



www.medline.eu



## Technical Data Sheet

# Sensicare® PI

## Sterile Synthetic Isolex Polyisoprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

### Reference & Size

| MSG9055 | MSG9060 | MSG9065 | MSG9070 | MSG9075 | MSG9080 | MSG9085 | MSG9090 |
|---------|---------|---------|---------|---------|---------|---------|---------|
| 5,5     | 6,0     | 6,5     | 7,0     | 7,5     | 8,0     | 8,5     | 9,0     |

### Primary Material

Powder-Free Synthetic Isolex Polyisoprene 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 Polyacrylic and surfactant (Inner surface coated for dry and damp hand donning)

### Color

Cream

### Grip

Smooth

### 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)

Zinc Diethyldithiocarbamate (ZDEC), Zinc Mercaptobenzothiazole (ZMBT)  
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))

No natural rubber latex proteins and allergens.

### Thickness (per ASTM D3577 $\geq 0,10$ mm)

|            |         |
|------------|---------|
| Finger Tip | 0,23 mm |
| Palm       | 0,20 mm |
| Cuff       | 0,17 mm |



Retention period: End of life and support period

© 2020 Medline Industries Inc. or one of its subsidiaries. All rights reserved.

TDS\_SurgicalGlove\_MSG90xx-EN03

# Technical Data Sheet

## Sensicare® PI

Sterile Synthetic Isolex Polyisoprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

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

| MSG9055 | MSG9060 | MSG9065 | MSG9070 | MSG9075 | MSG9080 | MSG9085 | MSG9090 |
|---------|---------|---------|---------|---------|---------|---------|---------|
| 289     | 289     | 295     | 292     | 295     | 299     | 300     | 301     |
| 74      | 79      | 84      | 91      | 99      | 105     | 110     | 117     |

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

13,2 N

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

13,2 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<sup>-6</sup>

### 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



Retention period: End of life and support period

© 2020 Medline Industries Inc. or one of its subsidiaries. All rights reserved.

TDS\_SurgicalGlove\_MSG90xx-  
EN03