5      8½ : 108 ± 6 7 : 89 ± 5      9 : 114 ± 6
Dimensions - Length (mm)		5½ : min. 278      7½ : min. 287 6 : min. 280      8 : min. 288 6½ : min. 280      8½ : min. 290 7 : min. 283      9 : min. 290
Single wall thickness (mm)	Finger	<u>Specification</u> <u>Typical Value</u>
	Palm	0.21 ± 0.03      0.21
	Cuff	0.19 ± 0.03      0.18
		0.15 ± 0.03      0.15
Physical Properties	Tensile Strength (MPa)	Before aging : min. 24      After aging : min. 18
	Elongation (%)	: min. 750      : min. 560
	Force at break (N) - specification	: min. 9      : min. 9
	Typical Force at break (N)	: 18.5      : 16.0
Packing mode	Inner Wrapper	1 pair of gloves
	Pouch	1 inner wrapper
	Dispenser	50 pouches
	Outer carton	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 Y = year of packing      P = internal reference no. MM = month of packing      SS = size
Shelf life		3 years from date of manufacture
Pre-shipment Quality Inspection	Dimensions	N=13 (EN 455-2)
	Physical Properties	N=13 (EN 455-2)
	1000ml Water Leak	G-I, AQL 0.65 (EN 455-1)
	Major Visual Inspection	G-I, AQL 1.5
	Minor Visual Inspection	G-I, AQL 4.0
	Protein Content	N=8 (EN 455-3)
Powder Residues	N=3 pairs (EN 455-3)	
Product Conformance		<ul style="list-style-type: none"> <li>Medical Device in compliance with European Medical Device Directive 93/42/EEC (CE Class IIa): EN 455 Parts 1, 2, 3 &amp; 4</li> <li>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</li> <li>Regulation 2016/425 on personal protective equipment, as amended to apply in GB (in UK), UKCA 0086</li> <li>ASTM D3577</li> </ul>
Quality Assurance		<ul style="list-style-type: none"> <li>ISO 9001</li> <li>ISO 13485 Quality Management System</li> <li>ISO 14001 Environmental Management System</li> <li>US FDA Quality System Regulation (QSR)</li> </ul>

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.