

Powder Free Latex Surgical Gloves, Sterile

Gloves Specification:

- Rubber latex
- Micro roughened unique surface finish
- Natural
- Excellent instrument grip under both wet and dry conditions
- Low modulus latex compound reducing hand fatigue and providing added comfort
- Graduated thickness for fingertip sensitivity
- Sterile
- Soft and pliable
- Hand specific

Packing:

Pouch: 1 pair per pouch

Dispenser: 50 pairs per dispenser box

Outer Case: 4 dispensers per case

Pallet: 35 cases per pallet



Performance Specification:

| | |
|----------------------------------|-------------------------------------|
| Freedom from holes - BS EN 455-1 | |
| Water Tight Test | General Inspection Level 1, AQL 1.5 |

| Dimensions – BS EN 455-2 | 5.5 | 6 | 6.5 | 7 | 7.5 | 8 | 8.5 | 9 |
|--------------------------|--------|--------|--------|--------|--------|---------|---------|---------|
| Palm Width (mm) | 72 ± 4 | 77 ± 5 | 89 ± 5 | 89 ± 5 | 95 ± 5 | 102 ± 5 | 108 ± 6 | 114 ± 6 |
| Length (mm) | ≥ 250 | ≥ 260 | ≥ 260 | ≥ 270 | ≥ 270 | ≥ 270 | ≥ 280 | ≥ 280 |

| Force at Break – BS EN 455-2 | |
|------------------------------|------------------|
| Throughout shelf life | Minimum 9 Newton |
| After challenge test | Minimum 9 Newton |

| Biological Properties – BS EN 455-3 | |
|-------------------------------------|---|
| Powder Level | Less than 2 mg per glove |
| Protein Content (Latex only) | ≤50µg/g using the modified Lowry method |

| Viral Penetration – ASTM F1671-7 | |
|---|-----------------------|
| Phi-X174 Bacteriophage penetration | No visual penetration |

| Shelf Life Properties – BS EN 455-4 | |
|--|--|
| Currently shelf life is determined through accelerated ageing and is set at 3 years (whilst real time studies are in progress) | |

| Sterilisation Method – BS EN ISO 11137 | |
|--|-------------------|
| Sterilisation | Gamma Irradiation |

Quality Standards:

| | |
|----------------------------------|---|
| Manufacturing QMS | EN ISO 9001 / EN ISO 13485 |
| Glove | The BS EN 455 series of standards (parts 1,2,3 and 4) |
| Sampling & Inspection | ISO2859-1 |
| MDD Requirement | Medical Devices Directive 93/42/EEC (and subsequent amendments) |
| CE Classification | Class IIa Sterile Medical Device |
| Glove Care | Keep away from direct sunlight or Fluorescent light. Store at temperature no less than 5°C, no more than 25°C |
| Sterility Care | Sterile unless package is opened or damaged |

Packaging Artwork:

Inner



Outer



Pouch



Dimensions:

Pouch: L152mm x W285mm

Dispenser: L290mm x W150mm x H225mm

Outer: L588mm x W308mm x H237mm

Barcodes:

| Size | 5.5 | 6 | 6.5 | 7 | 7.5 | 8 | 8.5 | 9 |
|-------|-----|---------------|---------------|---------------|---------------|---------------|---------------|---|
| Inner | - | 5052755003893 | 5052755003909 | 5052755003916 | 5052755003923 | 5052755003930 | 5052755003947 | - |
| Outer | - | 5052755003954 | 5052755003961 | 5052755003978 | 5052755003985 | 5052755003992 | 5052755004005 | - |

Packaging Symbols:



Lot number



Compliant with the Medical Devices Directive



Keep dry



Date of manufacture



Single use - do not re-use



Keep away from sunlight



Use by



Contains Latex



Temperature limitation



Manufacturer



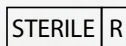
Powder Free



Recyclable packaging



Acceptable quality level



Sterilisation by gamma irradiation

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