



Declaration of Conformity

Manufacturer: HPC Healthline Limited, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

Product: GSBIO Powder Free Latex Surgical Glove

Brand Name: Biotex Plus

Classification: Class IIa (According to Annex IX, Rule 7 of Council Directive 93/42/EEC, as amended by directive 2007/47/EC).

Conformity Assessment Route: ANNEX II: Full quality assurance system assessment.

Harmonised Standards: Medical gloves for single use:

- BS EN 455-1 Freedom from Holes
- BS EN 455-2 Physical Properties
- BS EN 455-3 Biological Evaluation
- BS EN 455-4 Shelf Life Determination

Sterilization of health care products:

- BS EN ISO 11137 series of standards

HPC Healthline UK Ltd hereby declares that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for Medical devices, as amended by directive 2007/47/EC and requirements of the BS EN 455 and BS EN ISO 11137 series of standards.

Signature:

A handwritten signature in black ink, appearing to read 'D Greenwood'.

Name: David Greenwood

Place of Issue: Morden, UK

Position: Director

Date: 11th July 2016

File Ref: HPC-DOC-349 BIO100 MDD HPC

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Page: Page 1 of 1