


Technical Data Sheet

# Signature™ Latex Essential

## Sterile Latex Powder-Free Surgical Gloves with Synthetic Polymer Coating

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| **Reference & Size** | |

| MSG5955 | MSG5960 | MSG5965 | MSG5970 | MSG5975 | MSG5980 | MSG5985 | MSG5990 |
|---|---|---|---|---|---|---|---|
| 5,5 | 6,0 | 6,5 | 7,0 | 7,5 | 8,0 | 8,5 | 9,0 |

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| **Primary Material** | Powder-Free Natural Rubber Latex with Synthetic Polymer Coating |
| **Donning Agent** | Synthetic Polymer Coating (Inner surface coated for dry and damp hand donning) |
| **Color** | Cream |
| **Grip** | Smooth |
| **Former (Mold) Design** | Anatomical to replicate hand shape and maximize comfort during long procedures |
| **Cuff Design** | Tapered, beaded cuff design to prevent rolldown |
| **Chemical Additives (Accelerators)** | Zinc Diethyldithiocarbamate (ZDEC), Zinc Dibutyldithiocarbamate (ZDBC)<br>Residual chemical levels below detectable level according to UPB/P/003a test method |
| **Leachable Protein (per EN455-3 using ASTM D5712 (Modified Lowry Protein Method)** | <50 micrograms/glove of total extractable protein, in accordance with EN 455-3 using Modified Lowry Protein Method.<br>**Caution: Safe use of these gloves by or on Latex-sensitized individuals has not been established** |
| **Thickness (per ASTM D3577 ≥ 0,10 mm)** | Finger Tip 0,21 mm<br>Cuff 0,14 mm |
| **Freedom from Holes (per EN 455 AQL 1.5)** | 0.65 AQL Final Inspection |
| **Viral Penetration** | Tested and passed, in accordance with ASTM F 1671 |
| **Chemical Resistance** | The resistance to some chemicals has been assessed in accordance with EN ISO 374-1<br>The resistance to chemo has been assessed in accordance with ASTM D 6978<br>Results and recommendations for use with chemicals can be obtained on request |
| **Sterilization** | Gamma Irradiation, Sterility Assurance Level 10-6 |

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| **Cuff Length (per EN455-2 ≥ 270 mm size 7.5)**<br>**Width** | <table><tr><th>MSG5955</th><th>MSG5960</th><th>MSG5965</th><th>MSG5970</th><th>MSG5975</th><th>MSG5980</th><th>MSG5985</th><th>MSG5990</th></tr><tr><td>280</td><td>283</td><td>282</td><td>281</td><td>282</td><td>284</td><td>283</td><td>281</td></tr><tr><td>73</td><td>78</td><td>83</td><td>88</td><td>97</td><td>103</td><td>108</td><td>114</td></tr></table> |
| **Force @ Break Before Challenge (per EN455-2 ≥ 9 N)** | 16,7 N |
| **Force @ Break After Challenge (per EN455-2 ≥ 9 N, 7 days 70°C in an oven)** | 15,7 N |
| **Elongation @ Break Before Accelerated Aging (per ASTM D3577 ≥ 650%)** | 883% |
| **Elongation @ Break After Accelerated Aging (per ASTM D3577 ≥ 490%, 7 days 70°C in an oven)** | 884% |
| **Expiration Date** | 35 Months from Date of Manufacture<br>Manufacture and Expiration Dates are printed on packaging (YYYY-MM format) |
| **Packaging** | Polyethylene peel pouch material protects product during transport and storage from moisture and ozone and prevents tearing when opening to maintain a sterile environment<br>Packaged in space-saving folded configuration<br>50 pairs per dispenser box / 4 boxes per carton / 200 pairs per carton |
| **Regulations and Quality Standards** | Medline manufacturing locations are certified to EN ISO 13485<br>Product meets requirements of the EU Medical Device Directive (93/42/EEC)<br>Product meets requirements of European harmonized standards EN 455-1,2,3,4 |
| **PPE Certification** | Under the requirements of Council Directive 89/686/EEC “Personal Protective Equipment” Category III. Complies with standards EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, ISO 374-5 and ISO 16604. |
| **Storage Recommendations** | Protect from freezing. Avoid excessive heat. Keep dry. Product should be shielded from direct sunlight, fluorescent lighting, X-rays, moisture and ozone. Do not store in temperatures above 40°C. |
| **Country of Origin** | Malaysia |
| **Legal Manufacturer** | Medline Industries, Inc. |
| **Manufacturer’s Address** | Medline Industries, Inc.<br>Three Lakes Drive<br>Northfield, IL 60093 |
| **European Office** | Medline Industries Ltd.<br>No 5 Booths Park<br>Chelford Road<br>Knutsford, Cheshire<br>United Kingdom WA16 8GS |

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