



## Declaration of Conformity

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

**Product:** GSSYN Powder Free Polyisoprene Surgical Glove

**Brand Name:** Synthesis

**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:** 

**Name:** David Greenwood

**Place of Issue:** Morden, UK

**Position:** Director

**Date:** 11<sup>th</sup> July 2016

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