

## 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  $80 \text{ mm} \pm 10 \text{mm}$ MEDIUM 95 mm + 10 mm

LARGE 110 mm + 10mm

QUALITYSampling LevelsA.Q.LStandards MetFreedom from HolesG.11.5Meets 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 populataion 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

