



DATA SHEET

DERMAGRIP[®] Ultra

NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Reorder #	Size : XS S M L XL	D1500-18 D1501-18 D1502-18 D1503-18 D1504-18												
Product Part #	112xx.103711064													
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 (PMS 285 & PMS 292)													
Surface Treatment	Chlorination on donning side													
Powder Free Residue (mg/glove)	≤ 2													
Dimension	Size : XS S M L XL	<table border="1"> <thead> <tr> <th>Palm Width (mm)</th> <th>Length (mm)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Palm Width (mm)	Length (mm)	≤80	Min. 240	80 ± 10	Min. 240	95 ± 10	Min. 240	110 ± 10	Min. 240	≥110	Min. 240
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	<u>Spec</u> Min. 0.09 Min. 0.06 Min. 0.05												
Physical Properties	Spec Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% Force at Break (N)	<table border="1"> <thead> <tr> <th>Before Aging</th> <th>After Aging</th> </tr> </thead> <tbody> <tr> <td>Min 14</td> <td>Min 14</td> </tr> <tr> <td>Min 500</td> <td>Min 400</td> </tr> <tr> <td>N/A</td> <td>N/A</td> </tr> <tr> <td>≥ 6</td> <td>≥ 6</td> </tr> </tbody> </table>	Before Aging	After Aging	Min 14	Min 14	Min 500	Min 400	N/A	N/A	≥ 6	≥ 6		
Before Aging	After Aging													
Min 14	Min 14													
Min 500	Min 400													
N/A	N/A													
≥ 6	≥ 6													
Packing Mode	100 gloves (by weight) per dispenser and 10 dispensers per carton 150 gloves (by weight) per dispenser and 10 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"> 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	<ul style="list-style-type: none"> US FDA Quality System Regulation (QSR) ISO9001:2015 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 specifications.