



DATA SHEET



EDUO Diamond Nitrile Powder Free Gloves

Size / Reorder#	Orange	Blue	Black	Green
Small	E65-01-Orange	E65-01-Blue	E65-01-Black	E65-01-Green
Medium	E65-02-Orange	E65-02-Blue	E65-02-Black	E65-02-Green
Large	E65-03-Orange	E65-03-Blue	E65-03-Black	E65-03-Green
Extra Large	E65-04-Orange	E65-04-Blue	E65-04-Black	E65-04-Green
Extra Extra Large	E65-05-Orange	E65-05-Blue	E65-05-Black	E65-05-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	<u>Target weight (g per pcs)</u>	<u>Palm Width (mm)</u>	<u>Length (mm)</u>	
Small	6.1 ± 0.3	85 ± 5	Min. 240	
Medium	6.5 ± 0.3	97 ± 5	Min. 240	
Large	6.9 ± 0.3	108 ± 5	Min. 240	
Extra Large	7.3 ± 0.3	115 ± 5	Min. 240	
Extra Extra Large	7.7 ± 0.3	124 ± 5	Min. 240	
	<i>*Non-release criteria</i>			
Single-wall Thickness (mm) <i>*All sizes</i>	Finger Palm Cuff	<u>Smooth area</u>		<u>Textured area</u>
		0.12 ± 0.03		0.16 ± 0.03
		0.11 ± 0.03		0.14 ± 0.03
		Min. 0.08		Min. 0.08
		<i>*Non-release criteria</i>		<i>*Release criteria</i>
Physical Properties	Tensile Strength (MPa) Elongation (%) Force at break (N)	<u>Unaged</u>		<u>Aged</u>
		Min. 18		Min. 14
		Min. 500		Min. 400
		≥ 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 <i>*Single-Normal Sampling Plan</i>	Dimension Physical Properties 1000ml Water Leak Powder Residue Major Visual Inspection Minor Visual Inspection	N=13, Median; S-2, AQL 4.0 N=13, Median; S-2, AQL 4.0 G-1, AQL 1.5 N=5 G-1, AQL 2.5 G-1, AQL 4.0		
Product Conformance	<ul style="list-style-type: none"> <li>Medical Device: in compliance with MDR (EU)2017/745 (CE Class I)</li> <li>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</li> <li>EN 455: Part 1/2/3/4</li> <li>ASTM D6319</li> <li>ASTM D6978 (Chemotherapy testing)</li> <li>Food Safe Compliance               <ul style="list-style-type: none"> <li>FDA 21 CFR 177.2600: Orange, Blue, Black &amp; Green</li> <li>EU No. 10/2011: Orange, Blue &amp; Black</li> </ul> </li> </ul>			
Quality Assurance	<ul style="list-style-type: none"> <li>MDSAP ISO 13485:2016 Quality Management System</li> <li>ISO 9001:2015 Quality Management System</li> <li>EN ISO 13485:2016</li> </ul>			

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

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