DATA SHEET

DERMAGRIP® SafeDon™ Ultra LT SafeDon™

NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Reorder #	Size: :	XS S M L XL	D1500-80 D1501-80 D1502-80 D1503-80 D1504-80
Product Part #			1120x.10861750 (PMS 292)
510K # / MDL #			K133168/ D222519
Design and Feature			Ambidextrous, textured surface at fingers (E1)/(E4) and beaded cuff
Type			Powder free and non-sterile examination gloves
Material			100% nitrile (Acrylonitrile-butadiene)
Color			Blue (PMS292)
Surface Treatment			Chlorination on donning side
Powder Free Residue (mg/glove)			≤ 2
Dimension	Size: :	XS S M L XL	Palm Width (mm) / Length (mm) ≤80 / Min. 240 80 ± 10 / Min. 240 95 ± 10 / Min. 240 110 ± 10 / Min. 240 ≥110 / Min. 240
Single-wall Thickness (mm) *All sizes		Finger Palm Cuff	Spec Min. 0.07 Min. 0.06 Min. 0.05
Physical Properties	Spec Tensile Strength (MPa) Elongation (%) Force at Break (N)		Before Aging / After Aging Min 14 / Min 14 Min 500 / Min 400 Min 6 / Min 6
Packing Mode			250 gloves by weight (XS-L) per dispenser 240 gloves by weight (XL) per dispenser 8 dispensers per carton
Glove Marking			No marking.
Lot # identification on Finished Goods			Lot Number Structure: YMMPPPPSS (9 digits) Y = Year of Packing MM = Month of Packing PPPP = WRP's Packing Work Order # (PWO) SS = Size (00=XS, 01=S, 02=M, 03=L and 04=XL)
Recommended Shelf Life			5 years upon manufactured date.
Pre-shipment Inspection *Single-Normal Sampling Plan	Dimension Physical Properties 1000ml Water Leak Powder Free Residue Major Visual Inspection Minor Visual Inspection		N=13, Median; S-2, AQL 4.0 N=13, Median; S-2, AQL 4.0 G-I, AQL 1.5 N=5 G-I, AQL 2.5 G-I, AQL 4.0
Product Conformance			• Medical Device: in compliance with European MDR (EU) 2017/745 (CE Class I) • EN455 Parts 1, 2, 3 and 4 • Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, type tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type b, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 & EN 16523-1:2015, CE 2797 • ASTM D6319
Quality Assurance			• US FDA Quality System Regulation (QSR) • ISO9001:2015 Quality Management Systems • EN ISO13485:2016 & EN 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.