

DATA SHEET

PROFEEL®

DHD™ EXTRA PROTECTION

Powder Free Latex Surgical Gloves

Powder Free Latex Surgical Glove

Reorder#/Size	5½ : P3355-35 7½ : P3375-35 6 : P3360-35 8 : P3380-35 6½ : P3365-35 8½ : P3385-35 7 : P3370-35 9 : P3390-35	
Design and Features	Hand specific, curved fingers, Bisque-Finish and beaded cuff	
Type	Extra thick, 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 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 Palm Cuff	<u>Specification</u> 0.34 ± 0.03 0.29 ± 0.03 0.21 ± 0.03 <u>Typical Value</u> 0.32 0.28 0.22
Physical Properties	Tensile Strength (MPa) Elongation (%) Force at break (N) - specification Typical Force at break (N)	Before aging : min. 24 After aging : min. 18 : min. 750 : min. 560 : min. 12 : min. 9 : 24.0 : 22.0
Packing mode	Inner Wrapper Pouch Dispenser Outer carton	1 pair of gloves 1 inner wrapper 40 pouches 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	5 years from date of manufacture	
Pre-shipment Quality Inspection	Dimensions Physical Properties 1000ml Water Leak Major Visual Inspection Minor Visual Inspection Protein Content Powder Residues	N=13 (EN 455-2) N=13 (EN 455-2) G-I, AQL 0.65 (EN 455-1) G-I, AQL 1.5 G-I, AQL 4.0 N=8 (EN 455-3) N=3 pairs (EN 455-3)
Product Conformance	- Medical Device in compliance with European Medical Device Regulation (EU) 2017/745 (CE Class IIa): EN 455 Parts 1, 2, 3 & 4 - 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 - Regulation 2016/425 on personal protective equipment, as amended to apply in GB (in UK), UKCA 0086 - ASTM D3577	
Quality Assurance	- ISO 9001 - ISO 13485 Quality Management System - ISO 14001 Environmental Management System - 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.