



# ENCORE® Non-Latex PI Underglove

## SURGICAL GLOVES

### GENERAL DESCRIPTION

|                        |                                             |
|------------------------|---------------------------------------------|
| Material               | PI (Polyisoprene)                           |
| Powder Content         | Powder-Free                                 |
| Color                  | Green                                       |
| Shape                  | Anatomic with Curved Fingers                |
| Internal Glove Surface | Polymer Coated with DERMASHIELD™ Technology |
| External Glove Surface | Smooth with Micro-Textured Finish           |
| Cuff Style             | Beaded with SUREFIT™ Technology             |

### PHYSICAL PROPERTIES

| Thickness<br>Typical Average<br>(mm/mils) | Finger                        | Palm                         | Cuff                         |
|-------------------------------------------|-------------------------------|------------------------------|------------------------------|
|                                           | 0.20 ± 0.02<br>/ 7.87 ± 0.79  | 0.18 ± 0.02 /<br>6.89 ± 0.79 | 0.16 ± 0.02 /<br>6.10 ± 0.79 |
| Glove Length<br>Typical (mm/in)           | 303 / 11.9                    |                              |                              |
| Strength<br>Minimum                       | Before Aging / Fresh          |                              |                              |
|                                           | ASTM <sup>1</sup>             | EN <sup>2</sup>              | ISO <sup>3</sup>             |
| Elongation At Break (%)                   | -                             | -                            | -                            |
| Force At Break (N)                        | -                             | ≥ 9.0                        | -                            |
| Tensile Strength (MPa)                    | -                             | -                            | -                            |
|                                           | After Aging / After Challenge |                              |                              |
|                                           | ASTM <sup>1</sup>             | EN <sup>2</sup>              | ISO <sup>3</sup>             |
| Elongation At Break (%)                   | -                             | -                            | -                            |
| Force At Break (N)                        | -                             | ≥ 9.0                        | -                            |
| Tensile Strength (MPa)                    | -                             | -                            | -                            |
| Comfort<br>Maximum                        |                               | ASTM <sup>1</sup>            | ISO <sup>3</sup>             |
| Force at 300% Elongation (N)              |                               | -                            | -                            |
| Force at 500% Elongation (MPa)            |                               | -                            | -                            |

### ALLERGENIC SAFETY PROFILE

|                                        |                                                                                                |
|----------------------------------------|------------------------------------------------------------------------------------------------|
| Vulcanization<br>Chemical Accelerators | Xanthates, Zinc Dialkyldithiocarbamate                                                         |
| Primary Skin Irritation                | Not considered a primary irritant as per FHSA Regulation guidelines 16 CFR 1500 / ISO 10993-10 |
| Skin Sensitization                     | No evidence of delayed dermal contact sensitization as per ISO 10993-10                        |
| Protein Level                          | N/A: contains no natural rubber latex                                                          |
| Allergy Prevention                     | Latex (Type I)                                                                                 |

### SAFETY STANDARDS

|                                           |                                                                     |
|-------------------------------------------|---------------------------------------------------------------------|
| Freedom From Holes (AQL)                  | 0.65 AQL                                                            |
| Sterilization Method                      | GAMMA irradiation (25 kGy)                                          |
| Tested For Use With<br>Chemotherapy Drugs | Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)  |
| Viral Penetration                         | Passes ASTM F1671 using Phi X 174, Passes ISO 16604 using Phi X 174 |

### STANDARDS AND CERTIFICATIONS

|                                         |                                                                                                                     |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Product Standards                       | ASTM D6978, EN 16523-1, EN 374-2 and -4, EN 455 1-4, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016        |
| Quality /<br>Environmental<br>Standards | EN 556, ISO 11137-Part 1, ISO 13485, ISO 14001, ISO 9001                                                            |
| Product Certification                   | EU: CE Marked to Medical Device Regulation (EU) 2017/745 (Class IIa), PPE Regulation (EU) 2016/425 (Cat. III risks) |

<sup>1</sup> ASTM standards refer to ASTM D3577. <sup>2</sup> EN standards refer to EN 455-2. <sup>3</sup> ISO standards refer to ISO 10282.

Contact your Ansell representative for ordering or more information.

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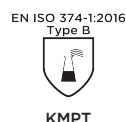
S U R G I C A L   G L O V E S

## PACKAGING AND STORAGE

|                             |                                                                                                                                                          |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Packaging                   | 50 pairs per box; 4 boxes per carton/case;<br>200 pairs per carton/case                                                                                  |
| Shelf Life                  | 3 years                                                                                                                                                  |
| Shared Storage Instructions | Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.                                                 |
| Disposal Recommendations    | Gloves and pouch should be disposed of as clinical waste. Paper inner wrap, box and carton/case are recyclable but can be disposed of as clinical waste. |

## ANSELL PRODUCT CODES

| Size | Code      | Size | Code      | Size | Code      |
|------|-----------|------|-----------|------|-----------|
| 5.5  | 330114055 | 6    | 330114060 | 6.5  | 330114065 |
| 7    | 330114070 | 7.5  | 330114075 | 8    | 330114080 |
| 8.5  | 330114085 | 9    | 330114090 |      |           |



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