

DATA SHEET

PROFEEL®

DOUBLE GLOVING SYSTEM

FOR PUNCTURE DETECTION

DHD NON - LATEX SURGICAL UNDERGLOVE AND OVERGLOVE

Powder Free & Latex Free Overglove & Underglove

Reorder#/Size		5½ : P3355-62 6 : P3360-62 6½ : P3365-62 7 : P3370-62	7½ : P3375-62 8 : P3380-62 8½ : P3385-62
Design and Features		Overglove: Hand specific, straight fingers, Bisque-Finish and beaded cuff Underglove: Hand specific, straight fingers, smooth finish for easy double gloving and beaded cuff One pouch contains one pair of overgloves as per size printed on the packaging and one pair of undergloves half a size larger.	
Type		Overglove & Underglove: Powder free, polymer coated – DHD™-technology (damp-hand-donning) – and gamma-sterilized surgical glove	
Material		Overglove & Underglove: Polyisoprene	
Colour		Overglove: Natural; Underglove: Green	
Surface Treatment		Overglove: Polymer coating for easy donning. Underglove: Polymer coating for easy donning. The outer surface is smooth.	
Powder Residues (mg/glove)		Overglove & Underglove: ≤ 2 (powder free)	
Dimensions – Palm width (mm)		Overglove & Underglove 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)		Overglove & Underglove 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	Overglove 0.22 ± 0.03 0.18 ± 0.03 0.14 ± 0.03	Underglove 0.20 ± 0.03 min. 0.15 min. 0.13
Physical Properties	Before Aging Tensile Strength (MPa) Elongation (%) Force at break (N)	Overglove min. 24 min. 750 min. 9	Underglove min. 24 min. 750 min. 9
	After Aging Tensile Strength (MPa) Elongation (%) Force at break (N)	Overglove min. 18 min. 560 min. 9	Underglove min. 18 min. 560 min. 9
Packing mode	1 st Inner Wrapper 2 nd Inner Wrapper Pouch Dispenser Outer carton	1 pair of overgloves 1 pair of undergloves 1 inner wrapper 25 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 Inspection	Quality Dimensions Physical Properties 1000ml Water Leak Major Visual Inspection Minor Visual Inspection 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=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.