



DATA SHEET



**NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE**

Reorder #	Size : XS S M L XL	D1500-84 D1501-84 D1502-84 D1503-84 D1504-84												
Product Part #	112xx.105611028													
510K # / MDL #	N/A													
Design and Feature	Ambidextrous, textured surface at fingers (E1) 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	<table border="1"> <tr> <td><u>Palm Width</u></td> <td><u>Length</u></td> </tr> <tr> <td>≤80</td> <td>Min. 240</td> </tr> <tr> <td>80 ± 10</td> <td>Min. 240</td> </tr> <tr> <td>95 ± 10</td> <td>Min. 240</td> </tr> <tr> <td>110 ± 10</td> <td>Min. 240</td> </tr> <tr> <td>≥110</td> <td>Min. 240</td> </tr> </table>	<u>Palm Width</u>	<u>Length</u>	≤80	Min. 240	80 ± 10	Min. 240	95 ± 10	Min. 240	110 ± 10	Min. 240	≥110	Min. 240
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Single-wall Thickness (mm) *All sizes	Finger Palm Cuff	<table border="1"> <tr> <td><u>Spec</u></td> </tr> <tr> <td>Min. 0.05</td> </tr> <tr> <td>Min. 0.05</td> </tr> <tr> <td>Min. 0.05</td> </tr> </table>	<u>Spec</u>	Min. 0.05	Min. 0.05	Min. 0.05								
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Physical Properties	Tensile Strength (MPa) Elongation (%) Force at Break (N)	<table border="1"> <tr> <td><u>Before Aging</u></td> <td><u>After Aging</u></td> </tr> <tr> <td>Min 14</td> <td>Min 14</td> </tr> <tr> <td>Min 500</td> <td>Min 400</td> </tr> <tr> <td>≥ 6</td> <td>≥ 6</td> </tr> </table>	<u>Before Aging</u>	<u>After Aging</u>	Min 14	Min 14	Min 500	Min 400	≥ 6	≥ 6				
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Min 14	Min 14													
Min 500	Min 400													
≥ 6	≥ 6													
Packing Mode	250 gloves by weight (240 for XL) per dispenser and 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	<ul style="list-style-type: none"> <li>Medical Device: In compliance with European MDR (EU) 2017/745 (CE CLASS I)</li> <li>EN455 Parts 1, 2, 3 and 4</li> <li>Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016 &amp; EN 16523-1:2015, CE 2797</li> <li>ASTM D6319</li> </ul>													
Quality Assurance	<ul style="list-style-type: none"> <li>US FDA Quality System Regulation (QSR)</li> <li>ISO9001:2015 Quality Management Systems</li> <li>EN ISO13485:2016 and ISO13485:2016 Quality Management Systems</li> </ul>													

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.