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Technical Data Sheet

OR Standard PF

Sterile Low-Protein Latex Powder-Free Surgical Gloves with Synthetic Polymer Coating

Reference & Size

MSG5255	MSG5260	MSG5265	MSG5270	MSG5275	MSG5280	MSG5285	MSG5290
5,5	6,0	6,5	7,0	7,5	8,0	8,5	9,0

V

Primary Material

Natural Rubber Latex with Synthetic Polymer Coating

Powder free in accordance with EN455-3 and ISO 21171

Caution: This product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.

Donning Agent

Synthetic Polymer Coating (Inner surface coated for dry and damp hand donning)

Color

Cream (Provides contrast when using a dark colored underglove)

Grip

Lightly Textured

Former (Mold) Design

Anatomical to replicate curved hand shape and minimize hand fatigue

Cuff Design

Tapered, beaded cuff design to prevent rolldown

Chemical Additives (Accelerators)

Zinc Diethyldithiocarbamate (ZDEC) and Zinc Dibutyldithiocarbamate (ZDBC)

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))

Below 50 micrograms/gram of total extractable protein

Hevein latex proteins below the limit of quantification according to FitKit third party testing per EN455-3 and ASTM D7427-16.

Caution: Safe use of these gloves by or on Latex-sensitized individuals has not been established

Thickness

(per ASTM D3577 \geq 0,10 mm)

Finger Tip	0.21 mm
Palm	0.19 mm
Cuff	0.17 mm



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Retention period: End of life and support period

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TDS_SurgicalGlove_MSG52xx-EN03

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Length (mm) & Width (mm) Per EN455-2

MSG5255	MSG5260	MSG5265	MSG5270	MSG5275	MSG5280	MSG5285	MSG5290
294	290	294	291	291	293	289	284
73	79	84	90	97	103	108	113

Force @ Break Before Challenge Testing (per EN455-2 ≥ 9 N)

14.6 N

Force @ Break After Challenge Testing (per EN455-2 ≥ 9 N, 7 days 70°C in an oven)

10.7 N

Freedom from Holes (per EN 455 AQL 1.5)

0,65 AQL Before Packaging
0,65 AQL Final Inspection

Viral Penetration

Tested and passed, in accordance with ISO16604 / ASTM F 1671

Chemical Resistance

The resistance to chemicals has been assessed in accordance with EN 16523-1 and chemo drugs under ASTM D 6978.

Results and recommendations for use with chemicals and chemo drugs can be obtained on request

Sterilization

Gamma Radiation, Sterility Assurance Level 10^{-6}

Expiration Date

35 Months from Date of Manufacture
Manufacture and Expiration Dates are printed on packaging (YYYY-MM format)

Packaging

Polyethylene peel pouch
Packaged in space-saving folded configuration
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 by BSI
Product meets requirements of the EU Medical Device Directive (93/42/EEC)
Product meets requirements of European harmonized standards EN 455-1, -2, -3 and -4

PPE Certification

Under the requirements of Personal Protective Equipment Regulation (EU)2016/425 Category III. Complies with standards EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5 and ISO 16604.

Storage Recommendations

Protect from freezing, avoid excessive heat. Shield from direct sunlight, fluorescent lighting, x-rays, moisture and ozone.

Manufacturer's Address

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