DERMAGRIP® NITRILE EXAMINATION GLOVES ULTRA PLUS SafeDon®

NITRILE ULTRA PLUS EXAMINATION GLOVES, POWDER FREE, NON-STERILE

PRODUCT CODE		Size XS : D1400-32 S : D1401-32 M : D1402-32	L : D1403-32 XL : D1404-32	
Product Number/SKU		142xx.102511062		
GLOVE TYPE		4.4gms, 270mm, Finger Textured, Powder Free Nitrile Exam Gloves, Non-sterile		
510K # / MDL #		N/A		
Design and Feature		Ambidextrous, Finger textured (E4) and beaded cuff		
Type		Powder free and non-sterile examination gloves		
Material		100% nitrile (Acrylonitrile-butadiene)		
Color		Blue (PMS285)		
Surface Treatment		Chlorination on donning side		
Powder Free Residue (mg/glove)		≤ 2		
Dimension (mm)	Size: : XS S M L XL	Palm Width ≤ 80 80 ± 10 95 ± 10 110 ± 10 ≥ 110	Length Min. 270 Min. 270 Min. 270 Min. 270 Min. 270	Weight (gms) TBA 4.0 ± 0.3 4.4 ± 0.3 5.2 ± 0.3 5.5 ± 0.3
Single-wall Thickness (mm) **All sizes*	Finger Palm Cuff	Spec 0.11 ± 0.02 0.08 ± 0.02 0.07 ± 0.02		
Physical Properties	Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% Force at Break (N)	Before Aging Spec Min. 14 Min. 500 N/A ≥ 6	After Aging Spec Min. 14 Min. 400 N/A ≥ 6	
Packing Mode		200 gloves (XS to L) and 180 gloves (XL) (by weight per dispenser.) 8 dispensers per carton /shipping case		
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	EN Standard N=13, Median N=13, Median G-I, AQL 1.5 N=5 G-I, AQL 2.5 G-I, AQL 4.0	ASTM Standard S-2, AQL 4.0 S-2, AQL 4.0 G-I, AQL 1.5 N=5 G-1, AQL 2.5 G-1, AQL 4.0	
Product Conformance		• Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013 & EN ISO 374-5:2016, CE2797; CE Class I Medical Device, in compliance with MDR (EU) 2017/745, type tested to EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 • ASTM D6319		
Quality Assurance		• US FDA Quality System Regulation (QSR) • ISO9001:2005 Quality Management Systems • 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 specification.