

SURGIXAL

POLYISOPRENE POWDER FREE SURGICAL (STERILE) GLOVE

Polyisoprene powder free surgical glove suitable for sterile work environments.



Synthetic polyisoprene glove emulates the properties and performance of a latex glove, but without the risk of later allergy. Free of Diphenyl Guanidine (DPG) and Mercaptobenzothiazole (MBT) chemical accelerators.

Anatomically designed for superb fit and comfort. Best used with an underglove for a complete double donning solution in puncture detection.

Suitable for extended periods of use with no skin irritation or dryness. !

KEY FEATURES AND BENEFITS

- High quality formulation for exceptional fit and comfort providing better tactile sensitivity when needed most.
- Free of Diphenyl Guanidine (DPG) and Mercaptobenzothiazole (MBT) chemical accelerators.!

RECOMMENDED AREAS OF USE!

- !Sterile surgical operating rooms
- !Medical cleanroom settings !

STANDARDS/COMPLIANCE



“Enhancing Life Through Protection”

PRODUCT SPECIFICATIONS

Material:	Polyisoprene and compounding materials safe for use in medical
Description:	Hand Specific, Beaded Cuff, Textured, Powder Free
Sterilization Method:	Gamma irradiation (Routine Dose: 25kGy-50kGy)

Standards of Conformance:	
Product conforms to the following test standards	
ASTM D3577	Disposable Surgical Rubber Glove – Specification
ASTM D412	Tensile Properties of Vulcanized Rubbers
ASTM D573	Accelerated Aging for Latex (at 70°C for 166 ± 2 hr)
ASTM D5151	Standard Test for Detection of Holes in Medical Gloves
ASTM D6124	Standard Test Method for Residual Powder of Medical Gloves
ISO 2859-1	Sampling Procedures for Inspection by Attributes Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection

Performance Requirement:								
Inspection Testing	Inspection Level				AQL			
Watertight Test	G1				0.65			
Visual Test	S4				Major 2.5			
					Minor 4.0			
Physical Dimension	S2				4.0			
Physical Properties	S2				4.0			
Particulate Residue	N = 5				≤ 2mg/glove			
Seal Strength	N = 20				Min. 1.2N			
Dye Penetration Test	N = 20				Accept 0 Reject 1			
Physical Dimensions:								
Size	5½	6	6½	7	7½	8	8½	9
Palm Width ± 4 (mm)	72	78	84	89	96	103	110	116
Glove Length ± 10 (mm)	290							
Cuff Thickness ± 0.04 (mm) [25mm from cuff edge]	0.15							
Palm Thickness ± 0.04 (mm) [Center of palm]	0.19							
Finger Thickness ± 0.04 (mm) [13±3mm from tip]	0.21							
Physical Properties:								
Test	Before Aging				After Aging			
Tensile Strength (MPa)	Minimum 17.0				Minimum 12.0			
Ultimate Elongation (%)	Minimum 650				Minimum 490			
Modulus at 500% Elongation (MPa)	Maximum 7.0				-			

Declaration letter

We, Dukes International (Australia) Co Pty Ltd / Dukes Manufacturing (Thailand/Malaysia) Co.,Ltd hereby declare that we do not use latex, vinyl or PVC in any form as a raw material for the production of “Nitrile powder free gloves” under “teX”, “teX PLUS”, “BIOFLEXX”, “SURGIXAL”, “OATSOFT”, “SILX”, “CANNAGRIP”, “GripeXX”, “CHEMIXX”, “KontaX”, “liteserV” and “GripfiX” brands.

The products manufactured and supplied by Dukes International Co Ltd and are free from latex, vinyl or PVC.

We declare that the above-mentioned productst are in conformity with the provisions of U.S FDA 510(k) Class LZA, LZC, OPJ and EU MDR 2017/745. Technical file no: OT-TF-001 and all supporting documentations are retained under premises of the manufacturer.

Sincerely,



DUKES INTERNATIONAL CO PTY LTD.
DUKES
AUSTRALIA - THAILAND

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