

Medisafe Technologies

Perfect Fit. Perfect Feel.

# SURGICAL GLOVES

A Premium Synthetic Portfolio Like No Other

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
- > European Medical Device Directive 93/42/EEC, European Council Directive for PPE 89/686/EEC and EN 455
- > ASTM F1671: Resistance to Viral Penetration
- > EN 455-3: Low Endotoxin Content (less than 20 EU per pair)

# SURGICAL SPECIFICATIONS (POWDER-FREE)

LENGTH	PRODUCT CODE	DONNING	WEIGHT	THICKNESS (SW) mm / mil			STANDARD SPECIFICATIONS	
				Cuff	Palm	Finger		
<b>ISOPRENE</b>  300 mm / 11.8" (Minimum)	IR-SG-130	Polymer Coated	13.0 g	0.17 / 6.7	0.22 / 8.7	0.24 / 9.5	<b>TEXTURE</b> Full  <b>SIZE</b> 5.5 – 9.0	
	<b>TENSILE (MPa) BEFORE AGING</b> > 17		<b>MODULUS @ 300% (MPa) MAXIMUM</b> 1.5		<b>ELONGATION % MINIMUM</b> 900			<b>COLOR AVAILABLE</b> Natural White & Dark Green
<b>CHLOROPRENE</b>  300 mm / 11.8" (Minimum)  CR-SG-98 & CR-SG-130 CR-SG-135	CR-SG-98	Polymer Coated	9.8 g	0.10 / 3.9	0.13 / 5.1	0.15 / 5.9		
	CR-SG-130	Polymer Coated	13.0 g	0.13 / 5.1	0.17 / 6.7	0.19 / 7.5		
	CR-SG-135	Polymer Coated	13.5 g	0.13 / 5.1	0.17 / 6.7	0.19 / 7.5		
	<b>TENSILE (MPa) BEFORE AGING</b> > 17		<b>MODULUS @ 300% (MPa) MAXIMUM</b> 2.0 – 3.0		<b>ELONGATION % MINIMUM</b> 700			<b>COLORS AVAILABLE</b> Natural White
<b>TENSILE (MPa) BEFORE AGING</b> > 17		<b>MODULUS @ 300% (MPa) MAXIMUM</b> 1.5		<b>ELONGATION % MINIMUM</b> 900		<b>COLORS AVAILABLE</b> Natural White & Mint Green		

## 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<sup>-6</sup>

## 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 Thiurams 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.**