



DATA SHEET



EDUO Diamond Nitrile Powder Free Gloves

Size / Reorder#	Orange	Blue	Black	Green
Small	E105-01-Orange	E105-01-Blue	E105-01-Black	E105-01-Green
Medium	E105-02-Orange	E105-02-Blue	E105-02-Black	E105-02-Green
Large	E105-03-Orange	E105-03-Blue	E105-03-Black	E105-03-Green
Extra Large	E105-04-Orange	E105-04-Blue	E105-04-Black	E105-04-Green
Extra Extra Large	E105-05-Orange	E105-05-Blue	E105-05-Black	E105-05-Green
510K Number & MDL Number	K192635 & D369611	K161422 & D278303 (With chemo claims)	K210330 & D468140 (With chemo & fentanyl claims)	K951938 & D036492
Design and Feature	Ambidextrous, diamond embossed at palm and back of hand			
Type	Powder free and non-sterile			
Material	100% Nitrile (Acrylonitrile-butadiene)			
Colour	Orange, Blue, Black, and Green			
Surface Treatment	Polymer coating and chlorination			
Powder Residue (mg/glove)	≤ 2			
Size / Dimension	Target weight (g per pcs)	Palm Width (mm)	Length (mm)	
Small	9.8 ± 0.3	85 ± 5	Min. 290	
Medium	10.5 ± 0.3	97 ± 5	Min. 290	
Large	11.2 ± 0.3	108 ± 5	Min. 290	
Extra Large	11.9 ± 0.3	115 ± 5	Min. 290	
Extra Extra Large	12.6 ± 0.3	124 ± 5	Min. 290	
	<i>*Non-release criteria</i>			
Single-wall Thickness (mm)	Smooth area		Textured area	
Finger	0.22 ± 0.03		0.26 ± 0.03	
Palm	0.20 ± 0.03		0.23 ± 0.03	
*All sizes Cuff	0.13 ± 0.03		0.13 ± 0.03	
	<i>*Non-release criteria</i>		<i>*Release criteria</i>	
Physical Properties	Unaged		Aged	
Tensile Strength (MPa)	Min.18		Min.14	
Elongation (%)	Min. 500		Min. 400	
Force at break (N)	≥ 6		≥ 6	
Packing Mode	50 gloves by weight and 10 dispenser per carton			
Glove Marking	No marking			
Lot # Identification on Finished Goods	Lot Number Structure : YMMPPPPSS (9 Digits) Y = Year of packing (e.g. 2 for year 2022, 3 for year 2023, etc.) MM = Month of packing (e.g. 09 for Sept., 10 for Oct., etc.) PPPP = WRP's Packing Work Order# (PWO) SS = Size (01=S, 02=M, 03=L, 04=XL and 05=XXL)			
Shelf Life Claim	5 years upon manufacturing date			
Pre-shipment Inspection	Dimension	N=13, Median; S-2 AQL 4.0		
	Physical Properties	N=13, Median; S-2 AQL 4.0		
	1000ml Water Leak	G-I, AQL 1.5		
*Single-Normal Sampling Plan	Powder Residue	N=5		
	Major Visual Inspection	G-I, AQL 2.5		
	Minor Visual Inspection	G-I, AQL 4.0		
Product Conformance	<ul style="list-style-type: none"> Medical Device: in compliance with MDR (EU)2017/745 (CE Class I) EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, CE2797 EN 455: Part 1/2/3/4 ASTM D6319 ASTM D6978 (Chemotherapy testing) Food Safe Compliance <ul style="list-style-type: none"> FDA 21 CFR 177.2600: Orange, Blue, Black & Green EU No. 10/2011: Orange, Blue & Black 			
Quality Assurance	<ul style="list-style-type: none"> MDSAP ISO 13485:2016 Quality Management System ISO 9001:2015 Quality Management System EN ISO 13485:2016 			

Note: The above information is a guideline of typical performance values and characteristics of the product.

WRP ASIA PACIFIC SDN. BHD.



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