

PRODUCT INFORMATION/DATA SHEET

PRODUCT: STERILE PREMIER LATEX EXAMINATION GLOVE POWDER FREE IN PAIRS

COLOUR: NATURAL

SIZES & CODE Ref(s): SMALL-3301, MEDIUM-3302, LARGE-3303

PRIMARY USE: MEDICAL EXAMINATION FOR PROTECTION AGAINST CROSS INFECTION BETWEEN PATIENT AND WEARER

MATERIAL: NATURAL, DIPPED LATEX RUBBER, POWDER FREE, TEXTURED SURFACE, AND ROLLED (BEADED) CUFF.

DIMENSIONS:

Minimum Thickness:		0.15 mm at Palm
Minimum Length:		240 mm
Palm Width of Gloves:	SMALL	80 mm ± 10mm
	MEDIUM	95 mm ± 10mm
	LARGE	110 mm ± 10mm

QUALITY	Sampling Levels	A.Q.L	Standards Met
Freedom from Holes	G.1	1.5	Meets Standard
Physical Properties	S.2	4.0	BS EN455
Dimensions & Strength	S.2	4.0	Parts 1&2 British/European
Residual Extractable Protein (range) <20 mcg/g			Standards for Medical Gloves
Residual Accelerator Content (range) 0.15%			

PACKING & LABELLING: 1 Pair Gloves per pouch, 50 pouches per Dispenser Box and 4 Dispenser Boxes per Outer Carton (200 Pairs). All pouches, Dispenser Boxes and Outer Cartons marked with Product name, Premier Logo, size, code ref, Lot number, Expiry Date, and CE Mark. Each Outer Carton also bears Irradiation label, and all packing bear marking for Single use in accordance with current regulations.

SPECIAL STORAGE CONDITIONS; KEEP IN A COOL DRY PLACE AWAY FROM HEAT AND DIRECT SUNLIGHT

SHELF LIFE: 3 Year if stored as recommended above

RISK ANALYSIS: The Gloves will remain sterilised until the pouch is opened or torn. Residual protein and Residual accelerator levels have been reduced to very low level. Highly sensitised persons may develop Type 1 urticarian (CU) skin reaction and Type IV delayed allergic reaction to these gloves but this is less likely to occur than from contact with Powdered Gloves Approximately 2% of the general population have a CU sensitivity. Therefore, low risk category. Pack remains sterile until torn or opened. Possible break during use if caught on pointed or sharp object.

CLASSIFICATION: CLASS 1 - MEDICAL DEVICES DIRECTIVE 93/42/EEC

Dated: January 2003

Issue No.: 3

AMENDMENT RECORD: DOH Standard removed Oct 2002, Dimensions adjusted Jan 2003