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Technical Data Sheet

OR Standard
Sterile Latex Powdered Surgical Gloves

Reference & Size

MSG4155	MSG4160	MSG4165	MSG4170	MSG4175	MSG4180	MSG4185	MSG4190
5,5	6,0	6,5	7,0	7,5	8,0	8,5	9,0

Primary Material

Natural Rubber Latex

Powder content: 150.3 mg/glove 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

Absorbable corn starch powder

Color

White (Provides contrast when using a dark colored under glove)

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)

<60 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 ≥ 0,10 mm)

Finger Tip	0.21 mm
Palm	0.19 mm
Cuff	0.16 mm

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STERILE R

Retention period: End of life and support period

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

MSG4155	MSG4160	MSG4165	MSG4170	MSG4175	MSG4180	MSG4185	MSG4190
285	285	286	285	285	284	281	282
70	79	84	89	95	102	108	110

Force @ Break Before Challenge Testing (per EN455-2 ≥ 9 N)	16.6 N
Force @ Break After Challenge Testing (per EN455-2 ≥ 9 N, 7 days 70°C in an oven)	12.6 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	Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093 USA.
European Office	Medline International BV Nieuwe Stationstraat 10 6811 KS Arnhem - The Netherlands

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