



**SENTINEL™
OPTIMA PI**

Non-latex powder-free surgical gloves

**TECHNICAL
DATASHEET**

Product Description

| | |
|-------------------------|-------------------|
| Material | Polyisoprene |
| Colour | Natural |
| Shape | Anatomic |
| Cuff | Beaded cuff |
| External Surface | Textured surface |
| Internal Surface | Polyacrylic resin |

Physical Properties*

| | | |
|-------------------------------------------------------------|---------------|--------------|
| Thickness (single) Typical average values (mm) | Finger | 0.26 ±0.03 |
| | Palm | 0.22 ±0.03 |
| | Cuff | 0.20 ±0.03 |
| Minimum Length (mm) | 305 ±5 | |
| Strength (average values) | Before ageing | After ageing |
| | | |
| Elongation at Break (%) | 1020 | 1000 |
| Force at Break (N) | 18 | 17 |

* These figures are indicative only

Packaging & Storage

| | |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Packaging | 6 x 50 pairs / 300 pairs per carton |
| Shelf Life | 3 years |
| Storage Instructions | Keep out of the direct sunlight. Store in a cool and dry place. Keep away from sources of ozone or ignition. |

Key Features & Advantages

- ☒ Excellent fit and feel
- ☒ Free of casein and DPG accelerator
- ☒ Free of naturel rubber latex proteins
- ☒ Low chemical residual content

Manufacturing & Safety Standards

| | |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AQL (pinholes) | <ul style="list-style-type: none">Airleak tested. Conform European Norm AS/NZS 4179: Inspection Level I AQL 0.65Manufacturing Final Release. Conform AS/NZS 4179: Inspection Level I AQL 0.65In process control before packaging: Inspection Level I AQL 0.65 |
| Protein Content | Not applicable: contains no natural rubber latex |
| Primary Skin Irritation | Considered a negligible irritant as per ISO 10993-10 |
| Skin Sensitiveization | No evidence of sensitization as per ASTM D6355 Human Repeat Insult Patches. No evidence of delayed dermal contact sensitization as per ISO 10993-10 |
| Viral Penetration | Passes ASTM F 1671 using Phi X 174 |
| Cytostatic Permeation | ASTM D6978 Breakthrough Times available. |
| Sterilization | Gamma irradiation |
| CE Mark | Medical Device: Class IIa |
| Product Standards Conformance | AS/NZS 4179 ASTM D 3577 EN 455 parts 1, 2, 3, 4 |
| Manufacturing Standards | ISO 11137-1 ISO 13485 ISO 9001 |
| Registration Authority | Therapeutic Goods Administration (TGA) USFDA TUV SUD (0123): MD |

Product References

| | | | | |
|--------------------------------|------------|--------------|----------|--------------|
| Size & Product Code | 5.5 | ES-SAPI-0055 | 6 | ES-SAPI-0060 |
| | 6.5 | ES-SAPI-0065 | 7 | ES-SAPI-0070 |
| | 7.5 | ES-SAPI-0075 | 8 | ES-SAPI-0080 |
| | 8.5 | ES-SAPI-0085 | 9 | ES-SAPI-0090 |