Data Sheet

PROFEEL® DOUBLE GLOVING SYSTEM FOR PUNCTURE DETECTION
DHD NON - LATEX SURGICAL UNDERGLOVE AND OVERGLOVE

Powder Free Non-Latex Surgical Gloves, Sterile

Reorder #		Size: 5½ : P3355-62; 6 : P3360-62; 6½ : P3365-62; 7 : P3370-62; 7½ : P3375-62; 8 : P3380-62; 8½ : P3385-62
Product Part #		362xx.104121025
Design and Feature		*Overglove*: Hand Specific, curved fingers, bisque finish (SH3) and beaded cuff *Underglove*: Hand Specific, curved 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*: Powder free, polymer coated, damp-hand-donnable (DHD™) and Gamma-sterilized surgical gloves *Underglove*: Powder free, polymer coated, damp-hand-donnable (DHD) and Gamma-sterilized surgical gloves
Material		*Overglove & Underglove*: Polyisoprene
Color		*Overglove*: Natural / *Underglove*: Green
Surface Treatment		*Overglove*: Polymer coating on inner surface to ease donning *Underglove*: Polymer coated on inner surface to ease donning. Outer surface is smooth
Powder Free Residue (mg/glove)		*Overglove & Underglove*: ≤ 2
Protein Content (µg/dm²)		*Not applicable*
Dimension - Palm Width (mm)		*Overglove & Underglove*: Size: 5½ : 72±4; 6 : 77±5; 6½ : 83±5; 7 : 89±5; 7½ : 95±5; 8 : 102±6; 8½ : 108±6
Dimension - Length (mm)		*Overglove & Underglove*: Size: 5½ : Min 278; 6 : Min 280; 6½ : Min 280; 7 : Min 283; 7½ : Min 287; 8 : Min 288; 8½ : Min 290
Single-wall Thickness (mm)	Finger Palm Cuff	*Overglove* 0.24 ± 0.02 0.20 ± 0.02 0.16 ± 0.02
		Underglove 0.20 ± 0.02 Min. 0.15 Min. 0.13
Physical Properties	<u>Before Aging</u> Tensile Strength (MPa) Elongation (%) Force at Break (N)	*Overglove* Min. 17 Min. 650 Min. 9
		Underglove Min. 17 Min. 650 Min. 9
	<u>After Aging</u> Tensile Strength (MPa) Elongation (%) Force at Break (N)	*Overglove* Min. 12 Min. 490 Min. 6
		Underglove Min. 12 Min. 490 Min. 6
Packing Mode	Inner Wallet Inner Wallet Pouch Dispenser Carton	1 Pair of Overgloves in 1 Inner Wallet 1 Pair of Undergloves in 1 Inner Wallet 1 Inner Wallet of Overgloves + 1 Inner Wallet of Undergloves in 1 Pouch 25 Pouches in 1 Dispenser 4 Dispensers in 1 Outer Carton
Glove Marking		The cuff of each glove is marked with 'WRP', 'Hand & Size'
Lot # identification on Finished Goods		Lot Number Structure: **YMMPPPPSS** Y = Year of Packing; MM = Month of Packing; P = WRP's PWO; SS = Size
Product Shelf Life		5 years upon manufactured date.
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Powder Free Residue Major Visual Inspection Minor Visual Inspection	N=13 (EN455-2); S-2, AQL 4.0 (ASTM D3577) N=13 (EN455-2); S-2, AQL 4.0 (ASTM D3577) G-I, AQL 0.65 N=3 pairs G-I, AQL 1.5 G-I, AQL 4.0
Product Conformance		• EN455 Parts 1, 2 & 3 - In compliance with European Medical Device Directive 93/42/EEC (CE Class IIa) • ASTM D3577 • In compliance with the provisions of Regulation (EU) 2016/425 and type tested to EN420:2003+AI:2009, EN ISO 374-1:2016, EN374-2:2014, EN 16523-1:2015, EN374-4:2013 and EN ISO 374-5:2016, CE2797
Quality Assurance		• US FDA Quality System Regulation (QSR) • EN ISO9001:2015 • EN ISO13485:2016 & ISO13485:2016 Quality Management Systems

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