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Technical Data Sheet

DermAssure Green

Sterile Synthetic Polychloroprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

Reference & Size

MSG6555I	MSG6560I	MSG6565I	MSG6570I	MSG6575I	MSG6580I	MSG6585I	MSG6590I
5,5	6,0	6,5	7,0	7,5	8,0	8,5	9,0

Primary Material

Powder-Free Synthetic Polychloroprene (Neoprene) with Synthetic Polymer Coating
Powder Free in accordance with EN455-3 and ISO 21171

Donning Agent

Synthetic Polymer Coating "E-Z glide" as an inner Multiple layer donning technology with Poli acrylic and surfactant (Inner surface coated for dry and damp hand donning)

Color

Dark Green (Ideal as an under glove for identifying micro perforations and other breaches)

Grip

Smooth (Specially treated surface allows for effortless double donning)

Former (Mold) Design

Anatomical with straight fingers and independent thumb to replicate hand shape improving comfort and reducing hand fatigue.

Cuff Design

Tapered, beaded cuff design with special texture to adhere to the surgical gown to prevent roll down.

Chemical Additives (Accelerators)

Not Made with Chemical Accelerators

Leachable Protein

(per EN455-3 using ASTM D5712 (Modified Lowry Protein Method))

No natural rubber latex proteins and allergens.

Thickness

(per ASTM D3577 \geq 0,10 mm)

Finger Tip	0,21 mm
Palm	0,19 mm
Cuff	0,16 mm



2797 Medical device
0086 Personal Protective Equipment



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EN02

01.INT.03.30

Technical Data Sheet

DermAssure Green

Sterile Synthetic Polychloroprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

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

MSG6555I	MSG6560I	MSG6565I	MSG6570I	MSG6575I	MSG6580I	MSG6585I	MSG6590I
286	289	280	288	288	292	285	285
73	80	85	90	99	105	108	116

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

11.0 N

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

9.2 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.
Long pack configuration for easier aseptic donning.
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.

Country of Origin

Malaysia

Manufacturer's Address

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093 USA.

European Office

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Nieuwe Stationstraat 10
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