

## **Declaration of Conformity**

**Distributor:** HPC Healthline Ltd, Colwood House, 158 Garth Road, Morden,

Surrey, SM4 4LZ, UK.

**Product**: GN661 Powder Free White Stretch Vinyl Exam Glove

Brand Name: Healthline

Classification: Class I (According to Annex IX, Rule 5 of Council Directive

93/42/EEC, as amended by directive 2007/47/EC).

**Conformity** ANNEX VII: Self declaration that the products of this

**Assessment Route:** declaration meet the provisions of Council Directive 93/42/EEC,

as amended by directive 2007/47/EC.

**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

HPC Healthline 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 series of standards.

Signature:

Name: David Greenwood Place of Issue: Morden, UK

**Position:** Director Date: 14<sup>th</sup> July 2016

File Ref: HPC-DOC-356 GN661 MDD Revision:

Healthline Medical, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, United Kingdom