

Powder Free Polyisoprene Procedure Gloves, Sterile

Gloves Specification:

- Polyisoprene
- Micro textured
- Natural
- Ergonomically designed with curved fingers for comfort and to minimise hand fatigue.
- Sterile
- Hand specific

Packing:

Pouch: 1 pair per pouch

Dispenser: 50 pairs per dispenser box

Outer Case: 4 dispensers per case

Pallet: 30 cases per pallet

Performance Specification:

Freedom from holes - BS EN 455-1	
Water Tight Test	General Inspection Level 1, AQL 1.0

Dimensions – BS EN 455-2	5.5	6	6.5	7	7.5	8	8.5	9
Palm Width (mm)	72 ± 4	77 ± 5	83 ± 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

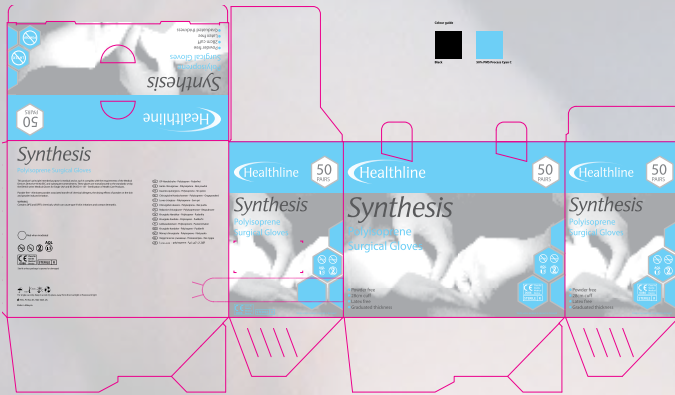
Quality Standards:

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 I 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:

Dispenser: L290mm x W150mm x H225mm

Outer: L588mm x W308mm x H237mm

Pouch: L124mm x W285mm

Barcodes:

Size	5.5	6	6.5	7	7.5	8	8.5	9
Inner	5052755004012	5052755004029	5052755004036	5052755004043	5052755004050	5052755004067	5052755004074	5052755004081
Outer	5052755004098	5052755004104	5052755004111	5052755004128	5052755004135	5052755004142	5052755004159	5052755004166

Packaging Symbols:



Lot number



Compliant with the Medical Devices Directive



Keep dry



Date of manufacture



Single use - do not re-use



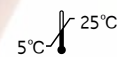
Keep away from sunlight



Use by



Contains Latex



Temperature limitation



Manufacturer



Powder Free



Recyclable packaging



Acceptable quality level



Sterilisation by gamma irradiation

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