At Medisafe, we’ve been manufacturing Surgical gloves for the past 12 years. Our Surgical portfolio is entirely synthetic, just like our Exam portfolio. We manufacture Surgical SKU’s from one of two polymers: Isoprene or Chloroprene. Each material provides unique performance characteristics that mimic Surgical gloves made from Natural Rubber, but without the latex composition. This means they are perfect for use by latex-sensitive individuals or for use in latex-free environments.

When you source Surgical gloves, the focus on quality is paramount. We get it. Therefore, we follow a stringent quality ethos during the manufacturing process. All our Surgical gloves meet or exceed the relevant ASTM, EN and ISO standards and are manufactured under ISO 13485, US FDA QSR and CE-certification Quality Management Systems.

We don’t stop there. Every Surgical glove is 100% inspected to ensure we meet an AQL 0.65 standard. This way you can be assured that only the highest quality gloves arrive at your facility.

At Medisafe
Surgical Gloves
Are a Core Part
of what we do.

**OUR SURGICAL PORTFOLIO OFFERS**

- Proprietary anatomical former design for a more natural fit
- Polymer-coating finishes that allow for damp or dry-hand donning
- Textured fingers and palm for enhanced grip and control
- Ultra-low modulus for enhanced comfort and reduced hand fatigue
- Powder-free finish to eliminate post-operative complications caused by powder
- A minimum 300 mm cuff-length for extended coverage and protection
- A beaded cuff to reduce the risk of glove roll-down once worn

**PRODUCT CONFORMANCE**

Our Surgical gloves are manufactured in accordance with these standards:

- International: ISO 10282, ISO 13485 and ISO 10993
- ASTM D3577, FDA Quality Standard Regulation
- ASTM F1671: Resistance to Viral Penetration
- EN 455-3: Low Endotoxin Content (less than 20 EU per pair)
# SURGICAL SPECIFICATIONS (POWDER-FREE)

## ISOPRENE

<table>
<thead>
<tr>
<th>LENGTH</th>
<th>PRODUCT CODE</th>
<th>DONNING</th>
<th>WEIGHT</th>
<th>THICKNESS (SW) mm / mil</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mm / 11.8’ (Minimum)</td>
<td>JR-SIG-330</td>
<td>Polymer Coated</td>
<td>13.0 g</td>
<td>0.17 / 6.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TENSILE (MPa) BEFORE AGING</th>
<th>MODULUS @ 300% (MPa) MAXIMUM</th>
<th>ELONGATION % MINIMUM</th>
<th>COLOR AVAILABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 17</td>
<td>1.5</td>
<td>900</td>
<td>Natural White &amp; Dark Green</td>
</tr>
</tbody>
</table>

## CHLOROPRENE

<table>
<thead>
<tr>
<th>LENGTH</th>
<th>PRODUCT CODE</th>
<th>DONNING</th>
<th>WEIGHT</th>
<th>THICKNESS (SW) mm / mil</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mm / 11.8’ (Minimum)</td>
<td>CR-SIG-98</td>
<td>Polymer Coated</td>
<td>9.8 g</td>
<td>0.10 / 3.9</td>
</tr>
<tr>
<td>CR-SIG-330</td>
<td>CR-SIG-335</td>
<td>Polymer Coated</td>
<td>13.0 g</td>
<td>0.13 / 5.1</td>
</tr>
<tr>
<td>CR-SIG-335</td>
<td>CR-SIG-335</td>
<td>Polymer Coated</td>
<td>13.5 g</td>
<td>0.13 / 5.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TENSILE (MPa) BEFORE AGING</th>
<th>MODULUS @ 300% (MPa) MAXIMUM</th>
<th>ELONGATION % MINIMUM</th>
<th>COLOR AVAILABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 17</td>
<td>2.0 – 3.0</td>
<td>700</td>
<td>Natural White</td>
</tr>
<tr>
<td>&gt; 17</td>
<td>1.5</td>
<td>900</td>
<td>Natural White &amp; Mint Green</td>
</tr>
</tbody>
</table>

## QUALITY AQL STANDARDS

- Major Defects — Pinholes: 0.65
- Visual Inspection for Major Defects: 1.5
- Visual Inspection for Minor Defects: 4.0

## PACKAGING

- Standard: 50 gloves per dispenser
- 4 dispensers per case
- Custom: Per customer requirements

## QUALITY INSPECTIONS

Every glove is 100% tested and visually inspected for quality.

## STERILIZATION

- Gamma Irradiation (> 25kGy)
- Sterility Assurance Level (SAL): 10^-6

## RESIDUAL POWDER CONTENT

Conforms to ASTM D6124:
Less than 2 mg per glove residual powder

## SELECT GLOVES ARE TESTED FOR

- ASTM D6978: Permeation Resistance to Chemotherapy Drugs
- EN 374-3: Resistance to Chemical Permeation
- Can be manufactured without the use of Thiruams or DPG accelerators, known to cause Type IV chemical allergies
- Non-detectable residual levels for common Accelerator chemicals
- Test results are available upon request

Disposable hand protection solutions you can trust.

www.medisafe-tech.com

For further information, please contact us at contact@medisafe-tech.com. Specifications are subject to change without notice. Please contact your Medisafe Sales specialist to confirm specifications prior to ordering.