# DERMAGRIP®-D

## For Dental & Diagnostic Procedures, NR Latex Powder Free Gloves

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|---|---|---|---|
| Reorder # | | Size: 5 ½ : D3155-44<br>6 : D3160-44<br>6 ½ : D3165-44<br>7 : D3170-44 | Size: 7 ½ : D3175-44<br>8 : D3180-44<br>8 ½ : D3185-44<br>9 : D3190-44 |
| Product Part # | | 312xx.10991050 | |
| 510K # / MDL # | | N/A | |
| Design and Feature | | Hand specific, straight fingers, textured surface at palm and fingers area and beaded cuff | |
| Type | | Powder free, chlorinated and non-sterile procedure gloves | |
| Material | | Natural rubber latex | |
| Color | | Natural to yellow | |
| Surface Treatment | | Light chlorination on both donning & application surfaces (1G-SBS) | |
| Protein Content | | This latex glove contains 50 microgram or less of total extractable protein per gram | |
| Powder Free Residue (mg/glove) | | ≤ 2 | |
| Dimension – Palm Width (mm) | | Size: 5 ½ : 72 ± 4<br>6 : 77 ± 5<br>6 ½ : 83 ± 5<br>7 : 89 ± 5 | Size: 7 ½ : 95 ± 5<br>8 : 102 ± 6<br>8 ½ : 108 ± 6<br>9 : 114 ± 6 |
| Dimension – Length (mm) | | Size: 5 ½ : 278<br>6 : 280<br>6 ½ : 280<br>7 : 283 | Size: 7 ½ : 287<br>8 : 288<br>8 ½ : 290<br>9 : 290 |
| Single-wall Thickness (mm) | Finger<br>Palm<br>Cuff | Min. 0.26<br>Min. 0.22<br>Min. 0.17 | |
| Physical Properties | Tensile Strength (MPa)<br>Ultimate Elongation (%)<br>Stress at 500% (MPa)<br>Force at Break (N) | (Before Aging) : min. 24<br>: min. 750<br>: max.5.5<br>: ≥ 6 | (After Aging) : min. 18<br>: min. 560<br>: Not applicable<br>: ≥ 6 |
| Packing Mode | | 50 pairs per dispenser (25 pairs right and 25 pairs left)<br>6 dispensers per carton | |
| Glove Marking | | The cuff of each glove is marked with 'DERMAGRIP-D', 'Hand and Size'. | |
| Lot # identification on Finished Goods | | Lot Number Structure: YMMPPPPSS<br>Y = Year of Packing SS = Size<br>MM = Month of Packing<br>PPPP = WRP's (PWO) | |
| Recommended Shelf Life | | 3 years upon manufactured date. | |
| Pre-shipment Inspection | Dimension<br>Physical Properties<br>1000ml Water Leak<br>Minor Visual Inspection<br>Major Visual Inspection<br>Protein Content<br>Powder Free Residue | S-2, AQL 4.0<br>S-2, AQL 4.0<br>G-I, AQL 1.5<br>G-I, AQL 4.0<br>G-I, AQL 2.5<br>N=8<br>N=3 (pairs) | |
| 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<br>• ASTM D3578 | |
| Quality Assurance | | • US FDA Quality System Regulation (QSR)<br>• ISO9001:2015 Quality Management Systems<br>• 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*.